6505-890-2012 (P. D. No. 3)

5.3 Packaging.

5.3.1 Unit of issue. One bottle containing 4 fl oz, or 1 gal, as specified, constitutes one unit of issue.

5.3.2 Packaging quantities. The number of units of issue indicated in the following table shall be packaged in each unit, intermediate, and exterior container, as applicable, for the required level of protection specified in the procurement document.

Packaging quantities

FSN	Unit package	Intermediate package	Exterior container
6505-890-2012	1 unit	Not required	4 units
6505-926-8926	Optional	Not required	36 units

5.3.2.1 Packing variation permitted. If the required number of units to be shipped is less than the number of units specified to be overpacked in an exterior container, such units shall be packed in an exterior container of suitable size and design, acceptable to a common carrier, which shall insure safe delivery to destination.

5.3.3 Level A.

5.3.3.1 Unit package for FSN 6505-890-2012. Each bottle shall be packaged in a double-wall corrugated fiberboard box of suitable size and design having a minimum bursting strength test of 275 pounds and constructed in accordance with PPP-B-636, class domestic. Closure shall be as specified in the box specification.

5.3.3.2 Unit package for FSN 6505-926-8926. At the option of the contractor, each unit shall be packaged in a box of appropriate size constructed in accordance with PPP-B-566 or PPP-B-676, except that commercial colors are acceptable. Closure shall be adequate to prevent spilling of contents under normal handling.

5.3.4 Level C. Units shall be packaged in standard commercial containers of the size and kind commonly used, which will afford the degree of protection required for shipment and use of the product for its intended purpose.

32-814 (Pt. 24) O - 74 - 26

6505-890-2012 (P. D. No. 3)

5.4 Packing.

5.4.1 Level B.

5.4.1.1 Exterior container. Exterior container shall be a box of appropriate size constructed in accordance with PPP-B-636, type CF, class domestic. Bursting strength of carton shall be in accordance with the special requirements of table II in PPP-B-636. Box design shall include partitions, liners and top and bottom pads.

5.4.1.2 Partitions. Partitions shall be full or shoulder height, half-slotted style, and fabricated of the same material as the box. The partitions shall form an individual snug-fitting cell for each immediate container. When unit boxes are used, partitions shall not be required.

5.4.1.3 Liners. Liners shall be one-piece, covering the sides and ends of the box, fabricated of double-faced corrugated fiberboard having a minimum bursting strength test of 200 pounds in accordance with PPP-B-636, type CF, class domestic.

5.4.1.4 Pads. Top, bottom, and tier pads, shall be fabricated of double-faced fiberboard, having a minimum bursting strength test of 200 pounds in accordance with PPP-B-636, type CF, class domestic.

Note: Liners and pads will not be required when unit boxes are fabricated of fiberboard conforming to the requirements of PPP-B-636, type CF, class domestic.

5.4.1.5 Closure. Closure shall be effected in accordance with PPP-B-636, method III.

5.4.2 Level A. Items packed for the degree of protection specified for Level B shall be further protected by being overpacked in an exterior container designed for a type 1 load and constructed in accordance with PPP-B-585, class 3, style 3; PPP-B-601, overseas type; PPP-B-621, class 2; or PPP-B-636, type CF, class weather-resistant. Grade W5c shall not be permitted for an exterior container. Bursting strength of fiberboard boxes shall be in accordance with Special Requirements of Table I of PPP-B-636.

5.4.2.1 Waterproof barrier. Each Level A wood box shall be lined with a waterproof barrier conforming to MIL-L-10547. Closure and sealing shall conform to applicable paragraphs of appendix thereto. Waterproof barrier shall not be required for fiberboard boxes.

5.4.2.2 Closure. Closure of wood boxes shall be in accordance with Appendix of applicable box specification. Closure and waterproofing of each fiberboard box shall be as specified in the appendix of PPP-B-636.

5.4.2.3 Strapping. Strapping, when required, shall be in accordance with appendix of applicable box specification.

Note: Strapping shall not be required for shipments forwarded to a receiving activity within the continental limits of the United States for storage and redistribution.

5.4.3 Level C. The subject commodity shall be packed in substantial commercial containers (export, when applicable) of the type, size, and kind commonly used for the purpose, so constructed as to insure acceptance and safe delivery by common or other carrier to the final destination called for in the contract or purchase order.

5.5 Marking.

5.5.1 Unit package. When furnished, each unit package shall bear the same information as required for its immediate container.

5.5.2 Exterior container. Exterior container shall be marked in accordance with Military Standard MIL-STD-129. The word "POISON" shall be shown in lieu of the item identification when shipment is forwarded by parcel post. The word "DRUGS" shall appear when means other than parcel post are utilized. Date of manufacture shall be shown in lieu of date packed.

Lot (control) numbers and the following legends shall be shown:

"SUBJECT TO DAMAGE BY FREEZING."
and
"GLASS HANDLE WITH CARE."

6505-890-2012

7 November 1972

ADDENDUM SHEET FOR IMPLEMENTING REQUIREMENT FOR CHILD-PROOF CLOSURE

In all Specifications and/or Defense Medical Purchase Descriptions, make the following change for the Federal Stock Nos. listed below:

FSN	FSN	FSN	FSN
6505-064-8765	6505-138-4425	6505-491-7557	6505-782-2675
6505-072-9346	6505-138-4995	6505-515-1577	6505-782-6761
6505-079-9059	6505-138-7400	6505-530-7099	6505-782-6762
6505-082-2687	6505-140-3050	6505-582-5370	6505-853-4799
6505-089-1282	6505-147-5900	6505-616-7861	6505-891-7555
6505-106-7395	6505-149-0220	6505-656-1466	6505-926-2154
6505-108-3505	6505-153-8660	6505-656-1468	6505-926-8926
6505-111-1200	6505-153-8699	6505-656-1470	6505-926-8985
6505-115-0000	6505-153-9745	6505-680-1908	6505-926-9026
6505-116-6500	6505-181-7678	6505-687-4469	6505-935-0987
6505-125-9922	6505-181-7686	6505-687-4482	6505-935-4095
6505-130-1500	6505-290-4162	6505-687-4484	6505-935-6568
6505-132-6904	6505-299-8743	6505-687-8486	6505-944-4130
6505-133-9600	6505-299-9516	6505-721-9383	6505-958-6587
	6505-299-9674	6505-765-0589	

Delete the currently specified closure and seal and substitute:

"CLOSURE P - Child-Proof" "SEAL A or B"

CLOSURE P, child-proof. Closure P is defined as a child-proof closure, that is, one which has been tested in accordance with the Regulations under the Poison Prevention Packaging Act of 1970, as promulgated by the Food and Drug Administration, and found to comply with or exceed the standards and requirements therein. In addition, the closure shall be such that it will prevent pickup of moisture and contamination of the product.

Six samples of the empty containers, with closure and seal in place, shall be forwarded, by the quality assurance representative from the first shipment on contract. Samples shall be marked for the attention of DPSC-ATTH-2.

Preparation For Delivery Amendment No. 10 dated 10 February 1973

Applicable to Exterior Container Markings only:

Markings for exterior containers shall be as specified in the Procurement documents, except that the "Item Description, Item Identification, Item Name, and Trade or Brand Name" shall not be shown on the exterior container. In addition, the words "Drugs", and "Poison", currently required on the exterior container shall also be deleted.

Markings on the exterior container shall be applied in sequence, and there shall be no blank spaces permitted between lines as a result of the deletion of the name, i.e., the quantity and unit of issue shall follow the FSN markings, and all other markings shall be moved up accordingly.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 1	DATE 5 April 1973

FEDERAL STOCK NO.	ITEM IDENTIFICATION	POTENCY	UNIT
6505-655-8355	TETRACYCLINE HYDROCHLORIDE CAPSULES, USP, 0.25 Gram, 100s	Not less than 48 Months	Bottle

Shall be Tetracycline Hydrochloride Capsules, U.S.P., as produced by Lederle Laboratories as "Achromycin V Capsules."

Each capsule shall contain 250 mg of Tetracycline Hydrochloride.

Shall conform to the pertinent provisions of the General Regulations for the Certification of Antibiotics and Antibiotic-Containing Drugs as promulgated by the Food and Drug Administration (F.D.A.), U.S. Department of Health, Education, and Welfare.

Each lot shall be certified by the F.D.A.

Not more than 4 months of the expiration dating period (potency period) shall have elapsed at the time of delivery to the Government.

Shall be supplied 100 capsules in a commercially available bottle.

Labeling shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act and, in addition, shall include labeling in accordance with commercial practice.

PREPARATION FOR DELIVERY

Packaging and packing. Level C. The subject commodity shall be packaged and packed in substantial commercial containers of the type, size, and kind commonly used for the purpose, so constructed as to insure acceptance and safe delivery by common or other carriers, at the lowest rate, to point of delivery called for in the contract or purchase order.

Marking.

Exterior containers. Exterior containers shall be marked with the Federal Stock No., Item Identification, quantity, expiration date, name of consignee, name of consignor, and contract or purchase order number. Marking shall include the legend:

"STORE AT CONTROLLED ROOM TEMPERATURE (59° - 86° F.)."

NOTE: The item identification shall be shown on exterior containers as follows:

TETRACYCLINE HYDROCHLORIDE CAPSULES, U.S.P.,
0.25 Gram, 100s

6505-655-8355 (P. D. No. 1)

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 4 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

Preparation For Delivery Amendment No. 10 dated 10 February 1973

Applicable to Exterior Container Markings only:

Markings for exterior containers shall be as specified in the Procurement documents, except that the "Item Description, Item Identification, Item Name, and Trade or Brand Name" shall not be shown on the exterior container. In addition, the words "Drugs", and "Poison", currently required on the exterior container shall also be deleted.

Markings on the exterior container shall be applied in sequence, and there shall be no blank spaces permitted between lines as a result of the deletion of the name, i.e., the quantity and unit of issue shall follow the FSN markings, and all other markings shall be moved up accordingly.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 3	DATE 28 September 1967

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-116-9325 and 6505-584-2338	SODIUM DIPHENYLHYDANTOIN CAPSULES, USP, 100 mg	Bottle

Shall be Parke, Davis and Company's "Dilantin Capsules 100 mg", and shall comply with the following requirements:

Shall be Sodium Diphenylhydantoin Capsules, 100 mg, in the quantity of capsules per bottle, as indicated for the appropriate stock number and item identification:

Federal Stock No. (FSN)	Item Identification
6505-116-9325	SODIUM DIPHENYLHYDANTOIN CAPSULES, USP, 100 mg, 100s
6505-584-2338	SODIUM DIPHENYLHYDANTOIN CAPSULES, USP, 100 mg, 1000s

FSN 6505-116-9325 and FSN 6505-584-2338 shall comply with the following:

Shall be Sodium Diphenylhydantoin Capsules and shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto. In addition, the capsules shall comply with the following:

Shall be suitable for use as an anticonvulsant.

Shall contain 100 mg of Sodium Diphenylhydantoin in each capsule, within the designated assay limit for the capsules.

The finished capsules shall contain not less than 95.0 percent and not more than 105.0 percent of the required amount of sodium diphenylhydantoin, when determined in accordance with the U.S.P. method of assay.

Capsule-to-Capsule Weight and Assay Variability Limit.

Accurately weigh the contents of 10 capsules individually. Assay the contents of an additional 10 capsules individually. The capsules shall comply with the following requirements:

1. The average weight of the contents of the 10 capsules shall be between 95 percent and 105 percent of the theoretical, in addition,
2. the weight of each of the 10 contents shall be between 90 percent and 110 percent of the theoretical.
3. The average of the 10 assays shall be between 95 percent and 105 percent of the required amount of sodium diphenylhydantoin, in addition,
4. each of the individual assays of the 10 contents shall be between 90 percent and 110 percent of the required amount of sodium diphenylhydantoin.

6505-116-9325 (P. D. #3)

If two capsules, but not more than two capsules fail paragraph 2, above, or if one capsule, but not more than one capsule fails paragraph 4, above, accurately weigh and assay the contents of an additional 20 capsules, individually. The capsules shall comply with the following requirements:

1. The average of the 30 weight shall be between 95 percent and 105 percent of the theoretical, in addition,

2. the weight of not more than 3 of the 30 contents shall be less than 90 percent or more than 110 percent of the theoretical; the weight of not more than 1 of the 30 capsules shall be less than 85 percent or more than 115 percent of the theoretical; and none of the 30 capsules shall weigh less than 75 percent or more than 125 percent of the theoretical.

3. The average of the 30 assays shall be between 95 percent and 105 percent of the required amount of sodium diphenylhydantoin, in addition,

4. the assay of not more than 3 of the 30 contents shall be less than 90 percent or more than 110 percent of the required amount of sodium diphenylhydantoin; the assay of not more than 1 of the 30 contents shall be less than 85 percent or more than 115 percent of the required amount of sodium diphenylhydantoin; and the assay of none of the contents shall be less than 75 percent or more than 125 percent of the required amount of sodium diphenylhydantoin.

The sodium diphenylhydantoin content (assay) of each capsule shall be determined in accordance with the U.S.P. method, suitably modified to accommodate assaying one capsule. The theoretical weight of each capsule shall be determined from the batch formulation record.

Melting range. The diphenylhydantoin obtained in the U.S.P. assay shall melt between 294° C. and 297° C.

Thin Layer Chromatography.

The pattern of the chromatograph for the capsules shall match that of the Standard Capsule Mixture, when determined using the following method:

Preparation of plate.

Coat a suitable plate using a slurry prepared by mixing 30 Gm Silica Gel D-5 and 60 ml of 0.1N Boric Acid. Activate the plate at 105° C. for 15 to 30 minutes.

6505-116-9325 (P.D. #3)

Preparation of Standard Capsule Mixture.

Standard Capsule Mixture is prepared with the same components and in the same proportions as is used in the manufacture of the finished product, except that the Sodium Diphenylhydantoin Standard* is used in lieu of the commercial Sodium Diphenylhydantoin bulk. A quantity of the Standard Capsule Mixture, equivalent to 100 mg of Sodium Diphenylhydantoin is used for this test.

Procedure.

Prepare three 15-ml, conical, centrifuge tubes as follows:

Tube No. 1 - contents of one finished capsule (sample); Tube No. 2 - 100 mg of Sodium Diphenylhydantoin Standard*; Tube No. 3 - a portion of the Standard Capsule Mixture equivalent to 100 mg of Sodium Diphenylhydantoin.

To each tube, add 5 ml of a 1:1 pyridine:water solution. Mix thoroughly and centrifuge. Spot the activated plate with 5 λ of each supernatant liquid. Before placing the plate in the developing chamber, remove the solvent by placing the plate in an oven at 105° C. for 10 to 15 minutes. Develop the plate for 60 minutes (10 cm) in a suitable developing chamber using n-butanol:acetone:water (40:50:10) as the developing solvent. After removing the plate from the chamber, place the plate in an oven at 105° C. to remove all solvents.

Observe the plate after spraying with a universal type solvent (0.5 Gm Potassium Permanganate in 15 ml concentrated Sulfuric Acid. Caution: Cool the Sulfuric Acid before adding the Potassium Permanganate.) Examine the plate using a shortwave ultraviolet light.

Disintegration test. Using the U.S.P. method, apparatus, and procedures for determining disintegration of uncoated tablets, the finished capsules shall disintegrate in one (1) hour. No retest is allowed.

Note: Although some particles may rise to the surface instead of settling through the screen during the operation of the apparatus, no particles shall remain which can be judged too large to pass through the screen. U.S.P. reference to soft mass as evidence of disintegration does not apply to the test.

*Available upon request from Directorate of Medical Materiel, Technical Operations Division, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa., 19101, Attention: Material Standards Branch, DPSC-ATSB-1.

6505-116-9325 (P. D. #3)

Dissolution rate.

The capsules shall release not less than 40 percent sodium diphenylhydantoin in 10 minutes, not less than 80 percent sodium diphenylhydantoin in 20 minutes, not less than 90 percent sodium diphenylhydantoin in 30 minutes, and not less than 95 percent sodium diphenylhydantoin in 40 minutes, based upon the total sodium diphenylhydantoin released after one hour. In addition, the capsules shall release not less than 93 percent and not more than 107 percent of the labeled amount of sodium diphenylhydantoin after 60 minutes.

Apparatus: U.S.P. Disintegration Apparatus.
Medium: Purified Water.

Preparation of Standard.

Prepare a standard solution of diphenylhydantoin by adding 75.0 mg of sodium diphenylhydantoin standard* to 100 ml of purified water, slightly alkalized with sodium hydroxide (2 drops of 1 N Sodium Hydroxide per 100 ml). Transfer 2.0 ml of the solution to a glass-stoppered test tube. Proceed with the acidification, extraction into chloroform, etc., as described below under Procedure.

Procedure.

Note: Spectrophotometric Grade solvents shall be used in the determination.

Place 1 capsule in each of six tubes, inserting a plastic disk in each tube. Immerse the basket rack assembly in 800 ml of purified water maintained at 37° C. ± 2° C. Operate the apparatus. Withdraw 5 ml aliquots of the solution after 10, 20, 30, 40, and 60 minutes.

*Available upon request from Directorate of Medical Materiel, Technical Operations Division, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa., 19101, Attention: Material Standards Branch, DPSC-ATSB-1.

6505-116-9325 (P.D. #3)

Treat each aliquot alike as follows:

Filter without delay through a 2-1/4 inch Whatman No. 4 paper, or equivalent. Transfer without delay, exactly 2.0 ml of the filtrate to a glass-stoppered test tube, add exactly 10.0 ml of chloroform, then 0.5 ml of diluted hydrochloric acid (10% HCl), and shake for 2 minutes. Centrifuge at about 1000 r.p.m. for 5 minutes to clarify the chloroform layer. Transfer exactly 5.0 ml of the chloroform solution, free from contamination with the aqueous phase, to an extraction flask. Evaporate to dryness on a steam bath under a current of air, reducing the application of heat as dryness is approached. Dissolve the residue in exactly 50.0 ml of 95 percent ethanol. With a suitable spectrophotometer, determine the absorbance of the solutions prepared from the sample, A_u, and the absorbance of the standard solution, A_s, at 220 mu, using a suitable spectrophotometer, 1 cm cells, relative to 95 percent ethanol as the blank.

Calculate the percent completion of dissolution as follows:

% completion of dissolution =

$$\frac{Au}{Au\ (1\ hr)} \times 100$$

Where: Au is the absorbance of the respective aliquots, and
Au (1 hr) is the absorbance after 1 hour

Calculate the percent of label claim in solution after 60 minutes, as follows:

% of label claim after 60 minutes =

$$\frac{Au\ (1\ hr)}{As} \times 100$$

Where: Au is the absorbance after 1 hour
As is the absorbance of the reference standard.*

*Available upon request from Directorate of Medical Materiel, Technical Operations Division, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa., 19101, Attention: Material Standards Branch, DPSC-ATSB-1.

6505-116-9325 (P. D. #3)

The Sodium Diphenylhydantoin used in the manufacture of the finished capsules shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto.

In addition to complying with the tests, standards, and requirements of the U.S.P., the sodium diphenylhydantoin used in the manufacture of the finished capsules shall comply with the following requirements:

Assay.

Shall assay to contain not less than 99.5 percent and not more than 100.5 percent sodium diphenylhydantoin, when assayed in accordance with the U.S.P. method.

Melting range.

The residue of diphenylhydantoin obtained in the U.S.P. assay shall melt between 294° C. to 297° C.

Thin layer chromatography.

The chromatograph of the sodium diphenylhydantoin powder used in the manufacture of the capsules shall match that of the sodium diphenylhydantoin standard* when determined by using the Thin Layer Chromatograph Procedure for the finished capsules, except that 100 mg of Sodium Diphenylhydantoin powder shall be used in lieu of the contents of a capsule, and a portion of the Standard Capsule Mixture.

The empty, hard, gelatin capsules used in the manufacture of the finished product shall be Size No. 3, and shall conform to the applicable paragraphs of Federal Specification U-C-115b, dated 10 February 1958, except as specified below:

3.1 Delete in its entirety and substitute:

"3.1 Material. The gelatin, used in the manufacture of the pharmaceutical capsules, shall be type A or type B or a suitable mixture of both and shall be in accordance with the requirements of the U.S.P. The gelatin may contain not more than 0.15 percent sulfur dioxide and may have a lower gel strength."

3.2.3.3 Appearance and color. The finished product (filled capsules) shall be white in color. The sealing band may be colored.

Capsules shall be uniform and free from manufacturing and other defects, such as, cracks, dents, splits, specks, etc.

*Available upon request from Directorate of Medical Materiel, Technical Operations Division, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa., 19101, Attention: Material Standards Branch, DPSC-ATSB-1.

6505-116-9325 (P. D. #3)

All ingredients entering into the finished capsules shall be of U.S.P. or N.F. quality or, if not included in either of these compendia, the ingredients shall be of the highest pharmaceutical grade.

Not more than 6 months shall have elapsed from the date of manufacture of the product to the date of delivery to the Government.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-186, dated 11 December 1961, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1 or 2

CLOSURE A, B, or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers.

FSN 6505-116-9325

Each immediate container label for FSN 6505-116-9325 shall bear the following information. However, the information is not required to appear in the sequence indicated.

(a) the item identification designated as "SODIUM DIPHENYLHDANTOIN CAPSULES, U.S.P."

(b) the quantity of active ingredient designated as "100 mg"

(c) the phrase "100 capsules" or a similar phrase

(d) the stock number designated as "FSN 6505-116-9325" or "Stock No. 6505-116-9325"

(e) the lot or control number

(f) the statement "Caution: Federal law prohibits dispensing without prescription."

(g) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(h) the date of manufacture

6505-116-9325 (P.D. #3)

Immediate containers.

FSN 6505-584-2338

Each immediate container label for FSN 6505-584-2338 shall bear the same information as required for the immediate container label for FSN 6505-116-9325 with the exception of subparagraphs (c) and (d), which shall read as follows:

(c) the phrase "1000 capsules" or a similar phrase

(d) the stock number designated as "FSN 6505-584-2338" or "Stock No. 6505-584-2338"

Packaging.

Unit of issue. One bottle containing 100 capsules, or 1000 capsules, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5.

Intermediate package. The number of units of issue specified in table I, column 2, for Procedure Code No. 3 for FSN 6505-116-9325, or Procedure Code No. 7 for FSN 6505-584-2338, indicated in column 1, shall be packaged in an intermediate package constructed in accordance with the applicable paragraph referenced in column 3, except that partitions shall not be required when unit package is furnished. As applicable, commercial colors shall be acceptable when carton conforming to Federal Specification PPP-B-566, PPP-B-665, or PPP-B-676 is utilized.

Packing. The number of units contained in the intermediate packages and total number of units of issue for the applicable procedure code, indicated in column 4, shall be overpacked in an exterior container, constructed in accordance with the applicable paragraph referenced in column 5 (level B) or column 6 (level A), for the level of protection specified in the procurement document, except that in column 4 for procedure code No. 7, delete "1/12" and substitute "12/12." Bursting strength of carton shall be in accordance with special requirements in table I of Federal Specification PPP-B-636, in lieu of bursting strength specified in the applicable paragraph referenced in column 5 (level B). Method I closure of Federal Specification PPP-B-636 shall be utilized on level B fiberboard packs. In addition, in line 10 of 5.4.4, delete "IV" and substitute "III; or Federal Specification PPP-B-636, type CF, class weather-resistant;" at end of 5.4.4.1, add "Case liner shall not be required for fiberboard boxes." Add the following new paragraph: "5.4.4.1.1 Closure. Closure of wood boxes shall be in accordance with appendix of applicable box specification. Closure of each fiberboard box shall be as specified in the appendix and waterproofing shall conform with 30.4 of Federal Specification PPP-B-636."

6505-116-9325 (P. D. #3)

Marking.

Unit package. When furnished, each unit package shall bear the same information as required for the immediate container.

Intermediate package. Each intermediate package shall be marked in accordance with Military Standard MIL-STD-129. When labels are utilized, waterproofing shall be required only when applicable carton is fabricated of water-resistant material. Lot (control) number, contract or purchase order number, name of contractor, and date of manufacture in lieu of date packed, shall be shown. Marking shall include the legend "STORE IN A COOL PLACE (50° - 80° F)."

Exterior containers. Exterior containers shall be marked in accordance with Military Standard MIL-STD-129. Lot (control) number and date of manufacture, in lieu of date packed, shall be shown. Marking shall include the legend: "STORE IN A COOL PLACE (50° - 80° F.)."

SUPPLIER RESPONSIBILITIES FOR INSPECTION

Such examinations and tests as are set forth in this specification, or as shall otherwise be appropriate or necessary to insure that supplies conform to specification requirements, shall be performed by and at the expense of the supplier. Suppliers who do not have facilities adequate for such tests shall arrange for the use of test facilities acceptable to the Government. Records of examinations and tests performed by the supplier shall be maintained by the supplier and made available to the Government, upon the Government's request, at any time, or from time to time, for a period of 3 years after delivery of the supplies to which such records relate.

32-814 (Pt. 24) O - 74 - 27

CONSIGNMENT INSTRUCTIONS

(Medical Items)

upplies shall be shipped to the destinations set forth under the item designation. The complete address for such destinations is set rth below. Only those addresses relating to destinations listed under the item designation are applicable to the contract/order issued hereunder.

ATLANTA
PARCEL POST SHIPMENTS
Commanding General
Atlanta Army Depot
Forest Park, Georgia 30050
For: Medical Supply Account,
Building 512

or RAILWAY EXPRESS *(less carload only)*, AIR EXPRESS and AIR FREIGHT
A33AAM
Transportation Officer
Atlanta Army Depot
Atlanta, Georgia
For: Medical Supply Account
Building 512

or ALL OTHER SHIPMENTS
A33AAM
Transportation Officer
Atlanta Army Depot
Army Depot, Georgia
For: Medical Supply Account
Building 512

*Central of Georgia Ry Co. or
Southern Ry Co.

COLUMBUS
PARCEL POST SHIPMENTS
Commander
Defense Construction
Supply Center
Columbus, Ohio 43215
For: DPSC *(MEDICAL)* Whse 27, Sec 11

or ALL OTHER SHIPMENTS
SW0700
Transportation Officer
Defense Construction
Supply Center
Columbus, Ohio
For: DPSC *(MEDICAL)* Whse 27, Sec 11

*Baltimore and Ohio RR Co.
or New York Central RR Co.
or Pennsylvania RR Co.

MECHANICSBURG
PARCEL POST SHIPMENTS
Commander
Defense Depot Mechanicsburg
Mechanicsburg, Pa. 17055
Attn: Medical Branch

or AIR FREIGHT SHIPMENTS
SW3100
Transportation Officer
Defense Depot Mechanicsburg
Harrisburg, Pennsylvania
Attn: Medical Branch

or ALL OTHER SHIPMENTS
SW3100
Transportation Officer
Defense Depot Mechanicsburg
Mechanicsburg, Pennsylvania
(Cumberland County)
Attn: Medical Branch

(No rail less than carload deliveries to this activity)
*Pennsylvania RR Co.

MEMPHIS
PARCEL POST SHIPMENTS
Commander
Defense Depot Memphis
Memphis, Tennessee 38115
For: DPSC *(MEDICAL SUPPLIES)*

or ALL OTHER SHIPMENTS
SW3500
Transportation Officer
Defense Depot Memphis
Memphis, Tennessee
For: DPSC *(MEDICAL SUPPLIES)*

*Illinois Central RR Co. or
St. Louis - San Francisco Ry Co.

NORFOLK
PARCEL POST SHIPMENTS
Commanding Officer
Naval Supply Center
Norfolk, Virginia 23511
Attn: Medical Stores Section

or ALL OTHER SHIPMENTS
N00189
Freight Terminal Officer
Naval Supply Center
Norfolk, Virginia
For: Medical Stores Section

*Norfolk and Western Ry Co.
or Chesapeake and Ohio Ry Co.

OAKLAND
PARCEL POST SHIPMENTS
Commanding Officer
Naval Supply Center
Oakland, California 94625
Attn: Building 212 - Stock

or ALL OTHER SHIPMENTS
N00208
Transportation Officer
Code 102.12 Naval Supply Center
Oakland, California
For: Building 212 - Stock

*Southern Pacific Co. or
Western Pacific RR Co.

TRACY
PARCEL POST SHIPMENTS
Commander
Defense Depot Tracy
Tracy, California 95376
For: Medical Stock

or EXPRESS *(Railway and Air)*
SW3200
Transportation Officer
Defense Depot Tracy
Stockton, California
For: Medical Stock

or ALL OTHER SHIPMENTS
SW3200
Transportation Officer
Defense Depot Tracy
Lyoth, California
For: Medical Stock

*Southern Pacific Co. or
Western Pacific RR Co.

* *Delivering Rail Carrier*

DPSC FORM 7778 . 1 EDITION MAY 67. OBSOLETE

CONSIGNMENT INSTRUCTIONS

(Public Health Items)

SHIPPING ADDRESS	MAILING ADDRESS
PHS/GSA Emergency Medical Supply Depot Bastrop, Texas	PHS/GSA Emergency Medical Supply Depot P. O. Box G Bastrop, Texas 78602
PHS/GSA Emergency Medical Supply Depot Branchton Road *Boyers, Pennsylvania	PHS/GSA Emergency Medical Supply Depot P. O. Box 52 Boyers, Pennsylvania 16020
PHS/GSA Emergency Medical Supply Depot c/o U. S. Naval Supply Depot Clearfield, Utah	PHS/GSA Emergency Medical Supply Depot Clearfield, Utah 84015
PHS/GSA Emergency Medical Supply Depot Crab Orchard Wildlife Refuge Crab Orchard, Illinois	PHS/GSA Emergency Medical Supply Depot P. O. Box A Carterville, Illinois 62918
PHS/GSA Emergency Medical Supply Depot c/o Ozark Terminal, Inc. Neosho, Missouri	PHS/GSA Emergency Medical Supply Depot P. O. Box 147 Neosho, Missouri 64850
PHS/GSA Emergency Medical Supply Depot Prairie, Mississippi	PHS/GSA Emergency Medical Supply Depot P. O. Box 156 Prairie, Mississippi 39756
PHS/GSA Emergency Medical Supply Depot Seneca, Illinois	PHS/GSA Emergency Medical Supply Depot Seneca, Illinois 61360
HS/GSA Emergency Medical Supply Depot uilding T-31 ilkins Air Force Station Shelby, Ohio	PHS/GSA Emergency Medical Supply Depot P. O. Box 272 Shelby, Ohio 44875
PHS/GSA Emergency Medical Supply Depot Building #21 U. S. Naval Supply Depot Spokane, *(Velox)* Washington	PHS/GSA Emergency Medical Supply Depot 3322 North Sullivan Road Spokane, Washington 99216
PHS/GSA Emergency Medical Supply Depot Rough and Ready Island Stockton, California	PHS/GSA Emergency Medical Supply Depot Rough and Ready Island Stockton, California 96202
PHS/GSA Emergency Medical Supply Depot Route 18 *Wampum, Pennsylvania	PHS/GSA Emergency Medical Supply Depot Wampum, Pennsylvania 16157
PHS/GSA Emergency Medical Supply Depot Building 235 608 Arsenal Street *Watertown, Massachusetts	PHS/GSA Emergency Medical Supply Depot Building 235 670 Arsenal Street Watertown, Massachusetts 02172
PHS/GSA Emergency Medical Supply Depot U. S. Naval Supply Center Cheatham Annex Williamsburg, Virginia	PHS/GSA Emergency Medical Supply Depot U. S. Naval Supply Center Cheatham Annex Williamsburg, Virginia 23185

*Rail Facilities not available at the Depot

DPSC FORM OCT 67 2278 - 2 EDITION MAY 67, OBSOLETE

TEDRAL

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 7	DATE 6 October 1970

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-753-4766	THEOPHYLLINE, EPHEDRINE HYDROCHLORIDE, AND PHENOBARBITAL TABLETS, NF, 1000s	Bottle

Shall be Theophylline, Ephedrine Hydrochloride, and Phenobarbital Tablets, N. F., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 31 October 1966, and Amendment 1, dated 25 March 1970, together with the options and additions stated herein:

S2 Classification. Shall be type I, class 1.

S5. 2 The following additional requirements and tests are added to this paragraph:

Shall contain the following formula per tablet, within the applicable assay limits:

Theophylline, (Hydrous)	0.130 Gram
Ephedrine Hydrochloride	0.024 Gram
Phenobarbital	0.008 Gram

The Ephedrine Hydrochloride used in the manufacture of the tablets shall be of N. F. grade, and the Theophylline (Hydrous) and Phenobarbital shall be of U. S. P. grade.

All other ingredients used in the manufacture of the tablets shall comply with S5. 1.

BLOOD LEVEL STUDY

Clinical Laboratory.

State licensed clinical laboratory or general clinical laboratory of a hospital accredited by the Joint Commission on Accreditation of Hospitals.

Qualifications of Investigator.

Licensed Medical Doctor with active clinical laboratory experience.

Supervision of Clinical Test.

The testing shall be performed under the supervision of the Head of the Clinical Laboratory. The findings shall be reported on stationery of the clinical laboratory.

6505-753-4766 (P. D. No. 7)

Subjects for Clinical Test.

Not less than thirty nor more than thirty-six subjects having bronchial asthma shall be selected. The ages of the subjects must range from young teen-age to over 65.

Performance of clinical test.

The subjects are standardized as follows:

1. Light breakfast consisting of cereal and/or dairy products shall shall be given. All xanthine containing beverages, such as, tea, coffee, and cocoa shall be excluded from the diet.

2. Subjects shall not take any theophylline-containing medication for at least 24 hours prior to zero hour.

3. Zero hour, which is 1/2 to 1 hour after breakfast, shall be established for administration of one tablet. Just prior to zero hour, a blood specimen shall be taken to determine that there is no residual theophylline serum content.

4. Subjects shall be under institutional regimen during the study.

5. Blood specimens shall be withdrawn at 30 ± 2 minutes and 240 ± 2 minutes after zero hour.

Method of Analysis.

The blood specimens shall be analyzed for theophylline content by the Schack and Waxler procedure, or by a method acceptable to the Government as being equally accurate and reproducible. The Schack and Waxler procedure is published in the Journal of Pharmacology and Experimental Therapeutics 9:283, 1949.

6505-753-4766 (P. D. No. 7)

Serum Theophylline Levels.

The average of the serum theophylline levels shall be not less than 150 micrograms percent (1.5 micrograms per milliliter) at 30 minutes, and not less than 300 micrograms percent (3.0 micrograms per milliliter) at 240 minutes. The average shall be based on determinations from not less than thirty (30) patients. In addition, not more than three of the serum theophylline determinations shall be less than 100 micrograms percent (1.0 micrograms per milliliter). All patients shall show serum theophylline concentrations. When the concentration is less than 100 micrograms percent (1.0 micrograms per milliliter) a value of 0.0 micrograms percent (0.0 micrograms per milliliter) shall be used in determining the average. Any individual values which are abnormally high (i.e., more than two and one-half times the respective originally-calculated 1/2 hour and 4 hour averages) shall be eliminated from the calculations.

Note: Not more than six patients may be eliminated from the study due to interferences in the serum, illness of patients, errors in analysis, etc., provided determinations from at least thirty patients are performed. Lack of serum theophylline content shall not be cause for elimination from the study. Results of all patients entering into the study, except those eliminated due to illiness, serum interference, or analysis errors, shall be reported.

S6.4.6 Hardness. The hardness of the tablets shall be not less than 3 when tested by the Stokes Hardness Tester. Twenty (20) tablets shall be tested and not more than 2 tablets may fall below the hardness requirement stated herein, or not less than 5 when tested by the Strong-Cobb hardness tester.

S6.4.7 Scoring. Tablets shall be scored.

S6.4.9.1 Disintegration, Disintegration time shall be not more than 4 minutes using purified water as the immersion fluid at a temperature of 37° C. ± 2° C.

6505-753-4766 (P. D. No. 7)

S6. 4. 11 Moisture content. Loss on drying shall be not more than 2. 50 percent, when determined as follows:

Grind 20 tablets to a fine powder. Take about 1. 5 gram of powder and weigh accurately. Record the weight. Dry to constant weight at 105° C. (usually requires about 4 hours). Cool in a desiccator and weigh accurately. Calculate the percent loss on drying.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1

CLOSURE B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall include the following information. However, the information is not required to appear in the sequence indicated.

(a) the item identification designated as "THEOPHYLLINE, EPHEDRINE HYDROCHLORIDE, AND PHENOBARBITAL TABLETS, N. F."

(b) the phrase "1000 tablets" or a similar phrase

(c) the formula of the tablets

(d) the lot or control number

(e) the Federal Stock No.

(See additional label information on page 5)

6505-753-4766 (P. D. No. 7)

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(g) the following or similar statements:

1. Dosage: Adults: 1 tablet; Children 6 to 12 years, 1/2 tablet. May be repeated in 4 hours. For other dosage and for children under 6 years-use only as directed by your physician.

2. Indications: For providing temporary relief from symptoms of bronchial asthma and hay fever. If condition persists, consult your physician.

3. Warning: Frequent or continued use may cause nervousness, restlessness, or sleeplessness. Individuals suffering from high blood pressure, heart disease, diabetes or thyroid trouble should not take this preparation except on physician's advice.

(h) the date of manufacture

Packaging and Packing.

Unit of issue. One bottle containing 1000 tablets, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5 of PPP-C-00186a.

6505-753-4766 (P. D. No. 7)

Procedure code. Procedure code No. 6 as specified in Table I of PPP-C-00186a shall apply, except that in column 2, of Table I, delete "12" and substitute "6" and in column 4, delete "12/24" and substitute "6/24."

Marking

Unit package. When furnished, each unit package shall bear the same information as required for the immediate container.

Intermediate package. Each intermediate package shall be marked as specified in 5. 5. 3 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of the date packed.

Exterior container. Exterior container shall be marked as specified in 5. 5. 4 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of the date packed.

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

Rider to P. D. No. 7 - FSN 6505-753-4766 dated 6 October 1970

REPORT ON BLOOD LEVEL STUDY

(a) The results of a Blood Level Study, performed in the manner described on pages 1 through 3 of Purchase Description No. 7, dated 6 October 1970, and in the form therein specified, shall be furnished as part of the bid or proposal and must be received before the time set for opening of bids or proposals. The report on Blood Level Study will be evaluated to determine compliance, with the above pages of the Purchase Description and any other specification requirement, of the material the bidder or offeror proposes to furnish.

(b) The following will require rejection of the bid or proposal:

(i) Failure to submit such report by the time specified, or

(ii) Failure of the report to show in detail that the Blood Level Study was performed in the manner described in the specification, or

(iii) Failure of the report to show that the material offered conforms to the requirements of the above pages of the Purchase Description, or

(iv) Failure to submit data demonstrating that the material subjected to the Blood Level Study complies with all chemical and physical requirements of the purchase description.

(c) The material delivered under any resulting contract shall be manufactured by the same method and process, and be of the same formulation, as the tablets subjected to the Blood Level Study. The batch production record of the lot(s) used in the clinical test shall be made available for review by the Government upon its request.

(d) The Government reserves the right to test, at its discretion, the material offered or delivered hereunder to determine compliance with specification requirement of a Blood Level Study contained in the aforesaid Purchase Description as well as any other specification requirement, and nothing contained herein shall in any manner be deemed to relieve the contractor from delivering material in strict accordance with the specification and any other requirements of this bid or proposal.

The Blood Level Study which is required to be submitted as part of the bid or proposal shall be furnished for initial approval. Subsequent submission of an approved Blood Level Study is waived, provided the offeror of the product certifies that no changes in the product formulation or manufacturing procedure have occurred.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 8	DATE 20 January 1972

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-116-7750	DIGOXIN TABLETS, USP, 0.25 mg, 100s	Bottle

Shall be Digoxin Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 1l0a, dated 30 October 1966, and Amendment-1, dated 25 March 1970, and as specified herein:

S2. Classification. Shall be type I, class 1.

S5.2 The following additional requirements and tests are added to this paragraph:

Shall be tablets containing 0.25 mg of Digoxin per tablet, within the applicable assay limits for the tablets.

S6.4.2 Color. Uncoated tablets shall be white.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 1 GRADE 1

CLOSURE A, B, or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "DIGOXIN TABLETS, U.S.P."

(b) the quantity of active ingredient per tablet designated as "0.25 mg"

(c) the phrase "100 tablets" or a similar phrase

(See additional label information on page 2)

(d) the Federal Stock No.

(e) the lot or control number

(f) the date of manufacture

(g) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(h) the statement "Caution: Federal law prohibits dispensing without prescription."

(i) the word "POISON" in prominent red letters.

Packaging and Packing.

Unit of issue. One bottle containing 100 tablets, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5 of PPP-C-00186a.

Procedure code. Procedure code No. 2 as specified in Table I of PPP-C-00186a shall apply.

Marking.

Unit package. When furnished, each unit package shall bear the same information as required for the immediate container.

Intermediate package. Intermediate package shall be marked as specified in 5.5.3 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of the date packed.

Exterior container. Exterior container shall be marked in accordance with 5.5.4 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of the date packed.

6505-116-7750 (P. D. No. 8)

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 2	DATE 21 July 1966

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-106-8700 and 6505-106-8715	DEXTROAMPHETAMINE SULFATE TABLETS, USP, 5 mg	See below

This purchase description covers the following items in the unit of issue as indicated for the appropriate Federal Stock No. (FSN) and item identification:

Federal Stock No. (FSN)	Item Identification	Unit
6505-106-8700	DEXTROAMPHETAMINE SULFATE TABLETS, USP, 5 mg, 6s	Box
6505-106-8715	DEXTROAMPHETAMINE SULFATE TABLETS, USP, 5 mg, 100s	Bottle

FSN 6505-106-8700 and FSN 6505-106-8715 shall comply with the following requirements:

Shall be Dextroamphetamine Sulfate Tablets, U.S.P., and shall be in accordance with all applicable requirements of Interim Federal Standard No. 00140 (Navy-BuMed), dated 17 December 1959, together with the options and additions stated herein:

S2. Classification. Shall be type I, class 1.

S5.2 The following additional requirements are added to this paragraph:

Shall be tablets containing 5 mg of Dextroamphetamine Sulfate per tablet, within the applicable assay limits for the tablets.

S6.4.2.1 Uncoated tablets. Tablets shall be white.

S6.4.7 Scoring. Tablets shall be scored.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-196, dated 11 December 1961, together with deletions or additions as indicated herein:

(See Page 2)

6505-106-8700 (PD # 2)

Immediate containers.

For FSN 6505-106-8700:

(See Packaging on page 4).

For FSN 6505-106-8715:

Immediate containers shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1 or 2

CLOSURE A, B, or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

For FSN 6505-106-8700:

Immediate containers. Labeling not required.

Unit packages. Each unit package label for FSN 6505-106-8700 shall bear the following information printed on one side. However, the information is not required to appear in the sequence indicated.

(a) the item identification designated as "DEXTROAMPHETAMINE SULFATE TABLETS, U.S.P."

(b) the quantity of active ingredient designated as "5 mg"

(c) the phrase "6 tablets" or a similar phrase

(d) the stock number

(e) the lot or control number

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designation shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor

6505-106-8700 (PD # 2)

The unit package shall be marked on the opposite side with the following or similar statements:

"6 tablets Dextroamphetamine Sulfate 5 mg

These tablets will relieve fatigue and enable you to stay awake.

Do not take unless extremely fatigued or very sleepy. Take only in emergencies and when authorized by an officer. Follow directions carefully.

DIRECTION: Take one (1) tablet if sleepy or two (2) tablets if extremely fatigued. Repeat this dose in six (6) hours if necessary, but do not take more than six (6) tablets in any one (1) week.

CAUTION: Since these tablets keep you awake, do not take when relief or rest is expected within six (6) hours, unless excessively exhausted. They should not be given to hysterical or severely wounded men.

Keep tablets in this box until all have been taken."

Note: The statement "Caution." Federal law prohibits dispensing without prescription" shall not appear on the unit package label for FSN 6505-106-8700.

For FSN 6505-106-8715:

Immediate containers.

Each immediate container label for FSN 6505-106-8715 shall bear the following information. However, the information is not required to appear in the sequence indicated.

(See labeling on page 4)

(a) the item identification designated as "DEXTROAMPHETAMINE SULFATE TABLETS, U.S.P."

(b) the quantity of active ingredient designated as "5 mg"

(c) the phrase "100 tablets" or a similar phrase

(d) the stock number

(e) the lot or control number

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designation shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor

(g) the statement "Caution: Federal law prohibits dispensing without prescription"

Packaging.

Unit of issue. One (1) box or one (1) bottle, as specified, constitutes one unit of issue.

Unit package.

FSN 6505-106-8700: Each unit shall be heat sealed between two sheets of cellulose acetate or other suitable material, with each tablet contained in an individual pocket formed by sealing the two sheets.

The material of which the above prescribed package is fabricated shall be so treated as to preclude the possibility of interaction between it and the tablets.

Each such package shall be assembled between a pair of suitable die-cut pads and packaged in a slide cover or carton of suitable design measuring approximately 3 by 3-1/4 by 3/16 inches. Package shall be adequately secured to prevent accidental opening.

FSN 6505-106-8715: At the option of the contractor, each unit shall be packaged as specified in 5.2.5.

32-814 (Pt. 24) O - 74 - 28

6505-106-8700 (PD # 2)

Intermediate package. The number of units of issue specified in Table I, column 2, for Procedure Code No. 1 for FSN 6505-106-8700, and Procedure Code No. 3 for FSN 6505-106-8715, indicated in column 1, shall be packaged in an intermediate package constructed in accordance with the applicable paragraph referenced in column 3, except that partitions shall not be required when unit package is furnished. Commercial colors shall be acceptable when carton conforming to Federal Specification PPP-B-566, PPP-B-665, or PPP-B-676 is utilized.

Packing. The number of units contained in the intermediate packages and total number of units of issue for the applicable procedure code, indicated in column 4, shall be overpacked in an exterior container, constructed in accordance with the applicable paragraph referenced in column 5 (level B), or column 6 (level A), for the level of protection specified in the procurement document, except for FSN 6505-106-8700, in table I, column 4, delete '12/432' and substitute '12/216' and in PPP-C-186, delete 5.4.3.1.2 and 5.4.3.1.3. Bursting strength of carton shall be in accordance with special requirements in table I of Federal Specification PPP-B-636, in lieu of bursting strength specified in the applicable paragraph referenced in column 5 (level B). Method I closure of Federal Specification PPP-B-636, shall be utilized on level B fiberboard packs. In addition, in line 10 of 5.4.4, delete "IV" and substitute "III; or Federal Specification PPP-B-636, type CF, class weather-resistant." At end of 5.4.4.1, add "Case liner shall not be required for fiberboard boxes." Add the following new paragraph: "5.4.4.1.1 Closure. Closure of wood boxes shall be in accordance with appendix of applicable box specification. Closure of each fiberboard box shall be as specified in the appendix, and waterproofing shall conform with 30.4 of Federal Specification PPP-B-636."

Marking.

Intermediate package. Each intermediate package shall be marked in accordance with Military Standard MIL-STD-129. When labels are utilized, waterproofing shall be required only when applicable carton is fabricated of water-resistant material. Lot (control) number, contract or purchase order number, and name of contractor shall be shown.

Exterior containers. Exterior containers shall be marked in accordance with Military Standard MIL-STD-129. Lot (control) number shall be shown.

SUPPLIER RESPONSIBILITIES FOR INSPECTION.

Such examinations and tests as are set forth in this specification, or as shall otherwise be appropriate or necessary to insure that supplies conform to specification requirements, shall be performed by and at the expense of the supplier. Suppliers who do not have facilities adequate for such tests shall arrange for the use of test facilities acceptable to the Government. Records or examinations and tests performed by the supplier shall be maintained by the supplier and made available to the Government, upon the Government's request, at any time, or from time to time, for a period of 3 years after delivery of the supplies to which such records relate.

MODIFICATION NO. 2
DATE: 1 March 1967

MODIFICATION TO DEFENSE MEDICAL PURCHASE DESCRIPTION

This modification forms a part of Defense Medical Purchase Description No. 2, dated 21 July 1966, and covers the following items to the extent specified herein:

Federal Stock No.	
6505-106-8700	DEXTROAMPHETAMINE SULFATE TABLETS, USP, 5 mg, 6s
6505-106-8715	DEXTROAMPHETAMINE SULFATE TABLETS, USP, 5 mg, 100s

Page 1:

Lines 11 and 12, delete "Interim Federal Standard No. 00140 (Navy-BuMed), dated 17 December 1959" and substitute "Federal Standard Fed. Std. No. 140a, dated 30 October 1966."

Under "S5.2" insert the following new paragraphs:

"The dextroamphetamine sulfate used in the manufacture of the finished tablets shall be in accordance with the tests, standards, and requirements of the U.S.P., and, in addition, shall comply with the following:

"Turbidity and color:

Prepare an 8 percent w/v aqueous solution and take immediate readings in a Klett-Summerson colorimeter, or other suitable instrument or apparatus giving comparable results, using a No. 42 filter. Centrifuge the solution and determine the readings on the clear, supernatant liquid. The difference between the second and first readings is due to turbidity. The second reading is due to color. Use distilled water as a blank to zero the instrument.

Limits: Not more than 25 divisions for color.
Not more than 15 divisions for turbidity.

6505-106-8700 (Mod. No. 2)

"Assay (in duplicate):

Transfer an accurately weighed sample (about 1.0 Gm) to a 1000 ml volumetric flask. Dissolve in and dilute to volume with distilled water. Record the ultraviolet absorption spectrum of the solution from 300 to 220 millimicrons on a Cary Recording Spectrophotometer, or other suitable instrument giving comparable results, using the following operating conditions: 1 cm cells, distilled water in the reference cell, low speed, large gear, slit width - not more than 0.15 mm at 257 mu. Record a base-line under the same conditions with distilled water in both cells.

Calculations:

$$\frac{(A_{257}\ (\text{max.}) - A_{285}) \times 0.995^{*} \times 1000 \times 100}{\text{Sample Wt. (mg)}} = \%\ \text{purity}$$

*0.995 = mg dextroamphetamine sulfate/ml/unit - A

Limits: 98 to 102 percent.

"All other ingredients entering into the preparation or manufacture of the tablets shall comply with S5.1."

S6.4.2.1 Uncoated tablets. Delete in its entirety and substitute:

"S6.4.2 Color. Uncoated tablets shall be white."

DEFENSE MEDICAL PURCHASE DESCRIPTION		NUMBER 2	DATE 1 March 1971
FEDERAL STOCK NO.	ITEM IDENTIFICATION	POTENCY	UNIT
6505-132-6904	ISONIAZID TABLETS, USP, 0.3 Gram, 100s	60 Months	Bottle

Shall be Isoniazid Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 31 October 1966, and Amendment-1, dated 25 March 1970, and as specified herein:

S.2 Classification. Shall be type I, class 1.

Shall be suitable for use as an antibacterial (tuberculostatic).

S6.4.9.1 Disintegration. Tablets shall disintegrate in not more than 15 minutes.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1 dated 27 October 1969, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 1 or 2 GRADE 1

CLOSURE A, B, or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "ISONIAZID TABLETS, U.S.P."

(b) the quantity of active ingredient designated as "0.3 Gram"

Note: The official abbreviation "g." may be used in lieu of "gram."

(c) the phrase "100 tablets" or a similar phrase

(d) the Federal Stock No.

(See additional label information on page 2)

32-814 587

SSC-1 Page 1 of 3 -M-

DPSC FORM 2037 OCT 64 REPLACES OMSC FORM T-4120/11, MAR 64, WHICH WILL BE USED UNTIL DEPLETED

(e) the lot or control number

(f) the expiration date

(g) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(h) the statement "Caution: Federal law prohibits dispensing without prescription."

(i) the statement "Protect from light."

(j) the statement "Keep Tightly Closed."

Packaging and packing.

Unit of issue: One bottle containing 100 tablets, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor each unit shall be packaged as specified in 5.2.5 of PPP-C-00186a.

Procedure code. Procedure code No. 4 as specified in Table I of PPP-C-00186a shall apply.

Marking.

Unit package. When furnished, each unit package shall bear the same information as required for the immediate container.

Intermediate package. Each intermediate package shall be marked in accordance with 5.5.3 and 5.5.8.1 of PPP-C-00186a.

Exterior container. Exterior container shall be marked in accordance with 5.5.4 and 5.5.8.1 of PPP-C-00186a.

6505-132-6904 (P. D. #2)

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsibile for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

MODIFICATION NO. 1
DATE: 6 February 1973

MODIFICATION TO DEFENSE MEDICAL PURCHASE DESCRIPTION

This modification forms a part of Defense Medical Purchase Description No. 8, dated 20 February 1969, and covers the following item to the extent specified herein:

Federal Stock No.	Item Identification
6505-138-4225	PROPYLTHIOURACIL TABLETS, USP, 50 mg, 100s

Page 1:

Preceding the paragraph "S6.4.2 Color" - Insert the following new paragraph:

"If (i) the quality assurance representative submits samples to the laboratory at the Defense Personnel Support Center, or (ii) the bidder or offeror is required by the terms of the Schedule or otherwise to submit samples to said laboratory, a quantity of 15 grams of Propylthiouracil powder used in the manufacture of each lot of Propylthiouracil Tablets, U.S.P., accompanied by a certificate of analysis listing all test results, shall be submitted with the finished product to the Technical Operations Division, Directorate of Medical Materiel, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, Pa. 19101, Attention: Quality Assurance Branch."

Under "PREPARATION FOR DELIVERY" - Delete the first paragraph in its entirety and substitute:

"Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-001866a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:"

Pages 2 and 3:

Packaging, Packing, and Marking - Delete and substitute:

"Packaging and Packing.

"Unit of issue. One bottle containing 100 tablets, as specified, constitutes one unit of issue.

"Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5 of PPP-C-001866a.

"Procedure code. Procedure code No. 2 as specified in Table I of PPP-C-001866a shall apply.

SSC-1

6505-138-4225 (Mod. No. 1)

"Marking.

"Intermediate package. Each intermediate package shall be marked as specified in 5.5.3 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of the date packed.

"Exterior container. Exterior container shall be marked in accordance with 5.5.4 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of date packed."

Page 4:

SUPPLIER RESPONSIBILITIES FOR INSPECTION - Delete in its entirety and substitute:

"SUPPLIER RESPONSIBILITY FOR INSPECTION

"Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

"Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

"No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein."

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 8	DATE 20 February 1969

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-138-4225	PROPYLTHIOURACIL TABLETS, USP, 50 mg, 100s	Bottle

Shall be Propylthiouracil Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 1l0a, dated 30 October 1966, together with the options and additions stated herein:

S2. Classification. Shall be type I, class 1.

S5.2 The following additional requirements and tests are added to this paragraph:

Shall be tablets containing 50 mg of Propylthiouracil per tablet, within the applicable assay limits for the tablets.

The Propylthiouracil used in the manufacture of the tablets shall meet the tests, standards, and requirements of the U.S.P., except that the U.S.P. limit of heavy metals shall be modified to read "not more than 10 parts per million."

The Propylthiouracil powder shall comply with the maximum limit for "Thiourea" as given in the British Pharmacopoeia, 1968, pages 846 and 624.

S6.4.2 Color. Uncoated tablets shall be white.

S6.4.7 Scoring. Tablets shall be scored.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-186, dated 11 December 1961, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1

CLOSURE A, B, F, or G SEAL A or B (for closures A, B, and F only)

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

(See labeling on page 2)

32-814 592

6505-138-4225 (P. D. No. 8)

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated.

(a) the item identification designated as "PROPYLTHIOURACIL TABLETS, U.S.P."

(b) the quantity of active ingredient designated as "50 mg"

(c) the phrase "100 tablets" or a similar phrase

(d) the stock number

(e) the lot or control number

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(g) the statement "Caution: Federal law prohibits dispensing without prescription."

(h) the date of manufacture.

Packaging.

Unit of issue. One bottle containing 100 tablets, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5.

Intermediate package. The number of units of issue specified for Procedure Code 2 shall be intermediate packaged in accordance with 5.3, except partitions shall not be required when unit package is furnished. Commercial colors will be acceptable on intermediate cartons.

APPROVED NEW DRUG APPLICATION REQUIRED

The supplier of any item(s) listed below must possess, at time of award of contract for such item(s), a New Drug Application which has been approved by the Food and Drug Administration.

FSN	Item Identification
6505-138-4225	PROPYLTHIOURACIL TABLETS, USP, 50 mg, 100s

Preparation For Delivery Amendment No. 10 dated 10 February 1973

Applicable to Exterior Container Markings only:

Markings for exterior containers shall be as specified in the Procurement documents, except that the "Item Description, Item Identification, Item Name, and Trade or Brand Name" shall not be shown on the exterior container. In addition, the words "Drugs", and "Poison", currently required on the exterior container shall also be deleted.

Markings on the exterior container shall be applied in sequence, and there shall be no blank spaces permitted between lines as a result of the deletion of the name, i.e., the quantity and unit of issue shall follow the FSN markings, and all other markings shall be moved up accordingly.

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-126-9375	MEPERIDINE HYDROCHLORIDE TABLETS, USP, 50 mg, 100s	Bottle

Shall be Meperidine Hydrochloride Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 30 October 1966, and Amendment-1, dated 25 March 1970, and as specified herein:

S2. Classification. Shall be type I, class 1.

Shall be suitable for use as an oral narcotic analgesic.

S5.2 The following additional requirements and tests are added to the paragraph:

Shall be tablets containing 50 mg of Meperidine Hydrochloride per tablet, within the applicable assay limits for the tablets.

S6.4.2 Color. Uncoated tablets shall be white.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1

CLOSURE A, B, or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "MEPERIDINE HYDROCHLORIDE TABLETS, U.S.P."

(b) the quantity per tablet designated as "50 mg"

(c) the phrase "100 tablets" or a similar phrase

(See additional label information on page 2)

6505-126-9375 (P. D. No. 6)

(d) the Federal Stock No.

(e) the lot or control number

(f) the date of manufacture

(g) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(h) the statement "Warning: May Be Habit Forming" or a similar statement

(i) the statement "Caution: Federal law prohibits dispensing without prescription."

(j) all information required by Federal Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act.

Unit packages. Each unit package shall bear the same information as required for the label of the immediate container and, in addition, shall bear the following:

(k) the statement "See enclosed literature" or a similar statement.

A circular, brochure, or other printed matter shall be packaged within each unit package setting forth as a minimum: Indications for use; Recommended dosage; Precautions and contraindications.

6505-126-9375 (P. D. No. 6)

Packaging and Packing.

Unit of issue. One bottle containing 100 tablets, as specified, constitutes one unit of issue.

Unit package. Each unit shall be packaged as specified in 5.2 of PPP-C-00186a.

Procedure code. Procedure code No. 3 specified in Table I of PPP-C-00186a shall apply.

Marking.

Intermediate package. Intermediate package shall be marked as specified in paragraph 5.5.3 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of date packed.

Exterior container. Exterior container shall be marked as specified in paragraph 5.5.4 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of date packed. The word "POISON" shall be shown in lieu of the item identification when shipment is forwarded by parcel post. The word "DRUGS" shall be shown when shipment other than parcel post is used.

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 5 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

General

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 1	DATE 30 January 1973

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-851-6589	MEPERIDINE HYDROCHLORIDE TABLETS, USP, 50 mg, 25s	Box

Shall be Meperidine Hydrochloride Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 30 October 1966, and Amendment-1, dated 25 March 1970, and as specified herein:

S2. Classification. Shall be type I, class 1.

S5.2 The following additional requirements and tests are added to this paragraph:

Shall be tablets containing 50 mg of Meperidine Hydrochloride per tablet, within the applicable assay limits for the tablets.

S6.4.2 Color. Uncoated tablets shall be white.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

Immediate containers (strip pockets). Shall comply with the following: Twenty-five (25) tablets shall be packaged in a commercially available, continuous foil strip package. Each tablet shall be sealed in its own light-resistant pocket and so designed that the end pocket can be removed and the seal on the adjoining pocket shall not be disturbed. The individual pockets shall be consecutively numbered from one (1) to twenty-five (25). One roll of the twenty-five tablets shall be contained in a carton (box) as specified. The numbers on the strip package roll shall be in reverse order so that the first pocket removed shall be number twenty-five (25) and the second number shall be twenty-four (24), etc.

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container (pocket) shall be permanently and legibly marked with the following information. The labeling shall appear in the center of the pocket and shall not extend into the heat-sealed area:

Labeling information in accordance with commercial practice. In addition, the numbering shall be in reverse order as specified under "Immediate containers (strip pockets)" see above. The date of manufacture shall not be required.

SSC-1 M

DPSC FORM 2087 OCT 68

REPLACES DMSC FORM 7-4130/11, MAR 64, WHICH WILL BE USED UNTIL DEPLETED

32-814 (Pt. 24) O - 74 - 29

6505-851-6589 (P. D. No. 1)

Unit packages. Each unit package (box) label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "MEPERIDINE HYDROCHLORIDE TABLETS, U.S.P."

(b) the quantity of active ingredient designated as "50 mg"

(c) the Federal Stock No.

(d) the lot or control number

(e) the date of manufacture

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(g) the statement "Caution: Federal law prohibits dispensing without prescription."

(h) the statement "Warning - May be habit forming."

(i) the following statements or similar statements:

1. Multiple dispensing package.
2. This package not for household use.

(j) the usual dosage

(k) all labeling information and the controlled substance schedule symbol as required by the Bureau of Narcotics and Dangerous Drugs regulations

(l) the unit of issue designated as

"1 BOX
(1 roll of 25 tablets)"

The parenthetical phrase shall appear in smaller characters than the unit of issue designation.

6505-851-6589 (P. D. No. 1)

Packaging.

Unit of issue. One box containing 25 tablets, as specified, constitutes one unit of issue.

Packaging quantities. The number of units of issue indicated in the following table shall be packaged in each unit, intermediate, and exterior container, as applicable for the required level of protection specified in the procurement document.

Packaging quantities

Unit package	Intermediate package	Exterior container
1 unit	10 units	120 units

Packing variation permitted. If the required number of units in the entire shipment is less than the number of units specified to be overpacked in an exterior container, such units may be packed in an exterior container of suitable size and design, acceptable to a common carrier, which shall insure safe delivery to destination.

Level A.

Unit package. One roll of twenty-five tablets shall be packaged in a dispensing, tamperproof type box of appropriate size and design. The numbers on the strip package roll shall be in reverse order so that the first pocket removed shall be number 25 and the second number shall be 24, etc. The box shall have one transparent plastic window on the side opposite that of the label.

Intermediate package. Intermediate package shall be a box of appropriate size and design constructed in accordance with PPP-B-566 or PPP-B-676, except commercial colors will be acceptable, or PPP-B-636, type CF, class domestic. Closure shall be adequate to prevent accidental opening under normal handling.

Level C. Units shall be packaged in standard commercial containers of the size and kind commonly used, which will afford the degree of protection required for shipment and use of the product for its intended purpose.

6505-851-6589 (P. D. No. 1)

Packing.

Level A.

Exterior container. Exterior container shall be designed for a type 2 load and constructed in accordance with PPP-B-585, class 3, style 3; PPP-B-601, overseas type; PPP-B-621, class 2; or PPP-B-636, class weather-resistant. Closure and strapping shall be as specified in the appendix of the applicable box specification. Fiberboard boxes shall conform to the special requirements specified in PPP-B-636.

Case liner. Each level A wood box shall be lined with a waterproof case liner conforming to Specification MIL-L-10547. Closure and sealing shall conform to applicable paragraphs of appendix thereto. Case liner shall not be required for fiberboard boxes. Each fiberboard box shall be waterproofed in accordance with 30.4 of PPP-B-636.

NOTE: Strapping shall not be required for shipments forwarded to a receiving activity within the continental limits of the United States for storage and redistribution.

Level B.

Exterior container. Exterior container shall be designed for a type 2 load and constructed in accordance with PPP-B-585, class 1, style 3; PPP-B-601, domestic type; PPP-B-621, class 1; or PPP-B-636, class domestic. Closure of wood boxes shall be as specified in the appendix of the applicable box specification. Closure of fiberboard boxes shall conform to method II of PPP-B-636. In addition, fiberboard boxes shall conform to the special requirements specified in PPP-B-636.

Level C. The subject commodity shall be packed in substantial commercial containers of the type, size, and kind commonly used for the purpose, so constructed as to insure acceptance and safe delivery by common or other carriers, at the lowest rate, to point of delivery called for in the contract or purchase order.

Marking.

Intermediate packages. Each intermediate package shall be marked in accordance with MIL-STD-129. When labels are utilized, waterproofing shall be required only when applicable carton is fabricated of water-resistant material. Lot (control) number, contract or purchase order number, and name of contractor shall be shown. The date of manufacture shall be shown in lieu of date packed.

Exterior container. Exterior container shall be marked as specified in MIL-STD-129. Lot (control) number shall be shown. The date of manufacture shall be shown in lieu of date packed. The Item Identification shall not appear on the exterior container.

6505-851-6589 (P. D. No. 1)

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

DATE: 30 January 1973

APPROVED NEW DRUG APPLICATION REQUIRED

The supplier of any item(s) listed below must possess, at time of award of contract for such item(s), a New Drug Application which has been approved by the Food and Drug Administration.

FSN	Item Identification
6505-851-6589	MEPERIDINE HYDROCHLORIDE TABLETS, USP, 50 mg, 25s

32-814 604

Benemid

DEFENSE MEDICAL PURCHASE DESCRIPTION | NUMBER 4 | DATE 11 June 1969

FEDERAL STOCK NO.	ITEM IDENTIFICATION	POTENCY	UNIT
6505-527-6885	PROBENECID TABLETS, USP, 0.5 Gm, 100s	60 Months	Bottle

Shall be Probenecid Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 30 October 1966, together with the options and additions stated herein:

S2. Classification. Shall be type I, class 1.

S5.2 The following additional requirements and tests are added to this paragraph:

Shall be tablets containing 0.50 Gm of Probenecid per tablet, within the applicable assay limits for the tablets.

S6.4.2 Color. Uncoated tablets shall be white.

S6.4.7 Scoring. Tablets shall be scored.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-186, dated 11 December 1961, together with the deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1

CLOSURE B or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item identification designated as "PROBENECID TABLETS, U.S.P."

(b) the quantity of active ingredient designated as "0.5 Gm"

(See additional label information on page 2)

DPSC FORM 2087 REPLACES DMSC FORM 7-4180/1, MAR 64, WHICH WILL BE USED UNTIL DEPLETED

6505-527-6885 (P. D. No. 4)

(c) the phrase "100 tablets" or a similar phrase

(d) the stock number

(e) the lot or control number

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(g) the expiration date

(h) the statement "Caution: Federal law prohibits dispensing without prescription."

(i) the following or similar statement: "Keep container tightly closed and store in a dry place, protected from sunlight and excessive heat."

(j) the recommended dosage

Unit packages. Each unit package label shall bear the same information as required for the label of the immediate container.

Circulars. A circular, brochure, or other printed matter shall be packaged within each unit package setting forth as a minimum: Indications for use, Administration, Precautions, Toxicity, and Side Effects.

Packaging.

Unit of issue. One bottle containing 100 tablets, as specified, constitutes one unit of issue.

Unit package. Each unit shall be packaged as specified in 5.2.5.

Intermediate package. The number of units of issue specified for Procedure Code 4 shall be intermediate packaged in accordance with 5.3, except partitions shall not be required when unit package is furnished.

6505-527-6885 (P. D. No. 4)

Packing. Packing shall be in accordance with 5.4 with the following exceptions:

5.4.3 Level B. Delete 200 lbs. bursting strength wherever referenced and substitute "Bursting strength of carton shall be in accordance with special requirements in table I of PPP-B-636."

5.4.4 Level A. Delete entirely and substitute:

"5.4.4 Level A. Items shall be packed for the degree of protection specified for Level B, and shall be further protected by being overpacked in an exterior container designed for type 1 load and constructed in accordance with PPP-B-585, style 3 for class 3 use; PPP-B-601, table III, using type I, class 1 plywood; PPP-B-621, table III; or PPP-B-636, type CF, class weather resistant. Bursting strength of fiberboard box shall be in accordance with special requirements of table II of PPP-B-636. Grade W5 shall not be permitted for exterior container. Closure of wood boxes shall be in accordance with appendix of applicable box specification. Closure of each fiberboard box shall be as specified in the appendix, and waterproofing shall conform with paragraph 30.4 of PPP-B-636."

5.4.4.1 Waterproof barrier. Delete entirely and substitute:

"5.4.4.1 Case liner. Each Level A wood box shall be lined with a waterproof case liner conforming to MIL-L-10547. Closure and sealing shall conform to applicable paragraphs of appendix thereto. Case liner shall not be required for fiberboard boxes."

5.5 Marking. Delete and substitute:

"5.5 Marking.

"5.5.1 Intermediate package. Each intermediate package shall be marked in accordance with Military Standard MIL-STD-129. When labels are utilized, waterproofing shall be required only when applicable carton is fabricated of water-resistant material. Lot (control) number, contract or purchase order number, and name of contractor shall be shown. Type I Shelf-Life markings as specified in paragraph 5.2.2.1 (a) of MIL-STD-129 shall be shown, except that date of manufacture shall not be shown.

"5.5.2 Exterior containers. Exterior container shall be marked in accordance with Military Standard MIL-STD-129. Lot (control) number shall be shown. Type I Shelf-Life markings as specified in MIL-STD-129 shall be shown, except that date of manufacture shall not be shown.

6505-527-6885 (P. D. No. 4)

SUPPLIER RESPONSIBILITIES FOR INSPECTION

Such examinations and tests as are set forth in this specification, or as shall otherwise be appropriate or necessary to insure that supplies conform to specification requirements, shall be performed by and at the expense of the supplier. Suppliers who do not have facilities adequate for such tests shall arrange for the use of test facilities acceptable to the Government. Records of examinations and tests performed by the supplier shall be maintained by the supplier and made available to the Government, upon the Government's request, at any time, or from time to time, for a period of 3 years after delivery of the supplies to which such records relate.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 9	DATE 11 August 1971

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-130-1500	NIACINAMIDE TABLETS, USP, 50 mg, 100s	Bottle

Shall be Niacinamide Tablets, U.S.P., and shall be in accordance with all applicable requirements of Federal Standard Fed. Std. No. 140a, dated 30 October 1966, and Amendment-1, dated 25 March 1970, and as specified herein:

S2. Classification. Shall be type I, class 1.

S5.2 The following additional requirements and tests are added to this paragraph:

Shall be tablets containing 50 mg of Niacinamide per tablet, within the applicable assay limits for the tablets.

S6.4.2 Color. Uncoated tablets shall be white.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 2 GRADE 1

CLOSURE A, B, or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "NIACINAMIDE TABLETS, U.S.P."

(b) the quantity of active ingredient designated as "50 mg"

(c) the phrase "100 tablets" or a similar phrase

(d) the Federal Stock No.

(See additional label information on page 2)

6505-130-1500 (P. D. No. 9)

(e) the lot or control number

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(g) the date of manufacture.

Packaging and Packing.

Unit of issue. One bottle containing one-hundred tablets, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5 of PPP-C-00186a.

Procedure code. Procedure code No. 3 as specified in Table I of PPP-C-00186a shall apply.

Marking.

Unit package. When furnished, each unit package shall bear the same information as required for the immediate container.

Intermediate package. Each intermediate package shall be marked in accordance with 5.5.3 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of the date packed.

Exterior container. Exterior container shall be marked in accordance with 5.5.4 of PPP-C-00186a, except that the date of manufacture shall be shown in lieu of the date packed.

6505-130-1500 (P. D. No. 9)

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 2	DATE 28 December 1967

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-753-4773	METHYL SALICYLATE, USP, 1 pt (473 cc)	Bottle

Shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto.

Shall be clear and free from sediment.

Shall be colorless or have no more color than A.P.H.A. color standard 5, when tested in accordance with the method specified in the "Standard Methods for the Examination of Water, Sewage, and Industrial Wastes," Tenth Edition, published by the American Public Health Association, Inc. Shall not be yellowish (beyond the limits of above test) nor reddish in color, although such is permitted in the U.S.P.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-186, dated 11 December 1961, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A CLASS 1 TYPE e STYLE 1 GRADE 1

CLOSURE A, B, or F SEAL A or B

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container shall be labeled as follows:

"FSN 6505-753-4773 Lot No.
METHYL SALICYLATE, U.S.P., 1 pt (473 cc)."
"(Synthetic)" or "(Natural)" - whichever is applicable.

"For External Use Only as a Liniment.
USE ONLY AS DIRECTED
CAUTION: Discontinue use if excessive irritation of the skin develops.

(See additional label information on page 2)

FOR INFORMATION ONLY
NOT FOR PROCUREMENT

179a

DPSC FORM 2087 OCT 65

REPLACES DMSC FORM T-4120/11, MAR 64, WHICH WILL BE USED UNTIL DEPLETED

6505-753-4773 (P. D. No. 2)

Avoid getting into eyes or on mucous membranes.
Do Not Take Internally.
CAUTION: Must be kept out of reach of children to prevent accidental poisoning.
Methyl Salicylate is also used for prescription compounding."

Label shall also include the name and address of the contractor. If the contractor is not the manufacturer, the label shall also state "Packaged by _____" or "Distributor _____" with the blank space filled in with the name and address of the packaging or distribution firm.

Packaging.

Unit of issue. One bottle, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5.

Intermediate package. The number of units of issue specified for Procedure Code 6 shall be intermediate packaged in accordance with 5.3, except partitions shall not be required when unit package is furnished. Commercial colors will be acceptable on intermediate cartons.

Packing. Packing shall be in accordance with 5.4 with the following exceptions:

5.4.3 Level B. Delete 200 lbs. bursting strength wherever referenced and substitute "Bursting strength of carton shall be in accordance with special requirements in table I of PPP-B-636."

5.4.4 Level A. Delete entirely and substitute:

"5.4.4 Level A. Items shall be packed for the degree of protection specified for Level B, and shall be further protected by being overpacked in an exterior container designed for type 2 load and constructed in accordance with PPP-B-585, style 3 for class 3 use; PPP-B-601, table II, using type I, class 1 plywood; PPP-B-621, table III; or PPP-B-636, type CF, class weather resistant. Bursting strength of fiberboard box shall be in accordance with special requirements of table II of PPP-B-636. Grade W5 shall not be permitted for exterior container. Closure of wood boxes shall be in accordance with appendix of applicable box specification. Closure of each fiberboard box shall be as specified in the appendix, and waterproofing shall conform with paragraph 30.4 of PPP-B-636."

6505-753-4773 (P. D. No. 2)

5.4.4.1 Waterproof barrier. Delete entirely and substitute:

"5.4.4.1 Case liner. Each Level A wood box shall be lined with a waterproof case liner conforming to MIL-L-10547. Closure and sealing shall conform to applicable paragraphs of appendix thereto. Case liner shall not be required for fiberboard boxes."

Marking. Delete 5.5 entirely and substitute:

"Marking.

"Unit package. When furnished, each unit package shall bear the same information as required for the immediate container.

"Intermediate package. Each intermediate package shall be marked in accordance with Military Standard MIL-STD-129. When labels are utilized, waterproofing shall be required only when applicable carton is fabricated of water-resistant material. Lot (control) number, contract or purchase order number, and name of contractor shall be shown.

"Exterior containers. Exterior container shall be marked in accordance with Military Standard MIL-STD-129. Lot (control) number shall be shown."

SUPPLIER RESPONSIBILITIES FOR INSPECTION

Such examinations and tests as are set forth in this specification or as shall otherwise be appropriate or necessary to insure that supplies conform to specification requirements shall be performed by and at the expense of the supplier. Suppliers who do not have facilities adequate for such tests shall arrange for the use of test facilities acceptable to the Government. Records of examinations and tests performed by the supplier shall be maintained by the supplier and made available to the Government, upon the Government's request, at any time, or from time to time, for a period of 3 years after delivery of the supplies to which such records relate.

SPECIFICATION ANALYSIS SHEET	Form Approved Budget Bureau No. 22-R255

INSTRUCTIONS: This sheet is to be filled out by personnel, either Government or contractor, involved in the use of the specification in procurement of products for ultimate use by the Department of Defense. This sheet is provided for obtaining information on the use of this specification which will insure that suitable products can be procured with a minimum amount of delay and at the least cost. Comments and the return of this form will be appreciated. Fold on lines on reverse side, staple in corner, and send to preparing activity. Comments and suggestions submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or serve to amend contractual requirements.

SPECIFICATION FSN: 6505-753-4773

ORGANIZATION

CITY AND STATE | CONTRACT NUMBER

MATERIAL PROCURED UNDER A

☐ DIRECT GOVERNMENT CONTRACT ☐ SUBCONTRACT

1. HAS ANY PART OF THE SPECIFICATION CREATED PROBLEMS OR REQUIRED INTERPRETATION IN PROCUREMENT USE?

A. GIVE PARAGRAPH NUMBER AND WORDING.

B. RECOMMENDATIONS FOR CORRECTING THE DEFICIENCIES

2. COMMENTS ON ANY SPECIFICATION REQUIREMENT CONSIDERED TOO RIGID

3. IS THE SPECIFICATION RESTRICTIVE?

☐ YES ☐ NO *(If "yes", in what way?)*

4. REMARKS *(Attach any pertinent data which may be of use in improving this specification. If there are additional papers, attach to form and place both in an envelope addressed to preparing activity)*

SUBMITTED BY *(Printed or typed name and activity - Optional)* | DATE

DD FORM 1 JAN 68 1426 REPLACES EDITION OF 1 OCT 64, WHICH MAY BE USED.

CAUTION

NOTICE TO BIDDERS/OFFERORS

DO NOT CONDITION OR BASE YOUR BID/OFFER ON ANY CURRENT PROCUREMENT ON THE INFORMATION SUBMITTED ON THIS FORM SINCE ANY CHANGES OR DELETIONS IN THE SPECIFICATIONS MAY RENDER YOUR BID/OFFER NON-RESPONSIVE IN WHICH CASE IT CANNOT BE CONSIDERED FOR AWARD.

Fold

DEFENSE PERSONNEL SUPPORT CENTER
2800 SOUTH 20TH STREET
PHILADELPHIA, PA. 19101

DEFENSE SUPPLY AGENCY
OFFICIAL BUSINESS

POSTAGE AND FEES PAID
DEFENSE SUPPLY AGENCY

HEADQUARTERS, DEFENSE PERSONNEL SUPPORT CENTER
ATTN: DIRECTORATE OF MEDICAL MATERIEL
2800 SOUTH 20TH STREET
PHILADELPHIA, PA. 19101

Fold

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 6	DATE 15 July 1971

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-299-9678	KAOLIN MIXTURE WITH PECTIN, NF, 1 gal (3.78 liters)	Bottle

Shall meet the tests, standards, and requirements of the N.F., including any supplements or revisions thereto.

The formulation of the Kaolin Mixture with Pectin shall be as indicated in the N.F., except that the quantity of pectin shall be such that the final mixture shall contain not more than 130 mg of pectin per fluid ounce. The quantity of all other ingredients used shall be 100 percent of that called for in the formula.

Shall be suitable for use as an antidiarrheal.

The pH of the formulation shall be 3.00 to 5.00 at 25° C., when determined potentiometrically, using the U.S.P. method.

The Kaolin used in the manufacture of the product shall be in accordance with the tests, standards, and requirements of the N.F., including any supplements or revisions thereto, and, in addition, shall be of a sieve size so that not less than 99.8 percent of the powder shall pass through a No. 200 standard sieve.

The Pectin and Sodium Saccharin used in the manufacture of the product shall be in accordance with the tests, standards, and requirements of the N.F., including any supplements or revisions thereto.

The Tragacanth (powdered), Benzoic Acid, Glycerin, Peppermint Oil, and Purified Water used in the manufacture of the product shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto.

N.F. Rx

Suitable, harmless, flavoring agents, buffering and/or preservative agents acceptable to the Food and Drug Administration may be contained in the product, provided the identities and quantities of such agents present in the preparation are declared on the label of the immediate container.

Not more than 4 months shall have elapsed from the date of manufacture of the product, to the date of delivery to the Government.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-001604a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

Immediate containers. Shall comply with the following classification:

GROUP A. CLASS 1 TYPE e STYLE 1 GRADE 1 or 2

CLOSURE A SEAL A

The immediate container shall be oversized in order to facilitate shaking of the mixture, prior to use.

SSC-1 M

6505-299-9678 (P. D. No. 6)

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "KAOLIN MIXTURE WITH PECTIN, N.F."

(b) the quantity of contents designated as "1 gal (3.78 liters)"

(c) the Federal Stock No.

(d) the lot or control number

(e) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(f) the statement "SHAKE WELL BEFORE DISPENSING."

(g) the statement "KEEP FROM FREEZING."

(h) the identities and quantities of flavoring agents, buffering and/or preservative agents, if such are used

(i) the following statement:

"Each fluid ounce contains
Kaolin- - - - - 90 grains
Pectin- - - - - 2 grains"

(j) the date of manufacture

(k) dosage for use as an antidiarrheal.

6505-299-9678 (P. D. No. 6)

Packaging and Packing.

Unit of issue. One bottle containing 1 gal (3.78 liters), as specified, constitutes one unit of issue.

Packaging quantities. The number of units of issue indicated in the following table shall be packaged in each unit, intermediate, and exterior container, as applicable, for the required level of protection specified in the procurement document:

Packaging quantities

Unit package	Intermediate package	Exterior container
1 unit	Not required	4 units

Packing variation permitted. If the required number of units in the entire shipment is less than the number of units specified to be over-packed in an exterior container, such units may be packed in an exterior container of suitable size and design, acceptable to a common carrier, which shall insure safe delivery to destination.

Level A.

Unit packages. Each unit shall be packaged in double-faced corrugated fiberboard box of appropriate size and design having a minimum bursting strength test of 275 pounds and constructed in accordance with PPP-B-636, type CF, class domestic. Box design shall include liner and top and bottom pads.

Liner. Liner shall be of one piece, covering the sides and ends of the carton and fabricated of the same material as the box. Liner shall be of the same height as the bottle.

Pads. Top and bottom pads shall be fabricated of the same material as the box and not more than 1/8 inch less than the inside length and width of the box. Pads shall be positioned on the top and bottom edge of the liner.

Closure. Closure shall be adequate to prevent spiling of contents under normal handling.

6505-299-9678 (P. D. No. 6)

Packing.

Level B.

Exterior container. Exterior container shall be a box of appropriate size constructed in accordance with PPP-B-636, type CF, class domestic. Bursting strength of box shall be in accordance with special requirements of table II of PPP-B-636. Closure shall conform to method II as specified in the appendix of the box specification.

Level A. Items shall be packed for the degree of protection specified for Level B, and shall be further protected by being overpacked in an exterior container designed for a type 1 load and constructed in accordance with PPP-B-585, class 3, style 3; PPP-B-601, overseas type; PPP-B-621, class 2; or PPP-B-636, class weather-resistant, grade V3c. Bursting strength of fiberboard box shall be in accordance with special requirements of table I in PPP-B-636. Closure and strapping of boxes shall be as specified in the appendix of the applicable box specification.

Case liner. Each Level A wood box shall be lined with a waterproof case liner conforming to MIL-L-10547. Closure and sealing shall conform to applicable paragraphs of appendix thereto. Case liner shall not be required for fiberboard boxes. Each fiberboard box shall be waterproofed in accordance with paragraph 30.4 of PPP-B-636.

Marking.

Unit package. Each unit package shall bear the same information as required for the immediate containers.

Exterior container. Exterior container shall be marked in accordance with MIL-STD-129. Lot (control) number shall be shown. Date of manufacture shall be shown in lieu of date packed. Marking shall include the legend:

"DO NOT PERMIT TO FREEZE."

6505-299-9678 (P. D. No. 6)

SUPPLIER RESPONSIBILITY FOR INSPECTION

Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

Iron—Triturate 2 g. of Kaolin in a mortar with 10 ml. of water and add 500 mg. of sodium salicylate: the mixture does not acquire more than a slight reddish tint.

Lead—To 1 g. of Kaolin contained in a centrifuge tube add 10 ml. of 5 percent nitric acid and digest for 1 hour in a boiling water bath. Centrifuge until the solids are completely separated and pour the supernatant liquid into a 100-ml. volumetric flask. Add 5 ml. of 5 percent nitric acid to the Kaolin, mix well, and digest for 15 minutes in a boiling water bath. Centrifuge, and add the supernatant liquid to the previous extract in the volumetric flask. Dilute to volume with water. A 50-ml. portion of this solution contains not more than 5 mcg. of lead (corresponding to not more than 10 parts per million) when tested according to the *Lead Limit Test*, page 813, using 3 ml. of ammonium citrate solution, 1 ml. of potassium cyanide solution, and 0.5 ml. of hydroxylamine hydrochloride solution.

Packaging and storage—Preserve Kaolin in well-closed containers.

CATEGORY—Adsorbent.

Kaolin Mixture with Pectin

Kaolin	200	g.
Pectin	10	g.
Tragacanth, powdered	5	g.
Benzoic Acid	2	g.
Sodium Saccharin	1	g.
Glycerin	20	ml.
Peppermint Oil	0.75	ml.
Purified Water, a sufficient quantity, To make	1000	ml.

Mix the kaolin with 500 ml. of purified water. Triturate the pectin, powdered tragacanth, and sodium saccharin with the glycerin and add to this, with constant stirring; the benzoic acid dissolved in 300 ml. of boiling purified water. Allow the mixture to stand until it cools to room temperature and all the pectin is dissolved. Add the peppermint oil and the kaolin–water mixture, mix thoroughly, and finally add sufficient purified water to make 1000 ml.

In order to obtain a product with suitable consistency when larger amounts are prepared, the quantity of tragacanth and, if necessary, the quantity of pectin may be altered. However, if the proportion of pectin in the formula is altered by more than 10 percent, the pectin content of the preparation must be clearly stated on the label.

Identification—Mix 550 mg. of the residue, obtained in the determination of *Residue on ignition*, with 12 ml. of water and 5 ml. of sulfuric acid in a porcelain crucible. Heat the mixture until the excess of water is removed and dense white fumes of sulfur trioxide appear. Cool, cautiously add 20 ml. of water, boil for a few minutes, and filter: a gray residue of impure silica remains on the filter. The filtrate responds to the tests for *Aluminum*, page 807.

Specific gravity, page 866—The specific gravity of Kaolin Mixture with Pectin is not less than 1.10 and not more than 1.15.

Residue on ignition—Weigh accurately about 10 g. of Kaolin Mixture with Pectin in a tared evaporating dish. Determine the volume by dividing its weight by the specific gravity. Evaporate on a steam bath and ignite at red heat to constant weight. The weight of the residue on ignition of Kaolin Mixture with Pectin is not less than 17.5 g. and not more than 19.5 g. in each 100 ml. (17.5 to 19.5 percent).

Salmonella, page 862—The test for *Salmonella* in Kaolin Mixture with Pectin is negative.

Packaging and storage—Preserve Kaolin Mixture with Pectin in tight containers.

CATEGORY—Adsorbent (antidiarrheal).

USUAL DOSE—30 ml. as needed.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 3	DATE 14 June 1971

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-926-9055	ACETAMINOPHEN ELIXIR, NF, 0.12 Gram per 5 cc, 1 gal (3.78 liters)	Bottle

1. SCOPE

1.1 This specification covers Acetaminophen Elixir, N.F.

2. APPLICABLE DOCUMENTS

2.1 Unless otherwise indicated, the issue in effect on date of invitation for bids or request for proposals, of the specifications and standards referenced in the body of this specification shall apply to the extent specified herein. These documents may be obtained as directed by the contracting officer.

3. REQUIREMENTS

3.1 Material. Shall be Acetaminophen Elixir and, except as specified herein, shall be in accordance with the tests, standards, and requirements of the N.F., including any supplements or revisions thereto. Shall contain in each 5 ml, 120 mg of Acetaminophen, within the designated assay limits for the elixir.

Shall be suitable for use as an analgesic.

3.1.1 Assay. The elixir shall assay to contain not less than 98.0 percent and not more than 105.0 percent of the required amount of acetaminophen when determined by the N.F. assay method.

3.1.2 pH. The pH of the elixir shall be not less than 4.70 and not more than 5.30 at 25° C., when determined potentiometrically using the U.S.P. method.

3.1.3 Alcohol content. The elixir shall contain not less than 6.5 percent and not more 8.0 percent alcohol by volume when determined by the U.S.P. Alcohol Determination.

3.1.4 In addition, the elixir shall comply with the following requirements:

3.1.4.1 Identity. The elixir shall comply with the identification test described in 4.4.1.1.

3.1.4.2 Specific gravity. The specific gravity of the elixir shall be not less than 1.221 and not more than 1.235 at 25° C., using a pycnometer.

3.1.4.3 Viscosity. The elixir shall have an absolute viscosity of not less than 45.0 cps and not more than 60.0 cps when measured with the Brookfield Viscosimeter, using spindle No. 1 at a speed of 12 r.p.m.

SSC-1

DPSC FORM 2087 OCT 65

REPLACES DMSC FORM T-4120/11, MAR 64, WHICH WILL BE USED UNTIL DEPLETED

6505-926-9055 (P. D. No. 3)

3.1.4.4 Index of refraction. The index of refraction of the elixir shall be not less than 1.4380 and not more than 1.4430 when measured on a suitable refractometer at 25° C.

3.1.4.5 Free p-aminophenol. The acetaminophen elixir shall contain not more than 0.05 percent of free p-aminophenol based on the amount of acetaminophen present when determined as described in 4.4.1.2.

3.2 Color. The elixir shall be red in color.

3.3 Flavor and palatability. The elixir shall be cherry flavored, and shall be palatable and pleasant to the taste with no unpleasant aftertaste. Not later than the time specified for opening of bids or receipt of proposals, the offeror shall submit to the contracting officer six (6) individually packaged samples (each containing 4 fl oz) of Acetaminophen Elixir representative of the product which the offeror proposes to furnish. Two (2) samples will be subjected to panel testing for a determination of palatability (see 4.4.1.3 Palatability Test). The remaining samples will be used by cognizant Government inspection and quality assurance activities for determining compliance of supplies furnished hereunder with the palatability requirement. Approval as to palatability of any sample submitted by the offeror will not constitute approval of the sample as to any other requirement of this specification. The requirement for submission of samples for use in determining compliance with the palatability requirement may be waived, provided the offeror states, in his bid or proposal, that the product he proposes to furnish is the same product he has offered to the purchasing activity on a previous procurement and the contracting officer determines that such product was previously procured and/or tested by the purchasing activity and found to comply with the palatability requirement.

3.4 Clarity. Shall be clear and free from undissolved or particulate matter.

3.5 Color stability. The color of the elixir shall not decrease in intensity (fade), as measured by visual comparison with fresh elixir after being subjected to the following conditions: Put 15 cc of the Acetaminophen elixir in half-ounce, colorless, flint-glass bottle and place under a G.E. lamp RS 275 Watt, 110-125 volt, 60 cycle, or equivalent lamp, at a distance of 18 inches for 48 hours. Maintain elixir temperature at 27° to 28° C.

3.6 Stability to cold. There shall be no crystallization of any of the ingredients, and no change in clarity of the elixir after being subjected to the following test: Put 15 cc of the Acetaminophen elixir in a half-ounce bottle and place under refrigeration at 5° C. for 5 days.

6505-926-9055 (P. D. No. 3)

3.7 Accelerated aging test:

Randomly select four (4) units of each lot offered for delivery to the Government. *Two (2) units shall be stored at 25° C. ± 2° C. (these are called the unaged samples), and the other two (2) units shall be subjected to constant storage at 55° C. ± 2° C. for two weeks (these are called aged samples). At the end of the two-week period, the aged samples shall be allowed to return to room temperature. All samples shall be tested at room temperature, and the findings shall be as follows:

(a) Upon visual examination, there shall be no difference in clarity between the aged elixir and the unaged elixir.

(b) There shall be no difference in taste between the aged and the unaged elixirs.

(c) When tested in accordance with the N.F. assay, the acetaminophen content of the aged elixir shall be not less than 97.0 percent of that obtained from an equal volume of unaged elixir.

(d) The aged elixir shall comply with the identity test described in paragraph 4.4.1.1

(e) The limit of free-p-aminophenol in the aged solution shall be not more than 0.10 percent, when tested by the method given in paragraph 4.4.1.2

*If difficulty in storing gallon size containers is encountered, pint size samples taken from the gallon bottles shall be used for storage and testing.

3.8 Ingredients.

3.8.1 Acetaminophen. The acetaminophen used in the manufacture of the finished elixir shall be in accordance with the tests, standards and requirements of the N.F., including any supplements or revisions thereto, and in addition, shall comply with the following requirements:

3.8.1.1 Description. Shall be a white, odorless, crystalline powder.

3.8.2 Alcohol. The alcohol entering into the manufacture of the product shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto.

3.8.3 Other ingredients. All other ingredients entering into the manufacture of the product shall be of U.S.P. or N.F. quality or, if not included in either of these compendia, they shall be of the highest pharmaceutical grade.

3.9 Workmanship. Workmanship shall be first class throughout. The material and its containers shall be free from defects which detract from their appearance or may impair their serviceability.

3.10 Delivery. Not more than 4 months shall have elapsed from the date of manufacture of the product, to the date of delivery to the Government.

4. QUALITY ASSURANCE PROVISIONS

4.1 Supplier responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

4.1.1 Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

4.1.2 No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

4.2 Lot. For purpose of this specification, a lot, batch, or control is that single, uniform, and homogeneous quantity of the elixir, produced from one formulation, subjected to the same compounding and manufacturing operation, and filled into final containers.

4.3 Sampling. Sampling shall be conducted in accordance with the procedures set forth in MIL-STD-105, with an acceptable quality level (AQL) of 1.0 percent defective for major defects and 2.5 percent defective for minor defects.

6505-926-9055 (P. D. No. 3)

4.4 Tests.

4.4.1 Finished elixir.

4.4.1.1 Identity test (visible). Transfer 10 ml of elixir, accurately measured, to a 50-ml volumetric flask. Add purified water to volume and mix. Determine the absorbance of the clear liquid in a 1 cm quartz cell at about 530 mu, with a suitable spectrophotometer and purified water as a blank, scanning from 750 mu to 325 mu. The absorbance shall be between 0.650 and 0.790.

4.4.1.2 Free p-aminophenol.

Equipment and Reagents.

Spectronic 20 or equivalent, equipped with 1 cm cells.

Sodium bicarbonate solution ($NaHCO_3$), 5% W/V aqueous.

Extracting solvent - Diethyl ether containing 1.5 ml of isoamyl alcohol per 100 ml.

Hydrochloric acid, 0.01N HCl.

Phenol solution, 1% aqueous.

Sodium carbonate solution (Na_2CO_3), 1N, approximately.

Sodium hypobromite solution - Add two drops of bromine water to 5 ml of 1N Na_2CO_3 and mix well. The solution should be slightly yellow. Prepare fresh.

Standard p-aminophenol solution. Dissolve 267.0 mg of p-aminophenol HCl (equivalent to 200 mg of p-aminophenol) in 1000 ml of purified water. Dilute 5.0 ml of standard solution to 100 ml with 0.01N HCl.

Procedure

Pipet 25.0 ml of sample into a 125 ml separatory funnel, allowing the pipet to drain for 10 to 15 minutes. Add 5 ml of 5% $NaHCO_3$ solution and mix. Add 50 ml of extracting solvent and shake vigorously for one minute, venting the funnel occasionally. Allow the layers to separate. Drain the lower aqueous layer into a small beaker and decant the ether layer into a 250 ml separatory funnel. Pour the aqueous layer back into the first separatory funnel and repeat the extraction process with two more 50 ml portions of extracting solvent. Combine all ether extracts in the second separatory funnel.

6505-926-9055 (P. D. No. 3)

Extract the ether solution with 2 x 25 ml portions of 0.01N HCl, collecting the aqueous extracts in a 100 ml volumetric flask. Dilute to volume with 0.01N-HCl.

Colorimetric step.

Into separate 25 ml volumetric flasks, pipet 5.0 ml of sample extract and 5.0 ml of standard dilution. To each flask, add 10.0 ml of 0.01N HCl and 2.0 ml of 1% phenol solution and mix. Add 2.0 of hypobromite solution to each flask, dilute to volume with purified water, and mix. Allow to stand 20 to 25 minutes and then measure the absorbance at 620 mu against purified water.

Calculation:

$$\text{Percent p-Aminophenol} = \frac{A^{620}_{\text{sample}}}{A^{620}_{\text{standard}}} \times 0.167$$

Report result to the nearest 0.01 percent.

4.4.1.3 Palatability test. A taste panel consisting of 10 members will be used to determine acceptability of samples. Samples will be prepared for testing (samples will be tested undiluted), coded, and served to panel members under controlled serving conditions, e.g., all samples will be of the same amount, and served at the same temperature; each panel member will receive an equal number of samples; the order of serving will be varied among panel members; an interval of at least five (5) minutes will elapse between successive samples and panel members will rinse their mouths with water (room temperature) after each sample; panel members will test without interference either from each other or from outsiders. The product offered shall be rated equal to or better than the FSN 6505-926-9055 Palatability Standard* when determined by the taste panel, using the following 9-point hedonic rating scale. The average rating of the sample shall be equal to or greater than the average rating of the standard, similarly prepared and tested.

1	2	3	4	5	6	7	8	9
Dislike extremely	Dislike very much	Dislike moderately	Dislike slightly	Neither like nor dislike	Like slightly	Like moderately	Like very much	Like extremely

*The FSN 6505-926-9055 Palatability Standard is available upon separate request to the contracting officer, Defense Personnel Support Center, Directorate of Medical Materiel.

6505-926-9055 (P. D. No. 3)

5. PREPARATION FOR DELIVERY

5.1 Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

5.1.1 Immediate containers. Shall comply with the following classification:

GROUP A	CLASS 1	TYPE e	STYLE 1	GRADE 1
CLOSURE A				SEAL A

5.2 Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

5.2.1 Immediate containers. Each immediate container label shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "ACETAMINOPHEN ELIXIR, N.F."

(b) the quantity of active ingredient per 5 cc (1 teaspoonful) designated as "120 mg"

(c) the quantity of contents designated as "1 gal (3.78 liters)"

(d) the Federal Stock No.

(e) the lot or control number

(f) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(g) the date of manufacture

(h) the statement "KEEP FROM FREEZING."

6505-926-9066 (P. D. No. 3)

5.3 Packaging and packing.

5.3.1 Unit of issue. One bottle containing 1 gal, as specified, constitutes one unit of issue.

5.3.2 Procedure code. Procedure code No. 8 of PPP-C-00186a applies.

5.4 Marking.

5.4.1 Intermediate package. In paragraph 5.5.3 of PPP-C-00186a, add: "Date of manufacture shall be shown in lieu of date packed. Marking shall include the legend:

"KEEP FROM FREEZING."

5.4.2 Exterior container. In paragraph 5.5.4 of PPP-C-00186a, add: "Date of manufacture shall be shown in lieu of date packed. Marking shall include the legends:

"KKEP FROM FREEZING"
and
"GLASS - HANDLE WITH CARE."

MAIL AND FREIGHT SHIPPING INFORMATION FOR RECEIVING ACTIVITIES

1. THESE INSTRUCTIONS ARE PUBLISHED AS INFORMATION ONLY IN ORDER TO INSURE DELIVERY AT DESTINATION FREE OF EXPENSE TO THE GOVERNMENT. SINCE THE INFORMATION IS SUBJECT TO CHANGE WITHOUT NOTICE FROM THE GOVERNMENT, APPLICABLE CARRIER'S TARIFF SHOULD BE CONS[illegible]
2. F.O.B. DESTINATION BIDDERS OR OFFERORS ARE CAUTIONED THAT SELECTION OF MODE OF TRANSPORTATION IS THEIR OPTION AND THAT DELIVERING RAIL CARRIERS ARE LISTED ONLY FOR INFORMATION IN THE EVENT SUCH MODE IS SELECTED.

CAUTION: SEE CLAUSE "FOB DESTINATION" FOR CONTRACTOR'S DELIVERY REQUIREMENTS AT DESTINATION UNDER FOB DESTINATION AWARDS
NOTE A: MAIL SHIPMENTS ARE NOT TO BE MADE TO WATER OR AERIAL PORTS OF EMBARKATION
NOTE B: FREIGHT SHIPMENTS TO WATER OR AERIAL PORTS OF EMBARKATION ARE NOT TO BE MADE WITHOUT PRIOR APPROVAL OF THE ADMINISTERING TRANSPORTATION OFFICER
NOTE C: RAIL SHIPMENTS MAY BE SUBJECT TO RESTRICTIONS PUBLISHED IN THE OFFICIAL LIST OF OPEN AND PREPAY STATIONS.

POST OFFICE ADDRESS (INCLUDE ZIP CODE)	DELIVERING RAILROADS	FREIGHT DESTINATIONS: RAIL — CARLOAD	RAIL — LESS CARLOAD	FREIGHT FORWARDER — SURFACE	FREIGHT FORWARDER — AIR	MOTOR — TRUCKLOAD	MOTOR — LESS TRUCKLOAD	EXPRESS SPECIAL	AIR
SECTION A - DISTRIBUTION DEPOTS									
ATLANTA - A33AAT OR A33AAM (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDING OFFICER) ATLANTA ARMY DEPOT FOREST PARK, GA. 30050	C OF GA, SOU	VIA C OF GA LEE, GA. VIA SOU ARMY DEPOT, GA.	VIA C OF GA LEE, GA. VIA SOU ARMY DEPOT, GA.	ARMY DEPOT, GA.	ARMY DEPOT, GA.	ARMY DEPOT, GA.	ARMY DEPOT, GA.	ATLANTA, GA.	ATLANTA, GA. ([illegible] MILES)
COLUMBUS - SW0700 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDER) DEFENSE CONSTRUCTION SUPPLY CENTER COLUMBUS, OHIO 43215	B&O., C&O, N&W, PC	COLUMBUS, OHIO	COLUMBUS, OHIO	COLUMBUS, OHIO	COLUMBUS, OHIO	COLUMBUS, OHIO	COLUMBUS, OHIO	COLUMBUS, OHIO	COLUMBUS, OHIO (2 MILES)
GREAT LAKES - N00128 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDING OFFICER) NAVAL TRAINING CENTER GREAT LAKES, ILL. 60088	CNW, EJ&E	VIA CNW UPTON, ILL. VIA EJ&E GREAT LAKES UPTON AREA, ILL.	GREAT LAKES, ILL.	GREAT LAKES, ILL.	GREAT LAKES, ILL.	GREAT LAKES, ILL.	GREAT LAKES, ILL.	GREAT LAKES, ILL.	CHICAGO, ILL. (32 MILES)
MECHANICSBURG - SW3100 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDER) DEFENSE DEPOT MECHANICSBURG MECHANICSBURG, PA. 17055	PC	MECHANICSBURG, PA. (CUMBERLAND COUNTY)	HARRISBURG, PA.	MECHANICSBURG, PA. (CUMBERLAND COUNTY)	MECHANICSBURG, PA. (CUMBERLAND COUNTY)	MECHANICSBURG, PA. (CUMBERLAND COUNTY)	MECHANICSBURG, PA. (CUMBERLAND COUNTY)	HARRISBURG, PA.	HARRISBURG, PA. (12 MILES)
MEMPHIS - SW3500 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDER) DEFENSE DEPOT MEMPHIS MEMPHIS, TENN. 38115	IC, SLSF, LN SLSW CRI & P, GMO, MP, SOU	MEMPHIS, TENN.	MEMPHIS, TENN.	MEMPHIS, TENN.	MEMPHIS, TENN.	MEMPHIS, TENN.	MEMPHIS, TENN.	MEMPHIS, TENN.	MEMPHIS, TENN. (4 MILES)
NORFOLK - N00189 (FREIGHT SHPTS - CONSIGN TO RECG OFCR MATL DEPT) (MAIL SHPTS - ADDRESS TO COMMANDING OFFICER) NAVAL SUPPLY CENTER NORFOLK, VA. 23512	N&W, C&O, SOU SCL, PC, NS, NFD	NORFOLK, VA. (SEE NOTE 1 BELOW)	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA. (SEE NOTE 1 BELOW)	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA. (5 MILES)
OAKLAND - N00228 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER, CODE 102.12, BLDG. 212) (MAIL SHPTS - ADDRESS TO COMMANDING OFFICER) NAVAL SUPPLY CENTER OAKLAND, CALIF. 94625	SP, WP, ATSF	OAKLAND, CALIF.	OAKLAND, CALIF.	OAKLAND, CALIF.	OAKLAND, CALIF.	OAKLAND, CALIF.	OAKLAND, CALIF.	OAKLAND, CALIF.	OAKLAND, CALIF. ([illegible] MILES) SAN FRANCISCO, CALIF. ([illegible] MILES)
OGDEN - SW3400 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDER) DEFENSE DEPOT OGDEN OGDEN, UTAH 84401	DRGW, SP, UP	OGDEN, UTAH	OGDEN, UTAH	OGDEN, UTAH	OGDEN, UTAH	OGDEN, UTAH	OGDEN, UTAH	OGDEN, UTAH	SALT LAKE CITY, UTAH (40 MILES) OGDEN, UTAH (6 MILES)
PHILADELPHIA - SW0100 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDER) DEFENSE PERSONNEL SUPPORT CENTER PHILADELPHIA, PA. 19101	B&O, PC	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA. (5 MILES)
RICHMOND - SW0400 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDER) DEFENSE GENERAL SUPPLY CENTER RICHMOND, VA. 23219	SCL	BELLBLUFF, VA.	BELLBLUFF, VA.	BELLBLUFF, VA.	RICHMOND, VA.	BELLBLUFF, VA.	BELLBLUFF, VA.	RICHMOND, VA.	RICHMOND, VA. (15 MILES)
SAN DIEGO - N00244 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDING OFFICER) NATIONAL CITY ANNEX NAVAL SUPPLY CENTER SAN DIEGO, CALIF. 92050	ATSF	NATIONAL CITY, CALIF.	NATIONAL CITY, CALIF.	SAN DIEGO, CALIF.	SAN DIEGO, CALIF.	NATIONAL CITY, CALIF.	NATIONAL CITY, CALIF.	SAN DIEGO, CALIF.	SAN DIEGO, CALIF. (6 MILES)
TRACY - SW3200 (FREIGHT SHPTS - CONSIGN TO TRANSP OFFICER) (MAIL SHPTS - ADDRESS TO COMMANDER) DEFENSE DEPOT TRACY TRACY, CALIF. 95376	SP, WP	LYOTH, CALIF.	LYOTH, CALIF.	LYOTH, CALIF.	LYOTH, CALIF.	LYOTH, CALIF.	LYOTH, CALIF.	STOCKTON, CALIF.	STOCKTON, CALIF. (18 MILES) OAKLAND, CALIF. (53 MILES) SAN FRANCISCO, CALIF. (64 MILES)

NOTE 1: WHEN SHIPMENTS AGGREGATE ONE OR MORE CARLOADS OR TRUCKLOADS OF A SINGLE COMMODITY, THE CONSIGNMENT INSTRUCTIONS SHOWN HEREIN DO NOT APPLY. OBTAIN SUCH INSTRUCTIONS FROM THE RECEIVING OFFICER MATERIAL DEPT., NAVAL SUPPLY CENTER, NORFOLK, VA. [illegible] PRIOR TO MAKING SHIPMENT. (MIXED CARLOAD, TRUCKLOAD SHIPMENTS WILL BE CONSIGNED AS SHOWN HEREIN).

DD FORM 1655 (Overprint 1, Mar 71)

Post office address (include zip code)	Delivering railroads	Freight destinations: Rail — Carload	Rail — Less carload	Freight forwarder — Surface	Freight forwarder — Air	Motor — Truckload	Motor — Less truckload	Express (specify)	Air
SECTION B - WATER PORTS OF EMBARKATION								(Surface or Air)	(Nearest Airport)
BALTIMORE (CONSIGN TO: TRANSPORTATION OFFICER) BALTIMORE OUTPORT, EAMTMTS DUNDALK MARINE TERMINAL	PC, B&O, WM	BALTIMORE, MD	BALTIMORE, MD.	BALTIMORE, MD	BALTIMORE, MD	BALTIMORE, MD	BALTIMORE, MD	BALTIMORE, MD	BALTIMORE, MD (11 MILES)
BAYONNE (CONSIGN TO: TRANSPORTATION OFFICER) MILITARY OCEAN TERMINAL, BAYONNE	CNJ, LV, PC	BAYONNE, N.J.	BAYONNE, N. J.	BAYONNE, N.J.	BAYONNE, N.J.	BAYONNE, N.J.	BAYONNE, N.J.	BAYONNE, N.J.	NEWARK, N.J. (8 MILES) NEW YORK (JFK) (20 MILES) NEW YORK (LA GUARDIA) (22 MILES)
LONG BEACH (CONSIGN TO: TRANSPORTATION OFFICER, M F: PIER B, BERTH 12) SOUTHERN CALIFORNIA OUTPORT, WAMTMTS	UP, SP, ATSF	LONG BEACH, CAL.	LONG BEACH, CAL.	LONG BEACH, CAL.	LONG BEACH, CAL.	LONG BEACH, CAL.	LONG BEACH, CAL.	LONG BEACH, CAL.	LONG BEACH, CAL. (7 MILES) LOS ANGELES, CAL. (11 MILES)
NEW ORLEANS (CONSIGN TO: TRANSPORTATION OFFICER) GULF OUTPORT, EAMTMTS	GMO, IC, LA&LN, MP, NOT, SP, TP	NEW ORLEANS, LA.	NEW ORLEANS, LA.	NEW ORLEANS, LA.	NEW ORLEANS, LA.	NEW ORLEANS, LA.	NEW ORLEANS, LA.	NEW ORLEANS, LA.	NEW ORLEANS, LA. (17 MILES)
NORFOLK (CONSIGN TO: FREIGHT TERMINAL OFFICER, WATER FREIGHT DIVISION) NAVAL SUPPLY CENTER	N&W, C&O, SOU SCL, PC, NS, NFD	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA.	NORFOLK, VA. (8 MILES)
OAKLAND (CONSIGN TO: TRANSPORTATION OFFICER) MILITARY OCEAN TERMINAL, BAY AREA OAKLAND ARMY BASE	SP, WP, ATSF	OAKLAND, CAL.	OAKLAND, CAL.	OAKLAND, CAL.	OAKLAND, CAL.	OAKLAND, CAL.	OAKLAND, CAL.	OAKLAND, CAL.	OAKLAND, CAL. (10 MILES) SAN FRANCISCO, CAL. (22 MILES)
PHILADELPHIA (CONSIGN TO: TRANSPORTATION OFFICER) PHILADELPHIA OUTPORT, EAMTMTS NORTHERN METAL COMPANY MARINE TERMINAL	PC, RDG (CAR FLOAT)	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILA., PA.	PHILADELPHIA, PA. (17 MILES)
SEATTLE (CONSIGN TO: TRANSPORTATION OFFICER) MTMTS TERMINAL UNIT, PACIFIC NORTHWEST	GN, NP, UP, CMSTP&P	SEATTLE, WASH.	SEATTLE, WASH.	SEATTLE, WASH.	SEATTLE, WASH.	SEATTLE, WASH.	SEATTLE, WASH.	SEATTLE, WASH.	SEATTLE - TACOMA (15 MILES)
SECTION C - AERIAL PORTS OF EMBARKATION								(Surface or Air)	(Nearest Airport)
CHARLESTON (CONSIGN TO: TRANSPORTATION OFFICER) CHARLESTON AIR FORCE BASE	SOU	TEN MILE, SC.	CHARLESTON, S.C.	CHARLESTON AFB, S.C.	CHARLESTON AFB, S.C.	CHARLESTON AFB, S.C.	CHARLESTON AFB, S.C.	CHARLESTON AFB, S.C.	CHARLESTON, S.C. (4 MILES)
DOVER (CONSIGN TO: TRAFFIC MANAGEMENT OFFICER, MARK FOR: AIR FREIGHT TERMINAL) DOVER AIR FORCE BASE	PC	DOVER, DEL.	DOVER, DEL.	DOVER AFB, DEL.	DOVER AFB, DEL.	DOVER AFB, DEL.	DOVER AFB, DEL.	DOVER AFB, DEL.	PHILADELPHIA, PA. (75 MILES) BALTIMORE, MD (85 MILES)
KELLY (CONSIGN TO: TRANSPORTATION OFFICER) KELLY AIR FORCE BASE	SP, MKT, MP	SAN ANTONIO, TEX.	SAN ANTONIO, TEX.	SAN ANTONIO, TEX.	SAN ANTONIO, TEX.	SAN ANTONIO, TEX.	SAN ANTONIO, TEX.	SAN ANTONIO, TEX.	SAN ANTONIO, TEX. (15 MILES)
MC CHORD (CONSIGN TO: COMMERCIAL TRANSPORTATION OFFICER, MARK FOR: AIR FREIGHT TERMINAL, BLDG 1422) MC CHORD AIR FORCE BASE	GN, NP	MC CHORD FIELD, WASH.	MC CHORD FIELD, WASH.	MC CHORD AFB, WASH.	MC CHORD AFB, WASH.	MC CHORD AFB, WASH.	MC CHORD AFB, WASH.	TACOMA, WASH.	SEATTLE-TACOMA (30 MILES)
MC GUIRE (CONSIGN TO: TRANSPORTATION OFFICER) MC GUIRE AIR FORCE BASE	P&A	FORT DIX, N.J.	FORT DIX, N.J.	MC GUIRE AFB, N.J.	MC GUIRE AFB, N.J.	MC GUIRE AFB, N.J.	MC GUIRE AFB, N.J.	MC GUIRE AFB, N.J.	PHILADELPHIA, PA. (31 MILES) NEWARK, N.J. (55 MILES)
NORTON (CONSIGN TO: TRANSPORTATION OFFICER) NORTON AIR FORCE BASE	SP, ATSF, UP	NORTON AFB, CAL.	NORTON AFB, CAL.	NORTON AFB, CAL.	NORTON AFB, CAL.	NORTON AFB, CAL.	NORTON AFB, CAL.	SAN BERNARDINO, CAL.	LOS ANGELES, CAL. (73 MILES) ONTARIO, CAL. (22 MILES) RIVERSIDE, CAL. (16 MILES)
TINKER (CONSIGN TO: TRANSPORTATION OFFICER) TINKER AIR FORCE BASE	ATSF	MIDWEST CITY, OKLA.	OKLAHOMA CITY, OKLA.	TINKER AFB, OKLA.	OKLAHOMA CITY, OKLA.	TINKER AFB, OKLA.	TINKER AFB, OKLA.	OKLAHOMA CITY, OKLA.	OKLAHOMA CITY, OKLA. (12 MILES)
TRAVIS (CONSIGN TO: COMMERCIAL TRANSPORTATION OFFICER) TRAVIS AIR FORCE BASE	SP	TOLENAS, CAL.	TOLENAS, CAL.	TRAVIS AFB, CAL.	TRAVIS AFB, CAL.	TRAVIS AFB, CAL.	TRAVIS AFB, CAL.	TRAVIS AFB, CAL.	OAKLAND, CAL. (25 MILES) SAN FRANCISCO, CAL. (72 MILES)

DD FORM 1655 (Reverse Side) (Overprint-1, Mar 72)

MODIFICATION NO. 1
DATE: 10 January 1969

MODIFICATION TO DEFENSE MEDICAL PURCHASE DESCRIPTION

This modification forms a part of Defense Medical Purchase Description No. 5, dated 21 September 1966, and covers the following items to the extent specified herein:

Federal Stock No.	Item Identification
6505-128-5705	THIMEROSAL TINCTURE, NF, 1 pt (473 cc)
6505-128-5710	THIMEROSAL TINCTURE, NF, 1 gal (3.78 liters)

For FSN 6505-128-5705 - include the following new statements on the label of the immediate containers:

"(j) the date of manufacture

"(k) the statement 'Do not use in combination with or following the application of acids, the salts of heavy metals, or iodine'

"(l) the statement 'The solution may be filtered, without loss of potency, to remove any small, shiny (silica) particles that may develop'

"(m) the statement 'After application of Thimerosal Tincture, permit to dry before covering with bandages or other occlusive dressings.'."

Page 5:

Intermediate package. Line 6, following "addition," delete remainder of paragraph and substitute: "date of manufacture shall be shown in lieu of date packed."

Exterior container. Line 3, following "addition," delete remainder of paragraph and substitute: "date of manufacture shall be shown in lieu of date packed."

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 5	DATE 21 September 1966

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-128-5705 and 6505-128-5710	THIMEROSAL TINCTURE, NF	Bottle

This purchase description covers the following items:

Federal Stock Number (FSN)	Item Identification
6505-128-5705	THIMEROSAL TINCTURE, NF, 1 pt (473 cc)
6505-128-5710	THIMEROSAL TINCTURE, NF, 1 gal (3.78 liters)

FSN 6505-128-5705 and FSN 6505-128-5710 shall comply with the following:

Shall be a fluorescent, orange-red, hydroalcoholic-acetone solution containing 100 mg Thimerosal per 100 ml.

Shall be in accordance with the tests, standards, and requirements of the N.F., including any supplements or revisions thereto for "Thimerosal Tincture", with the following additional requirements:

Shall assay to contain not less than 97.50 mg and not more than 104.0 mg Thimerosal ($C_9H_9HgNaO_2S$), in each 100 ml of Thimerosal Tincture.

Shall be clear and free from sediment.

The pH of the solution shall be between 8.10 and 8.80 when determined colorimetrically.

The pH determination shall be on the final solution which includes the dye. An acceptable method for making this determination is as follows:

> For this determination, a set of uniformly clear and colorless glass tubes (Nessler or comparison) will be used. A series of of standar solutions at specific pH values of 7.9, 8.1, 8.3, 8.5, and 8.9 containing thymol blue indicator are viewed transversely through an equal volume of the thimerosal tincture (containing the dye) in another glass tube.
>
> An identical volume of the colored thimerosal tincture containing thymol blue is viewed transversely through an equal volume of water in another glass tube. A comparison of the two (2) sets of tubes is made to the nearest matching pH value.

DPSC FORM 2087 OCT 65 REPLACES OMSC FORM 7-4120/11, MAR 66, WHICH WILL BE USED UNTIL DEPLETED

All viewing is done transversely against a white background, observing both the standard sets and the sample set through equal fluid depths.

All ingredients entering into the solution shall be of U.S.P. or N.F., quality, or if not included in either of these compendia, they shall be suitable for use in this preparation.

Not more than 6 months shall have elapsed from date of manufacture of the product to the date of delivery to the Government.

PREPARATION FOR DELIVERY

Shall be in accordance with all applicable requirements of Federal Specification PPP-C-186, dated 11 December 1961, together with deletions or additions as indicated herein:

Immediate containers. Shall comply with the following classification:

GROUP A	CLASS 1	TYPE e	STYLE 1	GRADE 1
CLOSURE A			SEAL A or B	

Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

FSN 6505-128-5705:

Immediate containers. Each immediate container label for FSN 6505-128-5705 shall bear the following information. However, the information is not required to appear in the sequence indicated.

(a) the item identification designated as "THIMEROSAL TINCTURE, N.F."

(b) the quantity of contents designated as "1 pt (473 cc)"

(c) the stock number

(d) the lot or control number

(See additional label information on Page 3)

(e) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(f) the word "POISON" in prominent red letters. Other label information may appear in red print.

(g) the word "FLAMMABLE"

(h) the statement "Protect from Light" or a similar statement

(i) the statement "Store in a Cool Place"

FSN 6505-128-5710:

Immediate containers. Each immediate container label for FSN 6505-128-5710 shall bear the following information. However, the information is not required to appear in the sequence indicated.

(a) the item identification designated as "THIMEROSAL TINCTURE, N.F."

(b) the quantity of contents designated as "1 gal (3.78 liters)"

(c) the stock number

(d) the lot or control number

(e) the name and address the of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(See additional label information on Page 4)

(f) the word "POISON" in prominent red letters. Other label information may appear in red print.

(g) the word "FLAMMABLE"

(h) the statement "Protect from Light" or a similar statement

(i) the statement "Store in a Cool Place"

Packaging.

Unit of issue. One bottle, as specified, constitutes one unit of issue.

Unit package. At the option of the contractor, each unit shall be packaged as specified in 5.2.5.

Intermediate package. The number of units of issue specified in table I, column 2, for Procedure Code No. 6, for FSN 6505-128-5705 and Procedure Code No. 8 for FSN 6505-128-5710, indicated in column 1, shall be packaged in an intermediate package constructed in accordance with the applicable paragraph referenced in column 3, except that partitions shall not be required when unit package is furnished.

Packing. The number of units contained in the intermediate packages and total number of units of issue for the applicable procedure code, indicated in column 4, shall be overpacked in an exterior container constructed in accordance with the applicable paragraph referenced in column 5 (level B), or column 6 (level A), for the level of protection specified in the procurement document. Bursting strength of carton shall be in accordance with special requirements in table I of Federal Specification PPP-B-636, in lieu of bursting strength specified in the applicable paragraph referenced in column 5 (level B). Method I closure of Federal Specification PPP-B-636 shall be utilized on level B fiberboard packs. In addition, in line 10 of 5.4.4, delete "IV" and substitute "III; or Federal Specification PPP-B-636, type CF, class weather-resistant"; at end of 5.4.4.1, add "Case liner shall not be required for fiberboard boxes." Add the following new paragraph: "5.4.4.1.1 Closure. Closure of wood boxes shall be in accordance with appendix of applicable box specification. Closure of each fiberboard box shall be as specified in the appendix, and waterproofing shall conform with 30.4 of Federal Specification PPP-B-636."

Marking.

Unit package. When furnished, each unit package shall bear the same information as required for the immediate container.

Intermediate package. Each intermediate package shall be marked in accordance with Military Standard MIL-STD-129. When labels are utilized, waterproofing shall be required only when applicable carton is fabricated of water resistant material. Lot (control) number, contract or purchase order number, and name of contractor shall be shown. Marking shall include the legend "STORE IN A COOL PLACE" and in addition, marking as required by I.C.C. Regulations shall also be shown.

Exterior containers. Exterior containers shall be marked in accordance with Military Standard MIL-STD-129. Lot (control) number shall be shown. Marking shall include the legend "STORE IN A COOL PLACE" and in addition, markings as required by I.C.C. Regulations shall also be shown.

SUPPLIER RESPONSIBILITIES FOR INSPECTION.

Such examinations and tests as are set forth in this specification or as shall otherwise be appropriate or necessary to insure that supplies conform to specification requirements, shall be performed by and at the expense of the supplier. Suppliers who do not have facilities adequate for such tests shall arrange for the use of test facilities acceptable to the Government. Records of examinations and tests performed by the supplier shall be maintained by the supplier and made available to the Government, upon the Government's request, at any time, or from time to time, for a period of 3 years after the delivery of the supplies to which such records relate.

DEFENSE MEDICAL PURCHASE DESCRIPTION	NUMBER 3	DATE 1 June 1971

FEDERAL STOCK NO.	ITEM IDENTIFICATION	UNIT
6505-890-2010 and 6505-926-9026	PROMETHAZINE HYDROCHLORIDE, CHLOROFORM, IPECAC FLUIDEXTRACT, AND POTASSIUM GUAIACOLSULFONATE SYRUP	Bottle

1. SCOPE

1.1 This specification covers the following items in the quantity per bottle as indicated for the appropriate Federal Stock No. (FSN) and Item Identification:

FSN	Item Identification
6505-890-2010	PROMETHAZINE HYDROCHLORIDE, CHLOROFORM, IPECAC FLUIDEXTRACT, AND POTASSIUM GUAIACOLSULFONATE SYRUP, 1 gal (3.78 liters)
6505-926-9026	PROMETHAZINE HYDROCHLORIDE, CHLOROFORM, IPECAC FLUIDEXTRACT, AND POTASSIUM GUAIACOLSULFONATE SYRUP, 4 fl oz (118 cc)

2. APPLICABLE DOCUMENTS

2.1 Specifications and standards. Unless otherwise indicated, the issue in effect on date of invitation for bids or request for proposals of the specifications and standards, referenced in the body of this specification shall apply to the extent specified herein. These documents may be obtained as directed by the contracting officer.

3. REQUIREMENTS

3.1 Material. Shall be a clear syrupy liquid. Each 5 cc of the preparation shall contain 5 mg promethazine hydrochloride, 0.17 minims ipecac fluidextract, 44 mg potassium guaiacolsulfonate, 0.25 minims chloroform, 60 mg citric acid (anhydrous), 197 mg sodium citrate, in a syrup base, and 7 percent alcohol.

3.2 Description. The finished preparation shall be green in color and have a pleasant taste and pleasing odor. Shall be suitable as an antihistaminic expectorant for symptomatic cough control in adults, infants, and children.

3.3 Additives. The finished preparation shall contain suitable preservatives. The coloring agent(s) or other ingredients, if such are used, and the preservatives in the product shall be in amounts as approved by the Federal Food and Drug Administration (F.D.A.) which will make the preparation attractive and palatable, and will properly preserve the product.

6505-890-2010 (P. D. No. 3)

3.4 Finished preparation.

3.4.1 Assay. The finished preparation shall assay to contain not less than 95.0 percent and not more than 110.0 percent of the required amount of Promethazine Hydrochloride (10-(2-Dimethylaminopropyl) phenothiazine hydrochloride) when determined as specified in 4.4.1.

3.4.2 Specific gravity. The specific gravity of the preparation shall be not less than 1.28 and not more than 1.30 at 25° C., when determined, using a pycnometer or a specific gravity balance.

3.4.3 pH. The pH of the undiluted preparation shall be not less than 4.70 and not more than 5.20 at 25° C., when determined potentiometrically, using the U.S.P. method.

3.4.4 Identification. The promethazine in the preparation shall be identified by an absorbance ratio with limits of 8.0 - 8.8 and by yellow crystal formation when determined as specified in 4.4.2.

3.4.5 Alcohol content. The finished preparation shall assay to contain not less than 6.5 percent and not more than 7.5 percent of the required amount of alcohol when determined as specified in 4.4.3.

3.4.6 Chloroform content. The finished preparation shall assay to contain not less than 90.0 percent and not more than 125.0 percent of the required amount of chloroform when determined as specified in 4.4.4.

3.4.7 The syrup shall be suitably flavored, and shall be palatable and pleasant to the taste with no unpleasant after-taste. Not later than the time specified for opening of bids or receipt of proposals, the offeror shall submit to the contracting officer six (6) individually packaged samples (each containing 4 fl oz) of the finished syrup representative of the product which the offeror proposes to furnish. Two (2) samples will be subjected to panel testing for a determination of palatability (see "Palatability Test paragraph 4.4.5). The remaining samples will be used by cognizant Government inspection and quality assurance activities for determining compliance of supplies furnished hereunder with the palatability requirement. Approval as to palatability of any sample submitted by the offeror will not constitute approval of the sample as to any other requirement of this specification. The requirement for submission of samples for use in determining compliance with the palatability requirement may be waived, provided the offeror states, in his bid or proposal, that the product he proposes to furnish is the same product he has offered to the purchasing activity on a previous procurement and the contracting officer determines that such product was previously procured and/or tested by the purchasing activity and found to comply with the palatability requirement.

6505-890-2010 (P. D. No. 3)

3.5 Active ingredients.

3.5.1 Promethazine hydrochloride. The promethazine hydrochloride used in the manufacture of the syrup shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto, and, in addition, shall comply with the following:

Description. Shall be a white to faint yellow, practically odorless crystalline powder.

3.5.2 Sodium citrate. The sodium citrate used in the manufacture of the syrup shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto, and, in addition, shall comply with the following:

Description. Shall be colorless crystals, or white, crystalline powder.

3.5.3 Citric acid. The citric acid used in the manufacture of the syrup shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto, and, in addition, shall comply with the following:

Description. Shall be colorless, translucent crystals, or white, granular to fine crystalline powder.

3.5.4 The ipecac fluidextract entering into the manufacture of the finished preparation shall be in accordance with the tests, standards, and requirements of the XVI, which was official from 1 October 1960 to 31 August 1965.

3.5.5 The potassium guaiacolsulfonate and the chloroform entering into the manufacture of the finished preparation shall be in accordance with the tests, standards, and requirements of the N.F., including any supplements or revisions thereto, and, in addition, shall comply with the following:

3.5.5.1 Potassium guaiacolsulfonate. Shall be white crystals or white crystalline powder.

3.5.5.2 Chloroform. Shall be a clear, colorless, mobile liquid, having a characteristic ethereal odor.

3.6 Other ingredients. All other ingredients entering into the manufacture of the finished preparation shall be of U.S.P. or N.F. quality, or if not included in either of these compendia, the ingredients shall be suitable for use in the preparation. In addition, the Liquid Glucose, U.S.P., shall be free from yeasts and molds and its bacterial count shall not exceed 500 organisms per gram of liquid glucose.

Liquid glucose exceeding these requirements may be used in the manufacture of the finished syrup, provided that the bulk lot of syrup, prior to filling, demonstrates compliance with the above requirements when determined by a suitable, accurate, and reproducible method.

3.7 Delivery. Not more than 4 months shall have elapsed from the date of manufacture of the product, to the date of delivery to the Government.

3.8 Workmanship. Workmanship shall be first class throughout. The material and its containers shall be free from defects which detract from their appearance or may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Supplier responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

4.1.1 Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of 3 years after delivery of the supplies to which such records relate.

4.1.2 No company supplying any ingredient(s) to the contractor will be considered an acceptable facility for the performance of any inspection requirements specified herein.

4.2 Lot. For purposes of this specification, a lot, batch, or control is that single, uniform, and homogeneous quantity of syrup, produced from one formulation, subjected to the same compounding and manufacturing operation, and filled into final containers.

4.3 Sampling. Sampling shall be conducted in accordance with the procedures set forth in MIL-STD-105, with an Acceptable Quality Level (AQL) of 1.0 percent defective for major defects and 2.5 percent defective for minor defects.

6505-890-2010 (P. D. No. 3)

4.4 Tests.

4.4.1 Promethazine hydrochloride assay in finished preparation. Use low actinic glassware throughout test.

Transfer an accurately measured sample of 25 cc to a 250-ml separator. Add 5 cc of purified water and 15 cc of 28 percent ammonium hydroxide. Completely extract the promethazine base with 40 cc portions of chloroform (about 6 extractions usually required), collecting the extractions in a second separator. Extract the ipecac with a 20 cc portion of 10 percent hydrochloric acid, followed by five (5) 15 cc portions of 1 percent hydrochloric acid. Wash the combined acid extracts with 25 cc of chloroform and add the chloroform washings to the main chloroform extract. (Discard the aqueous washings). Filter the combined chloroform extracts through a pledget of cotton previously wetted with chloroform, into a beaker and wash the separatory funnel and pledget of cotton with several small portions of chloroform. Evaporate the combined chloroform extracts on a water bath with the aid of a current of air to a volume of about 5-10 cc. Discontinue heating and continue evaporation with the aid of a current of air, to dryness. Add 50 cc of purified water and warm on a steam bath to dissolve the residue. Transfer the aqueous solution to a 500 cc volumetric flask with the aid of warm purified water. Cool to room temperature and dilute to the mark with purified water. Mix thoroughly, filter through a medium-porosity sintered glass filter rejecting the first few cc portion of filtrate, and collect the subsequent filtrate in a dry glass stoppered flask. (Reserve a portion of this filtrate for the preparation of the solution (for the identification test.). Determine the absorbancy of the clear filtrate, and a solution of Promethazine Hydrochloride U.S.P. Reference Standard, diluted to the same concentration as that of the sample, at 298 mu in a Beckman DU spectrophotometer, using a 1-cm quartz cell, with purified water as the reference liquid. Calculate percent of required amount of promethazine hydrochloride.

4.4.2 Identification.

a. Transfer exactly 10 cc of the clear filtrate obtained in 4.4.1 to a 100-cc volumetric flask. Dilute to the mark with purified water and mix thoroughly. Determine the absorbance at 249 mu with a Beckman DU spectrophotometer, using a 1 cm, quartz cell and purified water as the reference liquid.

Calculation: $\frac{10 \times A249}{A298}$ = ratio of absorbancies

b. Transfer 50 cc of sample to a 250 cc separatory funnel, add 50 cc of chloroform and 10 cc of anhydrous methanol. Stopper and shake vigorously for 5 minutes. Allow the two phases to separate and transfer the bottom layer to a 200 cc beaker. Evaporate to dryness on a steam bath with the aid of a current of air. Add 5 cc of 3.5 percent anhydrous methanol picric acid solution and heat on a steam bath for 5 minutes. Cool in an ice bath until yellow crystals appear.

6505-890-2010 (P. D. No. 3)

4.4.3 Alcohol content. Adjust the temperature of the sample to 25° C. and transfer exactly 100 cc to a distilling flask. Dilute with 150 cc purified water and distill, collecting about 90 cc distillate in a 100 cc volumetric flask immersed in an ice bath. Rinse the distillate into a separator, add 10 grams NaCl and 30 cc petroleum ether. Shake the mixture to extract volatile oils and $CHCl_3$. Draw off the water-alcohol layer into a distilling flask. Wash the petroleum ether solution in the separator with two 40 cc portions of saturated NaCl solution, adding the aqueous washings to the distilling flask. Distill, collecting about 90 cc distillate in a 100 cc volumetric flask immersed in an ice bath. Adjust the temperature of the distillate to 25° C. and dilute to the mark with purified water at the same temperature. Add about 5 Gm talc, mix, and filter. Determine the specific gravity of the filtrate at 25° C. in a pycnometer. Calculate percent required amount of alcohol.

4.4.4 Chloroform assay.

REAGENTS:

Cyclohexane - B.P. 80° - 81° C.
Chloroform - Suitable for Spectrophotometric use.

STANDARD CHLOROFORM SOLUTION:

Transfer exactly 5 ml of chloroform to a 250 ml volumetric flask containing about 150 ml of cyclohexane. Dilute to the mark with cyclohexane and mix well. Transfer exactly 20 ml of this solution to a 100 ml volumetric flask containing 50 ml cyclohexane. Dilute to the mark with cyclohexane and mix well (Chloroform concentration at this dilution is 0.40 ml/100 cc).

PROCEDURE: ALL TRANSFERS SHALL BE MADE AS RAPIDLY AS POSSIBLE.

Transfer about 20 ml of sample accurately measured to a suitable glass stoppered centrifuge tube (or other suitable vessel), add 4 glass beads and exactly 20 ml of cyclohexane. Stopper securely and shake vigorously for 5 minutes. Centrifuge at 3000 rpm for 5 minutes. Determine the absorbance of the cyclohexane solution in the sample and standard in 0.1 mm NaCl cells, using a suitable infrared spectrophotometer.

Calculate percent required amount of chloroform.

6505-890-2010 (P. D. No. 3)

NOTE: Set the instrument to the following operating conditions:

1. Double Beam.
2. 0.60 amps.
3. 763 cm-1
4. 1.1 mm slit.
5. 2.0% gain.
6. 8 period.
7. Use trimmer comb to set 100% transmission, then switch to O-1 absorbance.

4.4.5 Palatability test. A taste panel consisting of 10 members will be used to determine acceptability of samples. Samples will be prepared for testing (samples will be tested undiluted), coded, and served to panel members under controlled serving conditions, e.g., all samples will be of the same amount, and served at the same temperature; each panel member will receive an equal number of samples; the order of serving will be varied among panel members; an interval of at least five (5) minutes will elapse between successive samples and panel members will rinse their mouths with water (room temperature) after each sample; panel members will test without interference either from each other or from outsiders. The product offered shall be rated equal to or better than the FSN 6505-890-2010 and FSN 6505-926-9026 Palatability Standard*, when determined by the taste panel, using the following 9-point hedonic rating scale. The average rating of the sample shall be equal to or greater than the average rating of the standard, similarly prepared and tested.

1	2	3	4	5	6	7	8	9
Dislike extremely	Dislike very much	Dislike moderately	Dislike slightly	Neither like nor dislike	Like slightly	Like moderately	Like very much	Like extremely

*The FSN 6505-890-2010 and FSN 6505-926-9026 Palatability Standard is available, upon separate request to the contracting officer at the Defense Personnel Support Center.

5. PREPARATION FOR DELIVERY

5.1 Shall be in accordance with all applicable requirements of Interim Federal Specification PPP-C-00186a, dated 15 May 1969, and Amendment-1, dated 27 October 1969, and as specified herein:

5.1.1 Immediate containers. Each immediate container shall comply with the following classification:

GROUP A	CLASS 1	TYPE I	STYLE 1	GRADE 1
CLOSURE A				SEAL A

Each immediate container for FSN 6505-890-2010 shall be designed with a pour lip and with a single handle. If the handle is at the same height as the head of the bottle, the seal may partially cover the handle.

6505-890-2010 (P. D. No. 3)

5.2 Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

5.2.1 Immediate containers.

5.2.1.1 For FSN 6505-890-2010. Each immediate container label for FSN 6505-890-2010 shall bear the following information. However, the information is not required to appear in the sequence indicated.

(a) the item name designated as "PROMETHAZINE HYDROCHLORIDE, CHLOROFORM, IPECAC FLUIDEXTRACT, AND POTASSIUM GUAIACOLSULFONATE SYRUP"

(b) the quantity of contents designated as "1 gal (3.78 liters)"

(c) the quantity of active ingredients expressed in milligrams or minims per 5 cc (one teaspoonful)

(d) the Federal Stock No. designated as "FSN 6505-890-2010" or "Stock No. 6505-890-2010"

(e) the lot or control number

(f) the date of manufacture

(g) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(h) the statement "Caution: Federal law prohibits dispensing without prescription."

(i) the following or similar statements:

1. Keep tightly closed.
2. Protect from light.
3. Shake well.

(j) the statement "Store at controlled room temperature (59° - 86° F.)."

6505-890-2010 (P. D. No. 3)

5.2.1.2 For FSN 6505-926-9026. Each immediate container label for FSN 6505-926-9026 shall bear the following information. However, the information is not required to appear in the sequence indicated:

(a) the item name designated as "PROMETHAZINE HYDROCHLORIDE, CHLOROFORM, IPECAC FLUIDEXTRACT, AND POTASSIUM GUAIACOLSULFONATE SYRUP"

(b) the quantity of contents designated as "4 fl oz (118 cc)"

(c) the quantity of active ingredients expressed in milligrams or minims per 5 cc (one teaspoonful)

(d) the Federal Stock No. designated as "FSN 6505-926-9026" or "Stock No. 6505-926-9026"

(e) the lot or control number

(f) the date of manufacture

(g) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

(h) the statement "Caution: Federal law prohibits dispensing without prescription."

(i) the following or similar statements:

1. Keep tightly closed.

2. Protect from light.

3. Shake well.

(j) the statement "Store at controlled room temperature (59° - 86° F.)."

32-814 (Pt. 24) O - 74 - 32

6505-890-2010 (P. D. No. 3)

5.2.2 Circular.

5.2.2.1 For FSN 6505-890-2010. A quantity of not less than 4 circulars, brochures, or other printed matter shall be packaged within each intermediate package for FSN 6505-890-2010, setting forth as a minimum: Indications for use, dosage and administration, precautions and contraindications, and side effects. The circulars shall be packaged in a manner acceptable to the Food and Drug Administration for individual issue of the bottle. Full disclosure information may be included on the label of the immediate container and each intermediate package, or on the unit package, if furnished, in lieu of the individual circulars.

5.2.2.2 For FSN 6505-926-9026. A circular, brochure, or other printed matter shall accompany each immediate container for FSN 6505-926-9026, setting forth as a minimum: Indications for use, dosage and administration, precautions and contraindications, and side effects.

5.3 Packaging.

5.3.1 Unit of issue. One (1) bottle containing 4 fl oz or 1 gal, as specified, constitutes one unit of issue.

5.3.2 Packaging quantities. The number of units of issue indicated in the following table shall be packaged in each unit, intermediate, and exterior container, as applicable, for the required level of protection specified in the procurement document.

Packaging quantities

Size	Unit package	Intermediate package	Exterior container
4 fl oz	1 unit	12 units	48 units
1 gal	1 unit	Not required	4 units

5.3.2.1 Packing variation permitted. If the required number of units in the entire shipment is less than the number of units specified to be overpacked in an exterior container, such units may be packed in an exterior container of suitable size and design, acceptable to a common carrier, which shall insure safe delivery to destination.

5.3.3 Level A.

5.3.3.1 Unit package.

5.3.3.1.1 Four fl oz. At the option of the contractor, each unit shall be packaged in a box of appropriate size constructed in accordance with PPP-B-566, PPP-B-676 or PPP-B-636, type CF, class domestic. Commercial colors are acceptable on unit boxes. Closure shall be adequate to prevent spilling of contents under normal handling.

5.3.3.1.2 One gal. Each glassbottle shall be packaged in double-faced corrugated fiberboard box of appropriate size and design having a minimum bursting strength test of 275 pounds and constructed in accordance with PPP-B-636, type CF, class domestic. Box design shall include liner and top and bottom pads.

5.3.3.1.2.1 Liner. Liner shall be of one piece, covering the sides and ends of the carton and fabricated of the same material as the box. Liner shall be the same height as the bottle.

5.3.3.1.2.2 Pads. Top and bottom pads shall be fabricated of the same material as the box and not more than 1/8 inch less than the inside length and width of the box. Pads shall be positioned on the top and bottom edge of the liner.

5.3.3.1.2.3 Closure. Closure shall be adequate to prevent spilling of contents under normal handling.

5.3.3.2 Intermediate package. Intermediate package shall be a box of appropriate size constructed in accordance with PPP-B-636, type CF, class domestic and having a minimum bursting strength test of 200 pounts. Box design shall include partitions. When unit boxes are used, partitions are not required.

5.3.3.2.1 Partitions. Partitions shall be full or shoulder height, half-slotted style, fabricated of the same material as the box. The partitions shall form an individual snug fitting cell for each immediate container.

5.3.3.2.2 Closure. Closure shall be as specified in the appendix of PPP-B-636.

5.4 Packing.

5.4.1 Level B.

5.4.1.1 Exterior container. Exterior container shall be a box of appropriate size constructed in accordance with PPP-B-636, type CF, class domestic. Bursting strength of box shall be in accordance with special requirements of table II of PPP-B-636. Closure shall conform to method II as specified in the appendix of the box specification.

6505-890-2010 (P. D. No. 3)

5.4.2 Level A. Items shall be packed for the degree of protection specified for Level B, and shall be further protected by being overpacked in an exterior container designed for a type 1 load and constructed in accordance with PPP-B-585, class e, style 3; PPP-B-601, overseas type; PPP-B-621, class 2; or PPP-B-636, class weather-resistant, grade V3c. Bursting strength of fiberboard box shall be in accordance with special requirements of table I in PPP-B-636. Closure and strapping of boxes shall be as specified in the appendix of the applicable box specification.

5.4.2.1 Case liner. Each Level A wood box shall be lined with a waterproof case liner conforming to MIL-L-10547. Closure and sealing shall conform to applicable paragraphs of appendix thereto. Case liner shall not be required for fiberboard boxes. Each fiberboard box shall be waterproofed in accordance with paragraph 30.4 of PPP-B-636.

5.5 Marking.

5.5.1 Unit package. Each unit package shall bear the same information as required for the immediate container.

5.5.2 Intermediate package. Each intermediate package shall be marked in accordance with MIL-STD-129. When labels are utilized, waterproofing shall be required only when applicable box is fabricated of water-resistant material. Lot (control) number, contract or purchase order numer, and name of contractor shall be shown. Date of manufacture shall be shown in lieu of date packed. Marking shall include the legend:

"STORE AT CONTROLLED ROOM TEMPERATURE (59° - 86° F.)."

5.5.3 Exterior container. Exterior container shall be marked in accordance with MIL-STD-129. Lot (control) number shall be shown. Date of manufacture shall be shown in lieu of date packed. Marking shall include the legend:

"STORE AT CONTROLLED ROOM TEMPERATURE (59° - 86° F.)."

Exhibit G

A typical example of prejudice against a smaller drug manufacturer (first page of a letter received from the Miflin, McCambridge Company, dated February 13, 1974)

THE MIFFLIN, MCCAMBRIDGE COMPANY

6400 RHODE ISLAND AVENUE
RIVERDALE, MARYLAND 20840

February 13, 1974

Mr. Joseph Barrows
The N.A.P.M.
342 Madison Avenue
New York, New York 10017

Dear Joe:

I enjoyed the meeting this past weekend, and I am sure you had much to do with the outstanding program. My homages to you and George and the others for it.

About defense contracts, concerning which you enquired:

We do not bid on them and have not done so for some seven or eight years.

The last bid we received from them took more time, more effort, more technical personnel and more clerical people than all our other orders on hand at that time. It was a bid for ¼ and ½ grain saccharin tablets.

We had inspectors inspecting everything that went into the order, disrupting our routine production regularly.

We had government chemists standing in back of our chemists for two weeks while we tested and retested the materials and the product.

We bought, per their specifications, special overpackaging that would have survived the Titanic, much more a truck-trip to Illinois and California where it went.

After about one and a half months of chaos in our plant, they accepted it, signed the papers and we shipped it.

Four months later, we got it all back (freight paid by us) because somebody decided that it met a thousand specifications of the government but he just wasn't quite satisfied. He thought maybe the tablets were not hard enough.

There it was, back in our plant, all packed in virtually people-proof containers, all with special government labeling unsuitable for commercial use, uneconomical to recondition for commercial sale. And for all our time, effort, disruption and expense, we collected not a single cent.

Exhibit H

NAPM Roster - Asterisk designates manufacturer of dosage form drugs.

NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS
342 Madison Avenue, New York, New York 10017

Membership List As of January 1974

Regular Members:

ALLIED LABORATORIES, INC.
975 Lake Road *
Medina, Ohio 44256

ANTHONY PRODUCTS CO.
11634 McBean Drive *
Elmonte, California

BARRE DRUG COMPANY, INC. *
4128 Hayward Avenue
Baltimore, Maryland 21215

BARTH-SPENCER CORP.
270 W. Merrick Road
Valley Stream, New York 11580

BELL PHARMACAL CORP.
1-85 At Exit U.S. 276 *
P.O. Box 1968
Greenville, S.C. 29602

BIOCRAFT LABORATORIES, INC.
92 Route 46 *
East Paterson, N.J. 07407

BIOPHARMA, INC.
625 Broadway
New York, N.Y. 10012

BOLAR PHARMACEUTICAL CO., INC.
130 Lincoln Street *
Copiague, New York 11726

CHROMALLOY AMERICAN CORP.
Route 7, P.O. Box 180-A *
vansville, Indiana 47712

COLUMBIA MEDICAL CO.
38 East 19 Street
New York, New York 10003

CONSOLIDATED MIDLAND CORP.
195 East Main Street *
Brewster, New York 10509

CRAMER PRODUCTS, INC.
153 West Warren *
Gardner, Kansas 66030

ROBERT DANIELS & CO., INC.
Div. of Generics Corp. of America
333 Sylvan Avenue *
Englewood Cliffs, N.J. 07632

DAY-BALDWIN, INC.
1460 Chestnut Avenue *
Hillside, N.J. 07205

DEL LABORATORIES, INC.
565 Broad Hollow Road *
Farmingdale, N.Y. 11735

ENCAPSULATIONS, INC.
269 Chestnut Street
Newark, New Jersey 07105 *

FARADAY LABORATORIES
100 Hoffman Place *
Hillside, New Jersey 07205

FOOD PLUS, INC.
77 Moonachie Avenue *
Moonachie, New Jersey 07044

Regular Members Con't

J & W LABORATORIES, INC. *
20 Markley Street
Port Reading, New Jersey 07064

HALSEY DRUG CO., INC. *
1827 Pacific Avenue
Brooklyn, New York 11233

HUDSON PHARMACEUTICAL CORP.
89 Seventh Avenue
New York, New York 10011

HEATHER DRUG COMPANY *
1 Fellowship Road
Cherry Hill, New Jersey

HUMPHREYS PHARMACAL, INC. *
63 Meadow Road
Rutherford, New Jersey 07070

INWOOD PHARMACAL, INC. *
303 Prospect Street
Inwood, New York 11696

KETCHUM LABORATORIES, INC. *
26 Edison Street
Amityville, New York 11701

LIFE LABORATORIES, INC. *
8111 Lankershim Blvd.
North Hollywood, Calif. 91605

LINDBERG NUTRITION SERVICE
3945 Crenshaw Blvd.
Los Angeles, Calif. 90008

LINDEN LABORATORIES, INC.
Div. of Chromalloy American Corp.
5353 Grosvernor Blvd. *
Los Angeles, Calif. 90066

MERICON INDUSTRIES, INC.
420 S.W. Washington Street *
Peoria, Ill. 61602

MIFFLIN McCAMBRIDGE CO.
6400 Rhode Island Avenue *
Riverdale, Maryland 20840

MURO PHARMACAL LABS., INC. *
121 Liberty Street
Quincy, Mass. 02169

REXAR/OBETROL PHARMACEUTICAL CORP.
396 Rockaway Avenue *
Valley Stream, New York 11581

O'CONNOR DRUG COMPANY *
12115 Woodbine Avenue
Detroit, Michigan 48239

ORMONT DRUG & CHEMICAL CO., INC.
223 South Dean Street *
Englewood, New Jersey 07631

PENNEX PRODUCTS CO., INC. *
Eastern Ave. at Pennex Drive
Verona, Penn. 15147

PHARMACAPS, ICN. *
P.O. Box 547
1111 Jefferson Avenue
Elizabeth, New Jersey 07207

PHARMADERM, INC. *
Cantiague Rock Road, Box 730
Hicksville, New York 11802

PHOENIX LABORATORIES *
175 Lauman Lane
Hicksville, New York 11801

PLUS PRODUCTS, INC. *
2425 E. 38th Street
Los Angeles, Calif. 90058

PRESTON PHARMACEUTICS *
P.O. Box 8
Butler, New Jersey 07405

PUREPAC CORPORATION *
200 Elmora Avenue
Elizabeth, New Jersey 07207

Regular Members Con't

REID-PROVIDENT LABORATORIES, INC.
25 Fifth Street, N.W.
Atlanta, Georgia 30308 *

REPUBLIC DRUG CO., INC.
175 Great Arrow,
Buffalo, New York 14207 *

SIMPAK CORPORATION
2021 15th Avenue West
Seattle, Washington 98119 *

STUR-DEE HEALTH PRODUCTS, INC.
Island Park
New York 11558

VITA-FORE PRODUCTS CO.
95-07 98 Street Inc.
Ozone Park, New York 11416 *

ITARINE COMPANY, INC.
27-15 North Conduit Avenue
Springfield Gardens, New York 11413 *

VITAMIN SPECIALTIES CO.
5521-25 Wayne Avenue
Philadelphia, Pa. 19144

WEST-WARD, INC.
745 Eagle Avenue
Bronx, New York 10456 *

XTTRIUM LABORATORIES, INC.
415 West Pershing Road
Chicago, Ill. 60609 *

ZENITH LABORATORIES
140 Le Grande Avenue
Northvale, New Jersey *

N.A.P.M.
ASSOCIATE MEMBERS

ARENOL CHEMICAL CORP.
40-33 23rd Street
Ling Island City, N.Y. 11101

CHASE MANHATTAN BANK
1 Chase Manhattan Plaza
New York, N.Y.

FALLEK PRODUCTS CO., INC.
460 Park Avenue
New York, N.Y. 10022

FOOD & DRUG RESEARCH LABS., INC.
Maurice Ave. at 58th Street
Maspeth, New York 11378

FREEMAN INDUSTRIES, INC.
100 Marbledale Road
Tuckahoe, New York 10707

GALLARD-SCHLESINGER CHEMICAL MFG. CORP.
584 Mineola Avenue
Carle Place, L.I., N.Y. 11514

R.W. GREEFF & CO., INC.
1 Rockefeller Plaza
New York, N.Y. 10020

GYMA LABORATORIES OF AMERICA, INC.
62-04 34th Avenue
Woodside, New York 11377

HEXAGON LABORATORIES, INC.
3536 Peartree Avenue
Bronx, New York 10469

HUNTINGTON LABS, INC.
P.O. Box 710
Huntington, Indiana 46750

HOLL FINE CHEMICAL, INC.
420 East 56 Street
New York, New York

LANCO CONTAINER CORP.
70 Washtington Street
Brooklyn, New York 11201

LEBERCO LABORATORIES
123 Hawthorne Street
Roselle Park, New Jersey 07204

P. LEINER & SONS, AMER., INC. *
20101 Nine Mile Road
St. Clair, Michigan 48040

DR. MADIS LABORATORIES *
375 Huyler Street
So. Hackensack, N.J. 07606

MAJESTIC DRUG CO., INC. *
721 East 136th Street
Bronx, New York 10454

MALLINCRODT CHEMICAL WORKS
P.O. Box 384
223 West Side Avenue
Jersey City, N.J.

MEER CORPORATION *
9500 Railroad Avenue
North Bergen, New Jersey 07047

WILLAIM DOUGLAS MC'ADAMS, INC.
110 Est 59th Street
New York, New York 10011

NAPP-LEMKE CORPORATION
195 Main Street
Lodi, New Jersey 07644

NATIONAL MAGNESIA CO., INC. *
83rd Street & Cooper Avenue
Brooklyn, New York 11227

S.B. PENICK & COMPANY
100 Church Street
New York, N.Y. 10008

Associate Members Con't.

PENN BOTTLE & SUPPLY CO.
7150 Lindbergh Blvd.
Philadelphia, Pa. 19153

J. RABINOWITZ & SONS, INC.
1300 Metropolitan Avenue
Brooklyn, New York 11237

S.S.T. CORPORATION
20 Vesey Street
New York, N.Y. 10007

SUPPOSITORIA LABS., INC.
135 Florida Street *
Farmingdale, New York 11736

TRUESDALE CHEMICAL SALES CO., INC.
140 East 40th Street
New York, N.Y. 10016

GEORGE UHE COMPANY, INC.
76 Ninth Avenue
New York, New York 10011

STERWIN CHEMICALS, INC.
90 Park Avenue
New York, New York 10016

AMERICAN ROLAND CORP.
16 Hudson Street
New York, N.Y. 10013

SIERRA INTERNATIONAL
1144 Clifton Avenue
Clifton, New Jersey 07013

Pursuant to your request we will inquire from our member firms the following:

The percentage of their total business and the dollar volume of the drugs which they manufacture for PMA firms.

As soon as this information is available to our executive headquarters we will submit same to your committee.

There are however, manufacturers who produce products for PMA members who are not affiliated with any association. Just recently we learned of a small company in the parenteral field who manufactures for PMA firms and is reported as having a dollar volume of over $9,000,000.00 per year.

We thank you for the opportunity to express our views and assure you of our fullest cooperation in implementing a National Drug Formulary which would include the 'Fixed Formula Concept.'

Respectfully submitted,
National Association of Pharmaceutical Manufacturers

Joseph Barrows

Joseph Barrows, Ph.G.,
Chairman, Board of Directors

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

TUESDAY, MARCH 5, 1974

U.S. SENATE,
SUBCOMMITTEE ON MONOPOLY OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 6202, Dirksen Senate Office Building, Senator Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson and Beall.

Also present: Chester H. Smith, Staff Director and General Counsel; Benjamin Gordon, Staff Economist; and John O. Adams, Minority Counsel.

Senator NELSON. Our first witness this morning is Major General Hayes, Principal Deputy Assistant Secretary of Defense of the Department of Defense.

General Hayes, the committee is very pleased to have you here this morning.

As you know, we had conducted some hearings 2 weeks ago involving an issue of standards applied to drugs by the DOD, and involving some criticisms of the FDA. We heard from the National Formulary, the U.S. Pharmacopeia and the FDA. Based on those hearings and based on the materials furnished the committee by the Department of Defense, I have prepared a statement which represents, of course, my viewpoint.

I would like to read this statement into the record and then I would appreciate it if you would comment on it during the course of your presentation.

On December 19, 1973, the Pharmaceutical Manufacturers Association issued a press release opposing HEW Secreary Weinberger's proposal that the Government limit its reimbursement for Medicare and Medicaid drugs to the lowest priced generic drug. In support of its opposition the president of the PMA, Joseph Stetler, made the following statement:

"Max Feinberg, an official of the Medical Materiel Defense Personnel Support Center in Philadelphia, reported this month that the rejection rate on DOD plant inspections is 45 percent and the rejection rate on precontract award sample inspections is 42 percent." (Source, Pharmacy Times, December 1973, p. 40.)

"Feinberg also recently stated that 6 of 11 potential suppliers of generic meprobamate were disqualified in 1973. Four others were disqualified earlier on quality grounds according to Feinberg," Stetler stated.

"Yet," Stetler emphasized, "these same drugs and others rejected by DOD are now on the market with the authority of FDA. If the Government intends to reimburse under medicare or medicaid for the cheapest drugs available, it may be buying these products for less advantaged citizens—the same products that it rejected for our Armed Forces."

Earlier that same day Mr. Stetler emphasized that:

"Substantially all of these rejected producers and their products are presently allowed on the market by the FDA." (Hearings before Senate Health Subcommittee, Dec. 19, 1973, Transcript, p. 169.)

PMA Counsel, Lloyd Cutler, in offering Mr. Feinberg's article in evidence, referred to him as: "* * * the man who is the expert for the rigorous testing that the Department of Defense carries on before it will buy drugs competitively, when they can be supplied by multiple sources. * * * He concludes that 40 percent of the products he tests from manufacturers who want to be adjudged in these bids should be rejected, *and those are products which the FDA, by and large, now allows on the market.*" (Hearings before Senate Health Subcommittee, March 5, 1974, Transcript, pp. 176–7. Emphasis added.)

Mr. Feinberg for several years has made public statements which, if true, should frighten the American people. As I have already shown, the Pharmaceutical Manufacturers Association has widely quoted Mr. Feinberg's statements and relied heavily on them in opposing Secretary Weinberger's proposals for drug reimbursement costs.

Mr. Feinberg has testified before state legislative bodies in opposition to the repeal of the antisubstitution laws. He appeared before the House of Delegates in Annapolis, Md., on February 17, 1972, in Kentucky on January 18, 1973, in Texas on March 23, 1973, and in New Hampshire on January 15, 1973.[1]

Mr. Feinberg's major claims in his speeches and articles can be summarized as follows—these are quotes:

1. "The rejection rate of DOD plant inspections is 45 percent and the rejection rate on precontract award inspections is 42 percent."

[1] See the following table:

STATE GOVERNMENT INSTITUTIONS

State	Date	Invitation from	Request to	Travel status	Reimbursed by
Maryland	Feb. 17, 1972	House of Delegates, Annapolis, Md.	General Hails, Commander, DPSC	TDY	U.S. Government.
Kentucky	Jan. 18, 1973	Chairman, Kentucky Formulary Council.	General Dreiseszun, Commander, DPSC.	---do---	State of Kentucky.
Texas	Mar. 23, 1973	Mr. Ace Pickens, General Counsel, Texas Medical Association.	Colonel Wold, Deputy Director, Medicel Material (telephonically).	---do---	Texas Medical Association.
New Hampshire	Jan. 15, 1973	Director of Public Health.	General Dreiseszun, Commander, DPSC.	---do---	New Hampshire Pharmaceutical Association.

2. "Based on my experience of drug plants, it is my firm conviction that the primary problem lies in the fact that many producers in the business today are in gross violation of FDA's good manufacturing practices regulations. Those same firms are manufacturing drugs on a daily basis."

3. "We have seen totally unacceptable housekeeping conditions involving dirt, filth, and rodents. We have reviewed production records that showed noncompliance with the companies' own standards. We have found instances where ingredients and finished products are not adequately tested."

4. With respect to problems of digoxin tablets—"This was no surprise to the drug specialists in DPSC because we know of many other examples demonstrating that compliance with laboratory standards is not necessarily indicative of clinical effectiveness."

On January 17 of this year, the subcommittee requested the Department of Defense to supply us with the names of the firms and the dates on which they allegedly committed "gross violations" of FDA's good manufacturing practices regulations; if and when these were reported to the FDA and other government purchasing agencies; and if so, when and in what detail, and the exact description of the violation. In addition, the subcommittee asked for an explanation of how the 45 percent plant and 42 percent product rejection rates were derived, as well as other information to support the claims that Mr. Feinberg had been making for several years.

Starting on January 30 and on several subsequent dates, the Department of Defense supplied us with a considerable amount of material which I shall place into the record of these hearings, together with an analysis by the United States Pharmacopeia and the American Pharmaceutical Association. The Food and Drug Administration also studied the material supplied to us by the DOD and sent members of its Office of Compliance to the DPSC Center in Philadelphia to ascertain precisely what kind of data could have been the basis of Mr. Feinberg's many speeches and articles.

What did the data show?

1. That the DPSC, in fact, surveys only about 10 percent of their prospective contractors and that this 10 percent is the result of a conscious selection process. In other words, DPSC has already concluded that the remaining 90 percent constitute prospective contractors who are fully capable—in the judgment of DPSC—of performing satisfactorily under the terms of the proposed contracts. So the rejection rate is only 4.5 percent of all prospective contractors, not 45 percent. Mr. Feinberg did say that the rejection rate on DOD plant inspections is 45 percent, but he did not mention that the inspections were performed on only 10 percent of the prospective contractors and that fully 95.5 percent of the contractors submitting a bid were judged by DPSC to be capable of performing under the terms of the proposed contracts.

But what about the 4.5 percent rejection rate? How serious were the alleged violations? What was the quality of the plant inspections?

The Commissioner of the Food and Drug Administration could find no relationship of the rejections to the quality of the drugs. He stated that: "Many of the statements are unsupported totally by any evidence, either in the paper or by any evidence that he [Mr. Feinberg] has provided to us."

Dr. Crout, the Director of FDA's Bureau of Drugs, said that: "* * * it is clear that most of the violations of GMP's, Good Manufacturing Practices, as we see them are relatively trivial and unrelated to the quality of the drug."

The DOD supplied 12 examples of what Mr. Feinberg characterized as "gross violations." Of the 12 entries, one firm is listed twice, thereby reducing the number of plants to a total of 11. It should be noted that 5 of the 11 examples are plants operated by members of the Pharmaceutical Manufacturers Association.

2. The Department of Defense revealed that only 5 percent of the drug products obtained based upon contracts awarded are, in fact, subjected to laboratory testing. The remaining 95 percent are judged satisfactory based upon other DOD information. In other words, the rejection rate is less than 2.5 percent of the drugs to be bought, not 42 percent.

What are these rejected drugs, and on what basis are they rejected?

According to the FDA Commissioner: "* * * the number of analyses of drugs done there are very small, and the principal analyses are done, not on production run of drugs, but on special runs of drugs done by a new company wishing to make the drug, in many instances, a company that has never made it before. And his 42 percent rejection rate is of a relative handful of drugs on a nonproduction run by companies, some of which have never made it before and have never sold drugs to the DOD before." [See page 9965.]

Now, Mr. Feinberg has never added these important details to his public statements. Instead, he has given the impression that the DOD has refused to accept a very large percentage of drugs which are being used by the American public. Even the President of the Pharmaceutical Manufacturers Association and his counsel, Mr. Cutler, were taken in by Mr. Feinberg.

3. With respect to problems of bioavailability, Mr. Feinberg has tried to give the impression that this is a serious problem with many drugs on the market. The DPSC stated that its employees knew about the digoxin problem in 1965. Dr. Crout, the Director of the FDA's Bureau of Drugs, said that the methodology which enabled the discovery of the problem was not available until 1969. Furthermore, digoxin is a very important drug and critical to many patients, and if, as DPSC claimed, they "knew" that this drug had problems, why didn't they inform the FDA about it?

As for the other drugs Mr. Feinberg says have bioavailability problems, Dr. Schmidt testified that Mr. Feinberg has provided the FDA with "no specific, special evidence of bioavailability problems that he has that we do not have. The drugs that he mentions as having bioavailability problems generally everybody knows and

has known about the problems, and indeed, we have moved to correct the majority of these problems." [See page 9967.]

The DPSC submitted only six drug items which it claims present problems of bioavailability or therapeutic effectiveness. Most of the complaints are rather old, going back to 1961. All these have been known. In fact, there is no indication as to the nature of the specific problems or complaints associated with the six drugs listed. Dr. Edward Feldmann of the American Pharmaceutical Association stated: "This paucity of complaints suggests that few drug problems either have occurred in recent years, or remain today." This conclusion is quite different from the impression that Mr. Feinberg has been giving in his speeches and articles.

4. A very interesting case is provided by the widely used tranquilizer meprobamate. In a speech at the Shoreham Hotel on November 8, 1973, sponsored by the National Pharmaceutical Council, an organization consisting of the 20 largest brand-name manufacturers, Mr. Feinberg referred to a recent comparison made of the wide discrepancy in price between the generic and brand name meprobamate tablets, and presented on the screen a list of generic suppliers of this drug taken from the Blue Book, and stated that out of 11 firms inspected by DPSC, 10 were disqualified as a result of plant visits.

DPSC data supplied to us, on the other hand, show that 3, not 10, firms were rejected for meprobamate. The "major deficiency" of one firm was:

"New plant where bid item is to be produced is not yet in operation."

The deficiencies found in the other two firms were discovered by the FDA not serious, correctible, and would not affect the quality of the drug.

It appears, therefore, from the testimony and analyses by the Food and Drug Administration, by the U.S. Pharmacopeia, and the American Pharmaceutical Association, that there is very little substance in Mr. Feinberg's claims, charges, and innuendos.

But considerable damage has been done. His speeches and articles, which have been misleading or deceptive, have done a great disservice by confusing physicians and pharmacists, state legislative bodies, and the American people by creating doubts about the quality of the drug supply in the marketplace and the capability of the FDA to protect the public. His efforts, supported by his association with the Department of Defense, have also served to impugn the integrity of our small business community, implying that only the large drug companies can be trusted and the small companies are constantly cutting corners to enrich themselves at the expense of the public welfare.

The Commissioner of the Food and Drug Administration testified that, even when Mr. Feinberg was informed by FDA representatives that there were inaccuracies in his speech, he still did not change it. [See page 9965.]

Dr. William Apple, the Executive Director of APhA, has told

us that: "* * * the Department of Defense has been casting clouds over the nation's drug supply for the last several years with statements made by some of their spokesmen." [See page 10164.]

The subcommittee would appreciate hearing the comments of the representative of the Department of Defense on the testimony of the Food and Drug Administration, the U.S. Pharmacopeia, and the National Formulary respecting the charges that have been made by Mr. Feinberg, and then later we would also like comment on the special standards which are established for drugs purchased by the DOD and which are claimed by Mr. Feinberg to be higher standards than those required by the Food and Drug Administration.

I am sorry to take so much time reading such a long introductory statement, but since the matter is of very great importance, because the Department of Defense is very prestigious and its name is being used, I think it is necessary to lay the whole record out and clarify it, if possible.

Please proceed.

STATEMENT OF MAJ. GEN. GEORGE J. HAYES, MEDICAL CORPS, U.S. ARMY, PRINCIPAL DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH AND ENVIRONMENT); AND LT. COL. THEODORE D. WOOD, DIRECTOR OF MATERIEL, OFFICE OF THE SECRETARY OF DEFENSE (HEALTH AND ENVIRONMENT)

General HAYES. Mr. Chairman, I would say your statement is like a breath of fresh air coming into a crowded room. This has cleared up confusion caused by some of the prior statements, and I would like at a later time to give some perspective on that. But I agree with everything you said in the statement.

I can now only say in response to Mr. Feinberg's speeches, I think it is only fair to recognize that Mr. Feinberg began his work at the DPSC at a time when there were questions about the quality of drugs in the open market. He did a great deal early on to help set standards, and actually some of those standards have been incorporated by the USP and the FDA.

Mr. Feinberg is a perfectionist. He also—I guess it is sort of like some of us old souls—he is fighting past wars and recounting the tales and sort of losing the historical perspective of then and now.

In your statement there is one comment that I would like to make to clarify and again get a perspective on the digoxin situation.

In March 1965, the U.S. Naval Hospital, Saint Albans, and in October 1965, Brooke General Hospital both complained that their physicians had noticed an unsatisfactory clinical response to a specific manufacturer of digoxin. Testing of this digoxin manufacturer revealed unacceptable lack of tablet content uniformity. The specific lots of digoxin were withdrawn from the system. In September of 1965, the USP, XVII, revised its recommended testing procedures for assays of individual tablets of various drugs of

which digoxin is one. Both the FDA and USP responded at that time to DPSC's inquiries about its concern over tablet uniformity. With the laboratory assistance of FDA, DPSC recalled another batch of digoxin in 1970. Lack of content uniformity was the reason for this recall.

With the advent of the radio immune assay technique for measuring serum digoxin in 1970–71 there came about the laboratory capability to compare the bioavailability of various batches of digoxin. Prior to this time the testing of digoxin tablet content uniformity had to be done by in vitro methods.

Now, that is one reason for the apparent confusion between the statement regarding digoxin on page 5 of your statement. We are really talking about two different things. The DPSC was alerted by the clinicians that something was wrong with the digoxin. Actually, clinical impression was the thing that led to suspecting the drug. It was not until later that a laboratory test of bioavailability of this substance became available.

Mr. GORDON. General Hayes, the material submitted to us states that FDA was not informed of the problem.

General HAYES. Well, further investigation of that leads to some suggestive but incomplete evidence that there was correspondence between us and the FDA. It is not conclusive, but I think it is very suggestive. Unfortunately, it was not followed up to any extent.

Senator NELSON. Do you have a standard routine policy now of notifying the FDA of any problems that you may come across in terms of the quality of drugs that the DOD uses or any other aspect of good manufacturing procedures?

General HAYES. At this time, yes.

Senator NELSON. When was that program instituted?

General HAYES. It was really implemented properly, I would say, only in about the last year and a half.

Senator NELSON. But it is now a part of the routine procedure?

General HAYES. It is routine now.

Senator NELSON. Go ahead.

Mr. GORDON. You were saying something, General, before I interrupted you.

General HAYES. No, that is all right.

Mr. GORDON. General, Mr. Feinberg secured permission to make the statements and write the articles we referred to, did he not?

General HAYES. That is correct.

Mr. GORDON. Now, the person who gave permission, the person with whom he cleared these statements, did he know what was being said and its significance?

General HAYES. I can't answer that, I just can't answer that question.

Let's put it this way: Mr. Feinberg followed the proper procedure. He obtained clearance.

Senator NELSON. Go ahead, General.

Where are you in your statement, General?

General HAYES. I am not in my statement. I am still responding.

Senator NELSON. All right. Go ahead.

General HAYES. If you would like, I could present the statement now.

Senator NELSON. Are you through commenting on my opening statement?

General HAYES. I am still in that position, but if you want me to, I can read my summary.

Senator NELSON. Finish your comments on that.

General HAYES. I think to carry along the line to clarify that comment on the clearances, the question of having permission given for members to do this kind of thing, appear before State legislatures and so on, in looking into it we found that our policy is a bit fuzzy, and we have now instituted a review of the whole business with the intent of clarifying and defining the policies so there will not be this kind of low level clearance for rather important speeches and appearances before legislatures.

Senator NELSON. Go ahead.

Senator BEALL. Mr. Chairman, I have a point.

I am not clear, General. Are you implying that in the future there will be clearance for an appearance itself on approval given in advance as to what the testimony will be?

General HAYES. Well, I think it is awfully difficult to clear testimony, but I think there would be certainly a discussion before the clearance to appear given as to the general scope and content.

Senator BEALL. But a statement is given freely without clearance? Or with clearance?

General HAYES. Let's put it this way: The statement I am going to give to this committee is cleared, completely, as to content and impact.

Senator BEALL. By whom?

General HAYES. By various concerns and components of the Department of Defense. In this instance, Installations and Logistics, Public Affairs, I think the Comptroller, and I think those are the major ones, and Legislative Affairs.

Senator BEALL. It is a complicated process.

General HAYES. It depends—sometimes you can get it done pretty quickly.

The point I am driving at is that the prepared statement will be cleared in this manner. As I say, you cannot control testimony except to review beforehand the general aim and tenor. We can't muzzle.

Senator BEALL. I was not suggesting can or should. I was just asking a question.

General HAYES. Well, I just carried it one step further.

Senator NELSON. But as I understand it, you stated in your opening statement you agreed with the summary presented in my opening statement.

General HAYES. I do.

Senator NELSON. I gather, at least from what I read, that Mr. Feinberg's statements and articles represented or purported to represent Department of Defense's policy and position. They did not; is that correct?

General HAYES. That is correct. They were personal opinion, and as I say, I will reiterate.

The history of all this has a bearing on it and the essence of what Mr. Feinberg was saying had a good bit of factual basis many years back, but unfortunately time has overcome that and yet the content and scope of the speeches haven't kept up with events, actually sort of limited to the past if I want to phrase it properly.

In saying that, I would also want to make it clear that I am not detracting from the good work Mr. Feinberg has done in the past.

I think that pretty much summarizes my reaction to your statement. As I again say, I think it clears the atmosphere very neatly and I think we ought to move on.

Senator NELSON. All right. Please proceed.

General HAYES. Well, I have a summary of my formal statement that has been submitted.

The Department of Defense is continuing its effort to reduce costs and to improve the procurement and supply of drugs. One such effort is that during this past year we appointed a full time Director of Materiel in our office. He is Lt. Colonel Theodore D. Wood and is sitting here with me at the table.

During this past year the Defense Personnel Support Center procured drugs valued at $91.4 million. To reduce costs and to broaden the base of competition the Center has expanded its use of requirements type contracts; it has placed increased emphasis on converting purchase descriptions to formal specifications, and it continues reviewing all specifications to eliminate nonessential or other restrictive features.

Directly related to this, the Defense Medical Materiel Board initiated a comprehensive review of all essential characteristics to eliminate those elements which might be unduly restrictive such as packaging, color, and tablet size. To date 400 drug items have been reviewed.

Other planned or ongoing actions are to strengthen the role of the Board, to implement and expand upon the GAO and OMB report recommendations and to evaluate alternate ways of procuring and distributing medical materiel.

Regarding the consolidation of quality assurance activities within the Food and Drug Administration, the Department of Defense is willing and ready to work with the FDA to develop a system which will meet the specific requirements of the Department. Assuming these requirements are met and the associated costs are reasonable, we are committed to the transfer of this function.

The military departments continue to promote the use of generic drug products through the Pharmacy and Therapeutic Boards and published formularies.

With respect to our policy on effective and noneffective drugs, we are following the directives of the Food and Drug Administration. All ineffective drugs proscribed by the FDA have been removed from our system.

This completes my remarks, Mr. Chairman, and I am open for questions.

Senator NELSON. Just one more issue that was raised by Mr. Feinberg. He has stated that the DOD has adopted specifications for

many drugs that exceed the standards of the United States Pharmacopeia, of the National Formulary, and of the Food and Drug Administration. In testimony from all three of these groups—the Food and Drug Administration, United States Pharmacopeia, and the American Pharmaceutical Association—each one stated that the extra requirements of the DOD in almost all cases have no medical significance, are redundant, are without merit, and whatever the intent, tend to eliminate competition. I assume you have read the testimony, of the USP, the National Formulary, and Food and Drug Administration on this point.

General HAYES. I have not seen it, but I am familiar with the content.

Senator NELSON. What would your comment be about these extra requirements of the DOD.

General HAYES. This really relates to the statement in the short summary which I will reread.

We have instituted a comprehensive review of all essential characteristics to eliminate those elements which might be unduly restrictive, such as package, color and tablet size. We have recognized this and we have taken action. We have already done 400 of these drug items and reviewed them and eliminated these types of things that you are talking about. We started that in August of 1973.

Senator NELSON. Well, do you agree with the general conclusion of FDA, USP and the National Formulary that in almost all cases these special requirements, as one of them put it, have no medical significance or are redundant or without merit and whatever the intent, tends to eliminate competition?

General HAYES. I can't answer in respect to all instances because that is what we are reviewing. But the intent and thrust of that statement we agree with entirely.

Mr. GORDON. General, would it be fair to say, then, or can we conclude, then, that the DOD is getting drugs which are no safer, no more effective, than the rest of the country?

General HAYES. I would say that is a fair conclusion.

Can I enlarge on that statement before this last one just one moment?

Senator NELSON. Sure.

General HAYES. When we are talking about medical quality we have a little problem in storage and shipping, as you know. That specification for a certain item we are always going to have to hold with will be different from the civilian procurement. But that is a logistics problem, to protect the integrity of the drug which is shipped. It is just a difference——

Senator NELSON. Are you talking about a packaging specification for a drug which you may be sending into a tropical area or may have to store under circumstances that are not as favorable as they would be here or that have to be shipped and hauled and moved under conditions that are quite different from what they would be within the continental United States? The packaging of drugs that are going to be used under those conditions must be special. Is that what you are saying?

General HAYES. That is right, preserve the quality of the drug at its optimum state under those circumstances. So we will have those differences for procurement purposes.

Senator NELSON. I understand. I don't think anybody would quarrel with that.

That same standard would not apply to drugs you were going to use in Department of Defense installations within the Continental United States and within the European theater?

General HAYES. Within the European theater contingencies arise.

Senator NELSON. For emergency——

General HAYES. Right.

Senator BEALL. General, just to put this in proper perspective for me, you indicated during the course of your remarks that Mr. Feinberg's statement had some merit sometime ago but apparently does not have merit today or is not applicable today. It leads me to believe that there was a time, perhaps, when things were not as good as they are now. I am wondering if you could tell me what was the overall quality of drugs prior to the time you adopted your present drug procurement policy, and what your experience is after the adoption of that policy today?

General HAYES. I sort of lost you in there.

Senator BEALL. All right. What experiences did physicians have with drugs prior to the time you adopted the present program at DOD and what is the experience that physicians now have with drugs procured under this program?

General HAYES. Well, sometime back we did have problems with drugs of a pill not dissolving in the gastrointestinal tract and, therefore, not delivering the medication. Early breakdown of drugs under intramuscular or intravenously because of improper buffering of solutions, these things have all been pretty much eliminated now and we just do not have the problem. This has been the interplay between our standards between the USP and the FDA.

Senator BEALL. Do I conclude, then, that they have been eliminated partially as a result of your program at DOD or——

General HAYES. I think this is a fair statement to make, yes.

Senator BEALL. But the condition does not exist any more? The danger is not there any more?

General HAYES. Well, I think there will always be a danger that something can happen. There will always have to be monitoring.

Senator BEALL. How did the Surgeons General relate to this? Did they recommend that you do what you are doing or did they recommend differently?

General HAYES. What Surgeon General?

Senator BEALL. The Surgeons General of the United States. Formerly the Surgeon General a few years ago when we were going through all this business.

General HAYES. I do not know how he related to it.

Senator BEALL. A suggestion did not come from the Surgeons General as presently constituted or formerly constituted to the Department of Defense to embark on this kind of activity?

General HAYES. To my knowledge, no.

Mr. GORDON. This is on a different subject. We have compared the prices you pay for drugs through central procurement, through the Federal Supply Schedule (FSS), and through local purchases. It is obvious that since the quantity both through FSS and local purchases are much smaller it is expected that the price will be higher. A reasonable difference would be 10, 15, or even 20 percent. In too many cases, however, the differences are much too great. Let me give you some examples. Ampicillin, .25 gram, 1000's, through central purchase the price is $41.75 from Bristol. From the same firm through FSS it is $56, about 35 percent higher. Chlorpheniramine, 4 milligram—1,000's: through central purchase the price is 81 cents, through local purchase the prices ranged from $21.66 to $19 to $6.64, about 2,674 percent to 820 percent as much. In addition, if this drug can be bought locally at $6.64; why should DOD pay as much as $21.66 even considering the local differences?

For diphenhydramine 25 mg. 1,000's the local purchase price ranged from $5.24 to $18.89. In addition, in many cases the FSS prices were higher than the local purchase price.

For dexamethasone 0.75 mg. the prices for bottles of 500 tablets are $32.76 and $33.40 either through local purchase or FSS. The cost of a bottle of 1,000 tablets is $72.56, either through local purchases or FSS. Why can't the DOD buy two bottles of 500 for $65.52 or $66.80 instead of paying $72.56 for one bottle of a thousand?

Aren't these price differences too big even though the FSS quantity might be quite small? A difference in cost can be expected but the differences between prices paid through central purchasing and local purchases and FSS appear to be extraordinarily great.

General HAYES. Yes, I agree with you it is too big, but there are some practical problems in this and this was one of the first jobs that I put Colonel Woods on of how do we get a handle on the local purchase problem and how can we diminish it both in volume and in cost. There are certain drugs the Defense Materiel Board does not put in the system until there is an assurance we will not be stuck with a large inventory of a drug that is not going to be used any more for several reasons. It may lose popularity or moved from the "possibly effective" to the "ineffective" class by FDA, and we will follow that, as I have said in the statement.

So that we have to tolerate some local purchase, otherwise we would lose more money if we stopped a large inventory centrally and then never used it.

Now, as to the question of the price at the local level, we really cannot do much about that if the supplier is charging in the given area the price differential that you measure, the hospital has no lever on that supplier.

Senator NELSON. I do not know how common this is, but what about the example of the diphenhydramine, 50 milligram, in bottles

of a thousand. The local purchase price was $25.98, but through the FSS, instead of a lower price, the DOD paid $43.82. It would astonish me that through your central purchasing or FSS you would pay approaching twice as much as at the local level.

General HAYES. I do not understand that, either.

Senator NELSON. I can understand how a mistake might be made and that might just be one, but in looking at the prices, if that happens very often, there is something wrong.

But the part that bothers me the most is at the local level where you would expect, that the price should be the highest, since that is something all the way down to the retailer. How could they make the mistake of paying $43 when they looked in the price listings in the Red Book you will find out the pharmacists are getting it cheaper than the Department of Defense? According to the Red Book 1973, this same drug is available to the druggist in the same strength and quantity for as low as $4.75.

General HAYES. Well, I do not understand that one, as I said, but if you go down the list Mr. Gordon referred to, that is a very rare instance.

Mr. GORDON. If there is a VA installation in the area of a DOD installation, and the DOD installation runs out of a particular drug, have they been going to the VA installation to buy drugs at a lower price?

General HAYES. I would think in the past that has not been the general thrust. This is one of the things—or to an adjacent military installation—this has not been done. This is one part of a bigger thing where we are trying to get our DOD medical units to work together across service lines. So this is a subject for the future, and I would think this is going to happen.

Mr. GORDON. But you are taking steps to buy, say, from VA installations if they are around DOD installations?

General HAYES. We have not taken that step yet, but we are considering it.

Mr. GORDON. General Hayes, there are a couple of things that trouble me. First of all, when did Mr. Feinberg join the Defense Department, do you know?

General HAYES. I cannot give the exact time. That has been a long time.

Mr. GORDON. Would it be maybe 30 years ago?

General HAYES. It was in the forties sometime, as I understand it.

Mr. GORDON. Now, in what era did the problems that Mr. Feinberg deals with occur, when did they take place?

General HAYES. I would say from the forties to about the early seventies. When I say early seventies, I mean real early seventies.

Senator NELSON. Thank you very much, General. We appreciate your taking time to come.

General HAYES. Thank you, sir.

[General Hayes' statement follows:]

STATEMENT

BY

MAJOR GENERAL GEORGE J. HAYES
MEDICAL CORPS, U.S. ARMY
PRINCIPAL DEPUTY ASSISTANT
SECRETARY OF DEFENSE (HEALTH
AND ENVIRONMENT)

BEFORE

THE

SUBCOMMITTEE ON MONOPOLY
SELECT COMMITTEE ON SMALL BUSINESS
UNITED STATES SENATE

MARCH 5, 1974

Mr. Chairman:

It is a pleasure to appear again before this subcommittee to discuss with you selected aspects of drug procurement and supply within the Department of Defense. With me this morning is Lieutenant Colonel Theodore D. Wood, MSC USA, Director of Materiel, Office of the Assistant Secretary of Defense (Health and Environment). In addition, and as you requested, Mr. Max Feinberg, Defense Personnel Support Center is also present in the room and will be available for your questions subsequent to my testimony.

Before addressing your specific questions and particularly in view of the recent interest in the Departments drug procurement effort, I believe it would be helpful to provide an overview of the medical materiel system within the Department.

At the Department level the Assistant Secretary of Defense (Installations and Logistics) has the responsibility for developing overall logistics, to include procurement and supply, policy. Within the framework of these policies the Office of the Assistant Secretary of Defense (Health and Environment) is responsible for establishing policies which are unique or peculiar to the management of the medical commodity. Operation of the medical materiel system is accomplished by the Defense Supply Agency, Defense Medical Materiel Board, and the military departments.

The Defense Supply Agency has the responsibility for total operation of the wholesale portion of the system. In fullfilling these responsibilities the agency performs the major logistic functions of cataloging, central procurement, inventory management, and distribution management. The major organizational elements within the Defense Supply Agency involved with the medical commodity are the Defense Personnel Support Center, Defense Contract Administration Service, and the Defense Supply Agency Depots.

The Defense Personnel Support Center located in Philadelphia is responsible for the functions of cataloging, central procurement, and inventory management. The Defense Supply Agency depots perform the medical storage and distribution management functions while the Defense Contract Administration Service administers all centrally awarded contracts to include performing such functions as plant surveys, review and evaluation of contractors procedures, product verification inspection and testing, and final product acceptance or rejection.

The Defense Medical Materiel Board is a joint activity of the Department of Defense responsible for providing coordination, advice and assistance on all professional and technical aspects of medical materiel. Specific functions performed by the Board include type classification of new

items for entry into the central supply system; evaluate items for retention or deletion from the system; develop essential characteristics for medical items and review resulting specifications for compliance with these characteristics; develop lists of suitable substitute items for medical materiel; monitor all materiel complaints; and maintain liaison with the Defense Supply Agency and all other governmental agencies on professional and technical matters involving medical materiel.

Each military department operates its respective retail or hospital level system. To facilitate and interface with the central or wholesale system each department has a field office which performs such functions as providing customer information and assistance; developing service peculiar requirements; and managing service unique materiel programs. All major hospitals maintain and operate a medical materiel account consistent with the local requirements. These supply accounts are operated in accordance with the appropriate military department directives.

Mr. Chairman I would like to now direct my comments to the questions contained in your February 11, 1974 letter to the Secretary of Defense.

1. The efforts of the Department of Defense to reduce the

cost and to improve the procurement and supply of drugs in the Federal Government.

As you are aware Mr. Chairman, the major activity within the Department procuring drugs is the Defense Personnel Support Center (DPSC). Last fiscal year the dollar value of drug purchases by the center amounted to $91.4M.

DPSC is continuing its effort to reduce the cost of drugs. One such area is in the procurement of single source drug items which are negotiated on a noncompetitive basis. Pursuant to Public Law 87-653, certified cost or pricing data must be obtained for negotiated contracts amounting to $100,000 or more, unless the price negotiated is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or the price is set by law or regulation. Contractors supplying these drug items to DPSC claim exemptions from the requirement of Public Law 87-653 to submit certified cost or pricing data on the bases that these items are commercial items with established catalog prices and are sold in substantial quantities to the general public.

The prices which DPSC receives on its single source drug procurements are as low er lower than those received by any

other class of customer. Typically, the DPSC procurements account for a small share of the total market for the specific item. The DPSC individual purchases, however, are generally much larger than the average quantity sold to commercial customers.

The pricing technique employed to ascertain whether the prices offered DPSC are fair and reasonable involves a comparison of the offered prices with the catalog prices and the prices paid by commercial and other customers. Where the quantities procured by DPSC under its purchases are comparable to the average quantities sold to commercial customers, the pricing job is not too difficult. However, as in the typical situation, DPSC purchases generally involve quantities which are larger than the average quantity sold to commercial customers. The problem of deciding whether the prices offered DPSC are fair and reasonable under this circumstance is much more difficult.

In order to resolve this pricing problem, DPSC has been meeting with the drug manufacturers to obtain additional information as to their pricing philosophies and concepts. Although the drug manufacturers are adamant in their refusal to divulge costs of manufacturing their products, they have indicated that the larger DPSC purchases are considered when

formulating their offers to DPSC. Procurement personnel at DPSC are continuing their efforts to obtain additional pricing information from the drug manufacturers. Hopefully, the additional pricing information will provide better support that the prices paid under DPSC contracts for these items are fair and reasonable.

The Center is expanding its use of requirements-type and indefinite quantity contracts. The requirements-type contract fixes the price for a one year period, while the indefinite contract reduces inventory investment and assures the customer fresh stock. To broaden the base of competition the Center continues to place emphasis on preparing competitive (generic) specifications and on converting purchase descriptions to formal specifications. Directly related is a continuing review of all specifications designed to increase competition by removing non-essential or other restrictive features from the specifications.

The Defense Medical Materiel Board commenced in August 1973 reviewing all essential characteristics in the drug and biological group to eliminate those essential characteristics which might be unduly restrictive in nature. To date, approximately 400 items have been reviewed. This review is coordinated with projected procurements by the Defense

Personnel Support Center so that purchase documents may be revised accordingly. In the area of packaging, where feasible, the commercially available packaging approved by the Food and Drug Administration is being utilized. References to color and tablet shape have been, with few exceptions, eliminated. An example of a revised essential characteristic is as follows:

"The Essential Characteristics for this item (NSN6505-00-762-2662) are revised as follows:

(1) Shall be Quinine Sulfate Tablets, USP, 0.324 Gm.

(2) Shall be supplied 1000 sugar coated tablets in a commercially available immediate container considered acceptable to the Food and Drug Administration (FDA) for the product contained therein and shall be of such compatibility that neither the contents nor the container are altered in any way by each other.

(3) Labeling shall meet the requirements of the Federal Food, Drug, and Cosmetic Act. The labels of the immediate container and the unit package (if supplied) shall be those usually furnished by the supplier as commercial practice. Addition to these labels shall be limited to the application of the FSN (NSN) to the unit package (if supplied) and the date of manufacture or expiration date to the immediate container (strip labeling is acceptable). When the

unit package is the shipping container, additional labeling may be applied."

A 6505 (drugs, biologicals and official reagents) review committee was established to review all stocklisted drug items by therapeutic category and make recommendations concerning their retention in or deletion from the Federal Supply System. The committee consists of the Staff Director, Defense Medical Materiel Board (DMMB), and the Pharmacy Consultants of the three services. Criteria used by the committee include cost, demand data, duplication, effectiveness classification, shelf life, and special military requirements (i.e., kits and assemblies). To date, 1,003 items have been reviewed; 844 items remain standard; 141 were reclassified to limited standard, and 18 were deleted. Five items previously limited standard have been reinstated to standard. Final action has not been completed on the remaining 278 items. They have been reviewed by the committee and their recommendations are being evaluated. To assure a continuing review, the Staff Director, DMMB, and the individual item monitors will continue this program for each new item presented for classification.

Continuous effort at all echelons within the Department is being made to reduce the cost and improve the procurement and supply of drugs. Action is currently underway to revise

and strengthen the role of the Defense Medical Materiel Board. A study plan is being developed to consider and expand upon the GAO and OMB report recommendations. Additionally, several tests of alternate ways of procuring and distributing medical supplies are being conducted by the military departments.

2. Your progress in implementing the recommendations included in the Comptroller General's report dated December 6, 1973.

In our response to the Comptroller General last month we indicated agreement with the objectives and principles set forth in the report. We agree and are committed to improving the coordination and cooperation among federal agencies engaged in the procurement and supply of medical materiel. Action on the specific elements contained in the recommendation has been limited to informal coordination with the concerned agencies pending evaluation and implementation of the OMB study report on the management of medical materiel and nonperishable subsistence. Similarly, final action on the recommendation that the Veterans Administration and the Department participate in developing joint specifications is awaiting the outcome of the OMB report. The Department agrees with this recommendation and no problem is anticipated in implementation.

We also agree with the recommendations regarding a revised policy on adopting items for central procurement and the need for a standard reporting system for drugs procured locally utilizing the National Drug Code (NDC) for identification purposes. Action has been initiated on these recommendations and implementing instructions are expected in the near future.

3. Your views concerning the consolidation within the Food and Drug Administration of quality assurance activities relating to federal procurement of drugs.

The Department of Defense believes the Food and Drug Administration can perform the quality assurance activities relating to the Department's procurement of drugs, and we are committed to the accomplishment of this transfer of function. The Department of Defense is willing and ready to work with the Food and Drug Administration in developing a system within the Food and Drug Administration which will meet the requirements of the Department of Defense.

Representatives of the Food and Drug Administration recently visited the Defense Personnel Support Center in Philadelphia, and representatives of the Department of Defense have twice visited headquarters of the Food and Drug Administration. Following these meetings the Food and Drug Administration believes it can perform the quality assurance activities

necessary for our drug procurement system in a responsive and satisfactory manner. Further meetings will commence within a month to discuss details of the proposed transfer of function. There is an obvious requirement that quality assurance activities in the drug procurement field must conform with the Armed Services Procurement Regulations and operate in a timely manner with military procurement acceptance procedures. The Defense Supply Agency and the Defense Medical Materiel Board will be tasked to work closely with the Food and Drug Administration in considering and insuring these important and necessary details are included in any final agreement.

The Department of Defense currently operates a system whereby quality assurance is integrated with other procurement activities. This system has provided over the years a satisfactory result in obtaining useable products while keeping the cost to the taxpayer to a minimum.

We are committed to further improvement of our drug procurement system.

4. The efforts of your Department to (a) promote the use of formularies and encourage the use of generic drug products, and (b) assure that only effective drugs are procured and used in Department of Defense programs.

Each military medical facility develops a separate formulary. The Pharmacy and Therapeutics Board of each facility is responsible for the formulary and the agents listed therein. Such a formulary is specifically tailored to meet the unique requirements of the facility. Formularies throughout the medical departments are arranged generically and may be cross indexed with brand-names. It must be remembered that for the most part, military physicians and dentists come from the civilian population for a brief period of service. It is difficult in this short period of time to completely re-orient the thinking of these physicians and dentists toward generic names; however, continued effort is made in this regard. Prescriptions written in military facilities are filled generically if they specify a brand-name product. Exception to this is rare. Prescriptions written by civilian practitioners are filled with the brand-name product if it is on hand or with the generic product if the physician has authorized substitution in writing. If the civilian practitioner has not given authorization for substitution of the generic product, he is contacted when feasible.

The Department of Defense policy with regard to drug effectiveness was revised in June of 1973 due to extended completion schedules for Drug Efficacy Study Implementation studies, and to account for situations where "ineffective"

and "possibly effective" ratings would be revised following minor formulation or labeling changes. Items in category 1A (classified "ineffective" and removed from the market) continue to be excluded from procurement and use. Items in category 1B (classified "ineffective" but allowed to remain on the market pending final resolution) are reviewed by the Defense Medical Materiel Board in conjunction with the Surgeons General to determine whether centrally procured stocks are to be withdrawn from issue and use. Procurement of "possibly effective" drugs is authorized where no alternative means of therapy is available and/or final determinations on their efficacy are expected to take extended periods of time. Stockage levels of these items are reduced both centrally and locally to reduce loss in the event that the item is finally classified "ineffective" and removed from the market.

Mr. Chairman, in closing I want to assure you that the Department of Defense is deeply committed to reducing the cost and improving the procurement and supply of drugs. The plans and actions which I have described here today are all designed to insure that our patient is getting a quality product at the lowest reasonable cost to the government.

Senator NELSON. Our next witness is Dr. Lyndon E. Lee, Jr., Assistant Chief Medical Director for Professional Services, Department of Medicine and Surgery, Veterans Administration.

Dr. Lee, the committee is very pleased to have you here this morning.

If you will identify your associates for the reporter and for the hearing record, we will appreciate it.

STATEMENT OF DR. LYNDON E. LEE, JR., ASSISTANT CHIEF MEDICAL DIRECTOR FOR PROFESSIONAL SERVICES, VETERANS ADMINISTRATION, ACCOMPANIED BY ROLAND F. HARDING, DIRECTOR, PHARMACY SERVICE; CLYDE C. COOK, DEPUTY DIRECTOR, SUPPLY SERVICE; DR. EUGENE M. CAFFEY, JR., DEPUTY DIRECTOR, MENTAL HEALTH AND BEHAVIORAL SCIENCES SERVICE; DR. RICHARD PARKER, CHIEF, INFECTIOUS DISEASE CONTROL, VA HOSPITAL, WASHINGTON, D.C.; JAMES FRANCESE, JR., CHIEF, QUALITY ASSURANCE, MARKETING CENTER, HINES, ILL.; AND JOHN T. MANNING, ASSISTANT GENERAL COUNSEL

Dr. LEE. It is a pleasure.

On my immediate right is Mr. Clyde Cook, Deputy Director of our Supply Services. On my immediate left is Mr. Harding, Director of the Pharmacy Service, and John Manning, Assistant General Counsel sitting next to Mr. Harding. We have also Dr. Eugene Caffey, who is Deputy Director of the Mental Health and Behavioral Sciences, Dr. Richard Parker, Chief of Infectious Disease. We also have with us Mr. James Francese, Jr., Chief of our Quality Assurance, Marketing Division for Drugs and Chemicals in our Marketing Center in Hines, Ill.

Senator NELSON. You may go ahead. Your statement will be printed in full in the record. You may present it in any way you desire.

Dr. LEE. Thank you, Mr. Chairman.

We welcome the opportunity to appear and to discuss with you the management of our program for the rational selection and dispensing of drugs, and the Veterans Administration procurement practices in support of our drug requirements. In summary, the total cost of the drugs used by this agency in fiscal year 1973 was slightly more than $86 million.

Senator NELSON. Does this involve the direct procurement by VA?

Dr. LEE. Yes.

Senator NELSON. But does it include drugs for veterans for which they are reimbursed?

Dr. LEE. No, sir.

Senator NELSON. What would that total, about?

Dr. LEE. About 5 million more, sir.

Senator NELSON. 5 million more?

Dr. LEE. Yes.

Mr. GORDON. Dr. Lee, your estimated 1970 expenditures for drugs was $57.2 million. Your expenditure in 1973 was $86 million, an increase of 50 percent in a 3-year period. What accounted for this very large increase?

Dr. LEE. Mr. Cook.

Mr. COOK. Mr. Gordon, in each of the last 3 years the number of patients treated in our hospitals has increased by 10 percent. The number of out-patients treated in the Veterans Administration has increased by an average of 30 percent each of the last 3 years primarily due to legislation that increased the number of veterans who were eligible for drugs and medicine at VA expense.

Senator NELSON. Please proceed, Doctor.

Dr. LEE. This single $86 million item represents more than 3 percent of all costs of operating the VA's medical program, and is a significant element of the cost of providing medical benefits to our Nation's veterans.

We have, Mr. Chairman, submitted a statement for the record. It may be that you would like me to scan this statement, including some response to questions posed by your staff, or perhaps you would prefer to enter questions at the moment. We can do either way.

Senator NELSON. If you have no objection, we may ask some questions as you go along. But you present it however you desire.

Dr. LEE. All right, sir.

You had presented some items to us. There are four. We will discuss each of these in sequence.

The first were the efforts of this Agency to reduce costs and to improve procurement and supply of drugs in the Federal Government;

Second, actions taken to implement the recommendations in the Comptroller General's report on drug procurement, dated December 6, 1973;

Third, our view concerning the consolidation within the FDA of quality assurance activities relating to Federal procurement;

Fourth, the efforts of this Agency to promote the use of formularies; encourage the use of generic drug products; and to assure that only effective drugs are procured and used in VA programs.

In that item 1, rather than read the entire statement I can run through the summary which has to do with reduction of cost and procurement.

We continue, Mr. Chairman, to carry out our efforts to procure more drugs competitively, using nonproprietary descriptions and generic designations.

Our drug procurement program is managed as an integrated unit, employing purchasing and supply through three different methods, which are complementary. These are (1) consolidation of requirements for central procurement and distribution through our wholesale depots; (2) contracts which are published in a Federal Supply Schedule against which our hospitals can write delivery

orders; and (3) local purchase action initiated by each hospital for its own individual needs where time does not allow ordering from other sources. I repeat, each of these is an interrelated effort.

We have established definite criteria for determining which items will be supplied through the central purchase and distribution system and through Federal Supply Schedules. The basic determination relates to the lowest total cost of supplying these items by each method. We procure for central distribution only those items on which the total savings through volume purchase prices will more than offset the overhead costs of maintaining a central system. We do not measure the costs of central purchasing and distribution on the basis of the purchase price alone. Since the costs of maintaining central systems are borne by the taxpayer, we feel that comparisons which relate to price only and not to total cost to the Government are incomplete and constitute unfair competition with private enterprise, especially small business wholesalers and distributors. Our current practice is to use this method of supply when the savings in purchase cost are approximately 12 percent greater than those we can obtain through Federal Supply Schedule contracts or local procurement.

On November 30, 1973, we stocked 633 drug items in three depots. These 633 items represent less than 2 percent of the various drugs and different brands of similar drugs available from Government stocks or from Government contractors.

In 1973 these 633 items accounted for $41 million, or 42 percent of the total VA drug budget. Because of their budget impact, we have concentrated on these.

Of these 633 drugs, 369—representing $34 million annual usage—are available from only one source, either because of patent rights or because there is only one firm holding an approved effective New Drug Application.

An additional 88 items—representing $2 million annual usage—are procured from a single source. In this category are those drugs which are manufactured in comparable formulations, but are not packaged by all manufacturers in the dosage form or size we require in our system. We are attempting to increase competitive procurement in this category and 19 of the 88 drugs will be procured generically at the time of our next purchase. Seventeen more being studied to see if we can increase competitive interest.

Since appearing before this subcommittee in 1971, we have increased the total number of items stocked on a generic basis from 105 to 176, and have increased the annual dollar volume of procurement for depot stock from $2 million to over $5 million. This is 17 percent of the drug item or over 30 percent of the drug item itself. We expect continuing progress in the near future. Since patents on several drugs of substantial cost have recently expired, we anticipate the number of firms who will obtain approved NDA's to market these products will increase, offering us opportunities for further competitive procurement. You might be interested in the statement of "Drug Topics of 1973" of a November study. It said 12 to 14 percent of prescription drugs sold in the United States are sold on

generic basis. In VA it is 30 percent, more than twice as much in terms of the numbers of generic purchasers. In other words, we in VA purchase over twice the national average on a generic basis.

We monitor weekly the number of firms approved by FDA to manufacture and market products previously available from a single source, and invite firms to bid on our needs for these products.

We have also initiated improvements in contracting for drugs through the Federal Supply Schedule. The contracts which support these schedules are negotiated, where practical, on a competitive, generic basis.

Senator NELSON. Let me ask a question at this point. I had asked General Hayes about an example of a much higher price being paid under the Federal Supply Schedule than the drug was available for and purchased at the local level. I have an example from VA's purchases in 1971. This is chlorpheniramine, a well-known antihistamine. For bottles of 1,000, 4 mg. tablets: through direct purchase the VA paid 76 cents. Through the Federal Supply Schedule VA paid $18.05. That is almost 30 times as much. What baffles me is how could a company charge that much? How could you agree to pay that differential? Then the VA purchased chlorpheniramine at the retail level as low as $7. So you have direct purchase 76 cents, Federal Supply Schedule $18.05, and retail level as low as $7.

I would think you would tell the company that is charging you 76 cents that when you ask $18 that you are through doing business with them. It is an unconscionable gouging of the Government, and why would you stand for that?

Mr. COOK. I imagine the purchase at $18.05 was a brand-name procurement. In any event, he was selling it in a noncompetitive situation. The chlorpheniramine at 86 cents is a purchase on a competitive basis, generic, if you will.

Senator NELSON. The purchase at $7 obviously was not competitive. Neither was the $18 on the Federal Supply Schedule.

Mr. COOK. I cannot account for that difference. The $7 may have very well been a generic drug.

Dr LEE. The other problem is how much was involved in each of these purchases. I rather suspect that $18 purchase was a small immediate necessity.

Mr. COOK. I went through the purchases reported by our stations for the last 6 months and I found only one instance where the hospitals making the purchase bought more than one bottle at a time other than through the central system.

Senator NELSON. Well, I would guess that the local purchase at $7 was not a large one, either, neither competitive nor large.

Mr. COOK. It was not.

Senator NELSON. Well, even if there were a competitive bid at 76 cents, how do you account for charging 30 times as much under the Federal Supply Schedule. Even if it were a different supplier, it seems to me you ought to reject that supplier. They all presumably meet USP standards.

For meprobamate 400 mg, 1,000s: the direct purchase was $2.60. The Federal Supply Schedule was $42. The lowest local purchase

was $24. So there is a case where the local purchase price was almost half of what the Federal Supply price was and the direct purchase was about one-twentieth of the Federal Supply price. I am inserting some other interesting examples into the record at this point.

[The information referred to follows:]

VETERANS' ADMINISTRATION—1972

Product	Direct purchase	FSS	Local purchase	
			Highest	Lowest
Ampicillin:				
250 mg 100	$3.61	$10.45	$25.25	$4.28
500 mg 100	7.19	12.50	48.00	6.25
Chlorpheninamine: 4 mg 1000	.76	18.05	21.66	7.00
Isoniazid		6.60	8.00	1.85
Meprobamate: 400 mg 1000	2.60	42.00	61.80	24.00
Chlorhydrate: 7½ gr 100	1.25	2.02	4.78	1.20
Erythromycin stearate: 250 mg 100	2.82	13.08	20.61	8.35
Diphenhydramine: 50 mg 1000	3.62	9.63	18.35	
Pentaerythritol tetranitrate: 10 mg 1000	9.44	22.41	27.00	24.65
Ferrous sulphate: 300 mg 1000	1.15	9.35	11.00	4.55
Conjugated estrogens: 1.25 mg 100	4.00	5.64	7.20	5.64

Mr. COOK. The drug is in our system at $2.60 on a competitive or generic basis. The $42 I suspect was charged by the innovator of the drug. The $24, I do not know. The reason we pay these prices in these purchases of 1's, 2's, 3's, is when we have a prescription written for a particular drug and it is not written in a manner that permits its dispensing on a generic basis. We have approximately one-third of the Nation's physicians writing prescriptions for our veterans. When they indicate they will accept only a particular drug we buy that drug on a local basis.

Senator NELSON. Are you talking about physicians who are prescribing in a veterans hospital?

Mr. COOK. They are not necessarily prescribing in a veterans hospital, but the prescription is filled in a Veterans Administration pharmacy. We encourage the so-called fee basis physician of which we have over 100,000 actively prescribing today; we encourage them to mail these prescriptions to our pharmacies to be filled rather than have them filled in the local retail pharmacy.

Senator NELSON. Well, when you say local purchase, does that not mean the local retail pharmacy?

Mr. COOK. In many cases that is true; yes, sir.

Senator NELSON. Well, then, it still baffles me why the price on the Federal Supply Schedule for meprobamate is $42 while the local pharmacy can charge and make a profit at $24.

Mr. COOK. Senator, I will check these, but in most cases you will find the differences as to whether the prescription was written for a particular product or not. They do maintain quite different price schedules, as you know.

Senator NELSON. Do you follow the policy, then, even though there is in the marketplace a number of versions of the same compound with varying prices, if the physician prescribes the highest priced one in the marketplace, you will pay that?

Dr. LEE. Let me remind you that 106 of our hospitals are affiliated

with 189 medical schools. We think this insures that our therapeutic practices in the VA in large measure parallel and reflect the teachings and practices in those academic institutions; in other words, the best currently recognized in the country, even though that may not always exactly be the same from station to station in each therapeutic instance.

However, internally in the VA hospitals we think we have fairly tight control on that, and our prescription blanks which, by the way we supply to the 100,000 or more fee basis physicians, has on it a specific place where there is a check which says "Another brand equal in quality of the same basic drug may be dispensed unless checked." If that is checked, it is the prerogative of the physician and we do not fight. We simply accept it.

The usual practice and the practice within the VA is that this is not checked and there is generic dispensing. It is our fee basis area where we have the difficulty.

Senator NELSON. Mr. Weinberger has announced it would be the policy for drugs reimbursed under medicare and medicaid that we will only reimburse for the lowest price of that particular drug within that particular class that is available. Is the VA going to follow that policy when HEW formerly adopts it?

Dr. LEE. We have not yet determined just exactly how to go at that. It will be very interesting to see if that can stick in HEW.

Mr. COOK. There is one difference. The Veterans Benefits Act specifically states that VA will reimburse the total cost; the veteran may not be charged any of the cost of the Federal care for which he is eligible.

Senator NELSON. Well, it seems the way you get around that is to send out a schedule. There are approximately 700 compounds in the marketplace under 20,000 names. That means that there are on the average 30 versions of the same compound in the marketplace for ecah of the 700 compounds. It would seem to me that you would simply advise the physicians that you are not going to permit them to prescribe the highest priced version of these compounds, unless there is a medically sound reason to do so. That, in effect, is what HEW is going to do. Of course, they will say we will not reimburse, which means if the doctor writes the prescription the patient may have to reimburse the difference. That will not cost very much because the doctor will have it called to his attention that the patient is paying out of his pocket for a drug which is available on the marketplace at a much smaller price.

Dr. LEE. With the fee basis physicians, we feel we cannot be quite as dictatorial.

Senator NELSON. Within the VA hospital you can. We raised this question, did we not, 2 years ago? The response was that it was very difficult; that it was very difficult to tell the doctor at the VA hospitals and various parts around the country that he cannot prescribe a particular brand that he wants to prescribe. It would seem to me that if anybody could establish a formulary, the Army and the VA ought to be able to do so. Many formularies require conformity of physicians in their prescribing practices, unless they have

a special reason for not prescribing the particular available brand on the formulary. Why could not the VA do that?

Dr. LEE. Since the testimony we gave you, we have continued to use rather the carrot than the stick to see if we cannot get our physicians to carry through just as you suggested. We feel there has been an increase in the use of generic drugs. However, as we look at the question you have raised and which is further along in testimony on the use of formularies, we would like to summarize our policy.

Every reasonable effort is being made to treat every patient with the most effective therapeutic agents which we think are indicated, and we procure these at the most favorable price we can obtain. Since there are differences of opinions we do not rigidly restrict professional practices by administrative direction.

We continue to rely on therapeutic agents and pharmacy review committees at each of our field stations to carefully screen all drugs approved for use at their stations in order to insure that the most effective products are selected for inclusion in that hospital's formulary. We continue to monitor the minutes of these meetings at the VA central office and provide an overview of their various practices at stations, and we continue in the central office a Commission on Therapeutic Agency for policy statements, for operational coordination, and for overviewing in our stations. We feel that this is a fairly tight schedule.

Mr. COOK. Senator, I would also like to observe that there are more physicians practicing in the VA hospitals who are not Federal employees than those who are.

Senator BEALL. On that point, Doctor, how many general practicing physicians who are working on a fee basis are aware of the cost of drugs?

Dr. LEE. I have no idea.

Senator BEALL. Does anybody inform them from the Federal Government that you can get a specific drug from different companies, and that X company sells it for so much, Y sells it for——

Dr. LEE. The first question, I have no way of knowing.

The second is: Do we inform these people? Yes, we do. We have made lists of these drugs through out hospital and we continue to try to educate them, and we feel that that is perhaps the best way to get at it. I am pleased to note the chairman on TV the other night also stated education seemed to be the best mode of approach.

Senator BEALL. With the expansion of the Federal Government's role in health delivery through the HMO legislation and this year probably the passage of some sort of national health insurance legislation, the Federal Government is becoming more involved and has a greater interest in drug procurement as an aspect of health care delivery. Has the American Medical Association shown any inclination to inform its members as to the relative cost of the drugs they may be using? Do you know this as a doctor?

Dr. LEE. I know they have made some various efforts but that has not been a part of our particular educational campaign.

Senator BEALL. Do you suggest to the American Medical Association it might be in the interest of the consuming public or the American Government they do?

Dr. LEE. We have not done this and we would be interested if the American Medical Association wanted a suggestion.

Senator BEALL. Do you think it would be advisable to give them one anyhow, whether they wanted it or not?

Dr. LEE. No, sir, in the context that we maintain public relations at the physician level.

Senator BEALL. It seems to me if you have information in the public good the intended recipient should not say whether he wants the information; just give it to them and let them bear the burden.

Dr. LEE. Some of our military cohorts suggest that one not volunteer.

Senator BEALL. Maybe some nonmilitary cohorts ought to suggest that maybe you do.

Senator NELSON. Please proceed.

Dr. LEE. We have increased the volume of drugs procured by this method from about $500,000 to $9 million in 3 years. The remaining items are contracted for on the basis of the suppliers' entire product line and not on an individual item basis. Offerers are required to disclose their best price to each category of customer such as wholesalers, distributors, State and local governments, nonprofit hospitals, et cetera. We negotiate with each supplier for a discount. If no price advantage below the lowest obtainable without a contract can be negotiated, we do not award a contract. Discounts are negotiated for the entire product line and not off list prices of individual items. This same practice is followed for multiple-award Federal Supply Schedules for other commodities purchased by the Federal Government in this manner as well as drugs. This is generally because of the large number of items involved. In the case of drugs alone, the estimates on the number of items and the various brands vary from 33,000 to over 60,000.

Since manpower was not available to negotiate individually for each item, we selected about 50 different items—over 250 contract line items—which we felt represent the significant dollar purchases —over $50,000 annually per item. We have negotiated for 30 of these drugs out of the 50 on an item-by-item basis and have just published an experimental contract—FSC Schedule 65, part 1, section C. We are still negotiating for the remaining 20. This schedule consolidates into one place the competing products and shows the exact price of each. It provides the purchaser for the first time with the opportunity to compare prices without research through voluminous catalogs and price lists.

Senator NELSON. How many classes of drugs are on that schedule?

Dr. LEE. There are 50 which we have been carrying through, 30 of which we have gone over item by item.

Senator NELSON. And this schedule shows the price range for a number of manufacturers; is that it?

Dr. LEE. Yes, sir.

Senator NELSON. And to whom is this sent?

Mr. COOK. It goes to each of our—in fact, it goes to all Federal purchasers of drugs.

Senator NELSON. When you say all Federal——

Mr. COOK. All Federal agencies who procure drugs may use this schedule.

Senator NELSON. Does it go to the physicians in the veterans hospitals?

Mr. COOK. In the hospitals, yes, sir.

Senator NELSON. Not to the 100,000 physicians who prescribe for VA patients?

Mr. COOK. For VA. There are over 300,000 physicians in active practice.

Senator NELSON. Do you have a copy of that schedule?

Mr. COOK. Yes, sir.

Senator NELSON. Would you submit it to the Committee, and we shall decide whether it will be helpful to put in the record.

Mr. COOK. Thank you.

[Testimony resumes at page 10471. The information referred to follows:]

32-814 (Pt. 24) O - 74 - 95

FOR THE PERIOD JANUARY 1, 1974 THROUGH DECEMBER 31, 1974

FSC 65 PART I SECTION C
Drugs and Pharmaceutical Products

ISSUED DECEMBER 18, 1973

CLASS 6505

FEDERAL SUPPLY SCHEDULE

NEW SCHEDULE: To receive future copies of this schedule, update your GSA Form 457, to include the mailing code 36SC 6510

CONTENTS

MAILING CODE 36SC 6510

CONTRACTS PREPARED AND ADMINISTERED BY VETERANS ADMINISTRATION MARKETING DIVISION FOR DRUGS AND CHEMICALS UNDER AN ASSIGNMENT BY THE ADMINISTRATOR, GSA PURSUANT TO GSA REG. 1-II-203.00

65, I - C

GENERAL INSTRUCTIONS

1. INFORMATION CONTAINED IN THIS SCHEDULE. This schedule lists only contractors which have received awards. Additional awards may be made, and, as awarded will be published in cumulative editions to this schedule. In cumulative editions to this Schedule, new information will be identified by a vertical line in the right hand margin.

2. No pricelists/catalogs will be furnished by contractors.

3. GEOGRAPHIC COVERAGE. The 50 States, Washington, DC and Puerto Rico.

4. PRIMARY USERS. All Federal agencies in the executive branch (except DoD and U.S. Postal Service) and the DC Government.

   Exemptions from primary use: Depot Stock requirement of HEW.

5. OTHER USING ACTIVITIES. Government activities, other than primary users, and Government cost-reimbursement type prime contractors (authorized in writing by a Federal agency) may place orders under this schedule.

6. MULTIPLE AWARDS. Multiple award Federal Supply Schedules cover contracts made with more than one supplier for comparable items at either the same or different prices for delivery to the same geographic area.

7. INCORPORATION OF FORMS. The following forms apply to all contracts in this schedule:

   a. Standard Form 32, General Provisions (Supply Contract), November 1969 edition.

   b. GSA Form 1424, GSA Supplemental Provisions, March 1972 edition, except:

      (1) Clauses 31 and 32 are modified by changing "Interim Federal Standard 00123B" to "Federal Standard 123C."

      (2) Clause 56 is deleted.

      (3) Delete all references to "General Services Administration" and "Administrator of General Services" and substitute "Veterans Administration" and "Administrator of Veterans Affairs" except in Paragraphs 23 and 31.

      (4) Clause 6 is modified to include the following:

      > Rejected goods will be held subject to contractor's disposition instructions for not more than 15 days after which merchandise will be returned to the contractor's address at his risk and expense.

   c. GSA Form 2891, Standard Provisions - Federal Supply Schedules, November 1973 edition.

9. PAYMENTS. Paying offices of the ordering activities shall make payment for accepted supplies or services in accordance with the terms and conditions of the contract (including Article 7, Payments, Standard Form 32 and Paragraph 9, Discounts, Standard Form 33A), promptly after receipt of proper invoices or vouchers from the contractor. When a delivery order specifies delivery to a port within the U.S.A. and the contract provides only for delivery to destination within the 48 contiguous States and Washington, DC, such payment shall be made promptly upon receipt of evidence of delivery to that port notwithstanding the fact that final destination of the supplies or services may be abroad.

SPECIAL PROVISIONS

1. IMPREST FUNDS. The contractor agrees to accept cash payment for purchases made under the terms of the contract in conformance with FPR 1-3.604.

2. EXCHANGES. The contractor will accept for exchange, all products bearing an expiration date when such expiration date has been reached, provided request therefore is initiated within a reasonable period (not to exceed 90 days after expiration date) and the products to be exchanged are presented in unopened containers or packages and in an undamaged condition.

3. DATE OF MANUFACTURE. Items manufactured in excess of one year prior to the date of the purchase order covering the item will not be accepted. Violation of this provision may result in termination of the contract pursuant to the clause of the General Provisions (SF 32) entitled "Default."

4. DATED MATERIAL. Not more than one half of the maximum potency period shall have expired prior to date of delivery.

5. CONTAINER PRICES. All prices include containers except where containers are reusable or where otherwide indicated. Reusable containers remain the property of the contractor. Containers which remain the property of the contractor will be returned in good condition as soon as practicable.

ORDERING INSTRUCTIONS

1. SCHEDULE CONTRACTING ACTIVITY. For assistance with this schedule, write or call the activity below citing FSC, Part, Section, and issue date:

   Veterans Administration
   Marketing Division for Drugs and Chemicals
   Box 76
   Hines, IL 60141
   Telephone: (312) 343-7200, Ext. 2826

2. TIME OF DELIVERY. The time of delivery shall not exceed the number of days shown in the LIST OF CONTRACTORS.

3. SMALL REQUIREMENTS. No ordering activity must order less than $50 for delivery to any one destination. Orders for less than that quantity may be placed by activities subject to acceptance by the contractor; however, contractors must accept all orders above the quantity listed in the LIST OF CONTRACTORS in the column titled MINIMUM ORDER.

4. MAXIMUM ORDER LIMITATIONS. Purchase orders cannot exceed the amount(s) shown in the LIST OF CONTRACTORS in the column titled MAXIMUM ORDER.

5. INSPECTION. This schedule provides for inspection at destination.

6. PACKAGING AND PACKING. Standard commercial practice (Level C of Federal Standard 102).

   If special or unusual packing is required, such packing requirements should be arranged with the contractor by the ordering activity.

7. BUY AMERICAN DIFFERENTIALS. Buy American differentials have been applied by GSA, as required, during the award process. Therefore, ordering activities should not attempt to apply these differentials before placing an order.

8. RECEIVING DOCK HOURS. State on the purchase order the time (local daylight or standard) that material can be received at destination.

9. RECEIVING DOCK LIMITATIONS. If there are limitations on size (height, width, or length) or weight of vehicle that can be accommodated at delivery point, state them on the purchase order.

10. DELIVERY ADDRESS. If delivery address is vague, include instructions in the purchase order that will assist carrier in reaching the delivery point.

ORDERING INSTRUCTIONS - Continued

11. JUSTIFICATION. When orders are placed at other than the lowest price available under a item and (1) the cost is more than $250 per line item, ordering activities must justify the purchase of the higher priced item; (2) the cost is $250 or less per line item, ordering activities should refer to their agency procurement regulations to determine if justification is required.

12. PLACING OF ORDERS. If an order is placed with any of the authorized agents, the order shall be addressed to the agent but in such manner as to shown the name of the contractor as principal and the addressee as agent for the contractor.

SUPPLIES AND SERVICES

INDEX NO.	SUPPLIES OR SERVICES	UNIT OF PURCHASE	PRICE (DOLLARS)
	Contractors are listed under the generic title followed by the manufacturer and his trade name in price sequence, starting with the lowest price in the case of more than one supplier.		
	SODIUM HEPARIN INJECTION, USP:		
	1000 units/ml:		
1	1 ml.	VI	A/P
2	10 ml:		
	Upjohn #8007 [25 vials per case]	CS	10.25
	Riker #410-01 (Lipo-Hepin). . .	VI	.52
	McGaw #W1400.	VI	.582
	American Quinine #0961 [10 vials per case].	CS	7.50
	Abbott #3672-02 (Panheparin 1000):		
	(a) Case of 25 vials.	CS	19.00
	(b) 100 cases, 25 vials per case	CS	14.25
	(c) 200 cases, 25 vials per case	CS	7.59
3	30 ml:		
	Riker #413-25 (Lipo-Hepin) [25 vials per case].	CS	23.75
	McGaw #W1405.	VI	1.150
	Upjohn #8008 [25 vials per case]	CS	42.50
4	5000 units/ml; 10 ml:		
	Abbott #3979-02 (Panheparin 5000):		
	(a) Case of 25 vials.	CS	68.75
	(b) 100 cases, 25 vials per case	CS	51.50
	(c) 200 cases, 25 vials per case	CS	34.30
	Riker #415-01 (Lipo-Hepin). . .	VI	1.19
	Upjohn #8009 [25 vials per case]	CS	31.75
	McGaw #W1410.	VI	2.344
	American Quinine #0983 [10 vials per case].	CS	18.00
	10,000 units/ml:		
5	4 ml:		
	Riker #421-01 (Lipo-Hepin). . .	VI	1.04
	Upjohn #8011 [25 vials per case]	CS	32.50
	McGaw #W1415.	VI	1.918
	Abbott #3987-03 (Panheparin 10,000):		
	(a) Case of 25 vials.	CS	56.35
	(b) 100 cases, 25 vials per case	CS	42.25
	(c) 200 cases, 25 vials per case	CS	24.99
6	5 ml:		
	Riker #425-01 (Lipo-Hepin). . .	VI	1.30
	American Quinine #0962 [10 vials per case].	CS	24.00
	Abbott #3987-04 (Panheparin 10,000):		
	(a) Case of 25 vials.	CS	68.75
	(b) 100 cases, 25 vials per case	CS	51.50
	(c) 200 cases, 25 vials per case	CS	30.63
	20,000 units/ml:		
7	2 ml:		
	Riker #432-01 (Lipo-Hepin). . .	VI	1.02
	McGaw #W1420.	VI	1.918
8	5 ml:		
	Upjohn #8013 [25 vials per case]	CS	61.00
	Riker #435-01 (Lipo-Hepin). . .	VI	2.70
	Abbott #6957-02 (Panheparin 20,000):		
	(a) Package of 5 vials. . . .	PG	45.90
	(b) Case of 25 vials. . . .	CS	149.00
	(c) 100 cases, 25 vials per case	CS	111.75
	(d) 200 cases, 25 vials per case	CS	71.05
9	10 ml:		
	Riker #438-01 (Lipo-Hepin). . .	VI	5.45
	40,000 units/ml:		
10	2 ml:		
	Riker #442-01 (Lipo-Hepin). . .	VI	2.08
	McGaw #W1425.	VI	3.22
	Abbott #6984-02 (Panheparin 40,000):		
	(a) Package of 5 vials. . . .	PG	36.75
	(b) Case of 25 vials. . . .	CS	119.15
	(c) 100 cases, 25 vials per case	CS	89.35
	(d) 200 cases, 25 vials per case	CS	67.10
11	5 ml:		
	Riker #445-01 (Lipo-Hepin). . .	VI	5.90
	LIDOCAINE HYDROCHLORIDE INJECTIONS:		
12	1% with Epinephrine, 1:100,000; 50 ml:		
	Astra #106-1 (Xylocaine with Epinephrine) [30 vials per case]	CS	24.90
13	2% with Epinephrine, 1:100,000; 50 ml:		
	Astra #103-1 (Xylocaine with Epinephrine) [30 vials per case]	CS	28.50
	LIDOCAINE HYDROCHLORINE INJECTIONS, USP:		
	1%:		
14	20 cc:		
	Astra #105-3 (Xylocaine) [30 vials per case].	CS	13.80
15	30 cc:		
	McGaw #W2005.	VI	.3757
	American Quinine #0625 [50 vials per case].	CS	20.00
16	50 cc:		
	American Quinine #0625 [50 vials per case].	CS	20.00
	McGaw #V2014.	VI	.5521
	Astra #105-1 (Xylocaine) [30 vials per case].	CS	24.00
	2%:		
17	20 cc:		
	Astra #102-2 (Xylocaine) [30 vials per case].	CS	14.70

65, I - C

4

SUPPLIES OR SERVICES - Continued

INDEX NO.	SUPPLIES OR SERVICES	UNIT OF PURCHASE	PRICE (DOLLARS)
18	**30 cc:**		
	American Quinine #0626 [50 vials per case]	CS	20.00
	McGaw #W2010	VI	.4141
19	50 cc:		
	American Quinine #0626 [50 vials per case]	CS	20.00
	McGaw #W2016	VI	.5904
	Astra #102-1 (Xylocaine) [30 vials per case]	CS	27.90
	NORMAL SERUM ALBUMIN, 5% (Human):		
20A	250 ml:		
	Armour #53-7670-01 (Albuminar-5); non-returnable, 10 units per case	CS	235.00
20B	500 ml:		
	Armour #53-7670-02 (Albuminar-5); non-returnable, 10 units per case	CS	440.00
	NORMAL SERUM ALBUMIN (Human) Salt Poor, 25%:		
21	20 ml:		
	Armour #53-7680-01 (Albuminar-25); non-returnable, 10 units per case	CS	85.00
22	50 ml:		
	Armour #53-7680-02 (Albuminar-25); non-returnable, 10 units per case	CS	210.00
23	100 ml:		
	Armour #53-7680-03 (Albuminar-25); non-returnable, 10 units per case	CS	390.00
	PLASMA PROTEIN FRACTION (Human) 5%:		
24	250 ml:		
	Armour (Plasma-Plex, 5%); non-returnable, 10 packages per case	CS	210.00
25	500 ml:		
	Armour (Plasma-Plex, 5%); non-returnable, 10 packages per case	CS	390.00
26	ANTIHEMOPHILIC FACTOR (Human) USP:		
	Armour #53-7655-02 (Factorate), 200-249 units; with 25 ml of diluent, non-returnable, 5 packages per case	CS	103.75
	Armour #53-7660-02 (Factorate), 250-299 units, with 25 ml of diluent, non-returnable, 5 packages per case	CS	151.25
	Armour #53-7665-02 (Factorate), 300-349 units, with 25 ml of diluent, non-returnable, 5 packages per case	CS	178.75
	Armour #53-7666-02 (Factorate), 350-399 units, with 25 ml of diluent, non-returnable, 5 packages per case	CS	206.25
27	TETANUS IMMUNE GLOBULIN (Human) USP; **250 units:**		
	Armour #53-7916-01 (Ar-Tet) 10 vials per case	CS	23.00
	Armour #53-7916-02 (Ar-Tet) 5 syringes per case	CS	11.75
	INSULIN INJECTIONS, USP; 10 ml:		
28A	40 units:		
	Squibb #3-0B55-10	VI	.54
	Lilly M-240 (Regular Iletin):		
	(a) Single vial	VI	.67
	(b) Case of 10 vials	CS	5.70
28B	80 units:		
	Squibb #3-0B56-10	VI	1.05
	Lilly M-280 (Regular Iletin):		
	(a) Single vial	VI	1.31
	(b) Case of 10 vials	CS	11.10
28C	100 units:		
	Squibb #3-0E34-10	VI	1.32
	Lilly M-210 (Regular Iletin):		
	(a) Single vial	VI	1.63
	(b) Case of 10 vials	CS	13.90
	INSULIN GLOBIN INJECTIONS, USP; 10 ml:		
29	40 units:		
	Squibb #3-0B47-10 (Globin Zinc)	VI	.76
30A	80 units:		
	Squibb #3-0B58-10 (Globin Zinc)	VI	1.46
30B	100 units:		
	Squibb #3-0E38-10 (Globin Zinc)	VI	1.67
	ISOPHANE INSULIN SUSPENSION, USP; 10 ml:		
31	40 units:		
	Squibb #3-0B61-10	VI	.63
	Lilly M-340 (NPH Iletin):		
	(a) Single vial	VI	.79
	(b) Case of 10 vials	CS	6.60
32A	80 units:		
	Squibb #3-0B62-10	VI	1.19
	Lilly M-380 (NPH Iletin):		
	(a) Single vial	VI	1.49
	(b) Case of 10 vials	CS	12.60
32B	100 units:		
	Squibb #3-0E33-10	VI	1.53
	Lilly M-310 (NPH Iletin):		
	(a) Single vial	VI	1.88
	(b) Case of 10 vials	CS	16.10
	INSULIN ZINC SUSPENSION, USP; 10 ml:		
33	40 units:		
	Squibb #3-0423-40 (Lente Insulin)	VI	.63
	Lilly M-440 (Lente Iletin):		
	(a) Single vial	VI	.79
	(b) Case of 10 vials	CS	6.60

INDEX NO.	SUPPLIES OR SERVICES	UNIT OF PURCHASE	PRICE (DOLLARS)
34A	30 units:		
	Squibb #3-0446-60 (Lente Insulin)	VI	1.19
	Lilly M-480 (Lente Iletin):		
	(a) Single vial	VI	1.49
	(b) Case of 10 vials	CS	12.60
34B	100 units:		
	Squibb #3-0E30-10 (Lente Insulin)	VI	1.53
	Lilly M-410 (Lente Iletin):		
	(a) Single vial	VI	1.88
	(b) Case of 10 vials	CS	16.10
	PROTAMINE ZINC INSULIN SUSPENSION, USP; 10 ml:		
35	40 units:		
	Squibb #3-0B59-10	VI	.63
	Lilly M-140 (Protamine, Zinc and Iletin):		
	(a) Single vial	VI	.79
	(b) Case of 10 vials	CS	6.60
36-1A	80 units:		
	Squibb #3-0B60-10	VI	1.19
	Lilly M-180 (Protamine, Zinc and Iletin):		
	(a) Single vial	VI	1.49
	(b) Case of 10 vials	CS	12.60
36-1B	100 units:		
	Squibb #3-0E37-10	VI	1.53
	Lilly M-110 (Protamine, Zinc and Iletin):		
	(a) Single vial	VI	1.88
	(b) Case of 10 vials	CS	16.10
	PROMPT INSULIN ZINC SUSPENSION, USP; 10 ml:		
36-2A	40 units:		
	Squibb #3-0561-40 (Similente Insulin)	VI	.63
	Lilly M-540 (Similente Iletin):		
	(a) Single vial	VI	.79
	(b) Case of 10 vials	CS	6.60
36-2B	80 units:		
	Squibb #3-0574-80 (Similente Insulin)	VI	1.19
	Lilly M-580 (Similente Iletin):		
	(a) Single vial	VI	1.49
	(b) Case of 10 vials	CS	12.60
36-2C	100 units:		
	Squibb #3-0E31-10 (Similente Insulin)	VI	1.53
	Lilly M-510 (Similente Iletin):		
	(a) Single vial	VI	1.88
	(b) Case of 10 vials	CS	16.10
	EXTENDED INSULIN ZINC SUSPENSION, USP; 10 ml:		
36-3A	40 units:		
	Squibb #3-0474-40 (Ultralente Insulin)	VI	.63
	Lilly M-640 (Ultralente Iletin):		
	(a) Single vial	VI	.79
	(b) Case of 10 vials	CS	6.60
36-3B	80 units:		
	Squibb #3-0560-60 (Ultralente Insulin)	VI	1.19
	Lilly M-680 (Ultralente Iletin):		
	(a) Single vial	VI	1.49
	(b) Case of 10 vials	CS	12.60
36-3C	100 units:		
	Squibb #3-0E32-10 (Ultralente Insulin)	VI	1.53
	Lilly M-610 (Ultralente Iletin):		
	(a) Single vial	VI	1.88
	(b) Case of 10 vials	CS	16.10
	PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION, USP; 15 ml:		
37	1%	VI	A/P
38	2%	VI	A/P
39	4%	VI	A/P
40	6%	VI	A/P
	POTASSIUM CHLORIDE INJECTIONS, USP:		
41	20 MEQ, 10 ml:		
	American Quinine #0622 (100 units per box)	BX	9.50
	McGaw #W1130	EA	.2837
	Abbott #3907-03:		
	(a) Case of 25	CS	8.87
	(b) 100 cases, 25 per case	CS	6.77
42	40 MEQ, 20 ml:		
	American Quinine #0991 (25 units per box)	BX	3.96
	McGaw #W1135	EA	.3451
	Abbott #3934-02:		
	(a) Case of 25	CS	9.95
	(b) 100 cases, 25 per case	CS	7.60
	RESERPINE TABLETS, USP:		
43	0.1 mg.	BT	A/P
44	0.25 mg; 1,000 tablets per bottle:		
	American Quinine #0890	BT	1.05
	Philips Roxane #054-4742-31	BT	2.00
	MEPERIDINE HYDROCHLORIDE INJECTIONS, USP:		
	CARTRIDGE NEEDLE UNITS; 2 ml, (1 ml fill):		
45	Needle size 22 Gage x 1-1/4"; 75 mg per ml.	CO	A/P
46	Needle size 22 Gage x 1-1/4"; 50 mg per ml	CO	A/P
47	Needle size 25 Gage x 5/8"; 50 mg per ml	CO	A/P
48	Needle size 22 Gage x 1-1/4"; 100 mg per ml	CO	A/P
	AMPULS:		
49	50 mg	CO	A/P
50	75 mg	CO	A/P
51	100 mg.	CO	A/P

SUPPLIES OR SERVICES - Continued

INDEX NO.	SUPPLIES OR SERVICES	UNIT OF PURCHASE	PRICE (DOLLARS)
	KETAMINE HYDROCHLORIDE INJECTIONS, VIAL 50 mg/ml:		
52	1 ml.	VI	A/P
53	10 ml:		
	Bristol #015-8340-96 (Ketaject)	VI	2.71
	Parke-Davis #35-1582-1 (Ketalar)	VI	2.90
	SODIUM WARFARIN TABS, USP:		
	2 mg:		
54	100 tabs.	CO	A/P
55	1,000 tabs.	CO	A/P
	2.5 mg:		
56	100 tabs.	CO	A/P
57	1,000 tabs.	CO	A/P
	5 mg:		
58	100 tabs.	CO	A/P
59	500 tabs.	CO	A/P
60	1,000 tabs.	CO	A/P
	7.5 mg:		
61	100 tabs.	CO	A/P
62	1,000 tabs.	CO	A/P
	10 mg:		
63	100 tabs.	CO	A/P
64	500 tabs.	CO	A/P
65	1,000 tabs.	CO	A/P
66	25 mg; 100 tabs	CO	A/P
	AMPICILLIN CAPSULES, USP; Unit-Dose:		
67	250 mg, 100 capsules:		
	Bristol #015-7992-66 (Polycillin)	CT	3.72
	Pfizer (Pen-A).	CT	6.33
	Upjohn #5765 (Pensyn)	CT	9.06
	Beecham-Massengill (Totacillin)	CT	9.09
68	500 mg, 50 capsules	CT	A/P
69	500 mg, 100 capsules:		
	Bristol #015-7993-66 (Polycillin)	CT	6.24
	Pfizer (Pen-A).	CT	9.94
	Upjohn (Pensyn)	CT	17.39
	Beecham-Massengill (Totacillin)	CT	17.72
	DEXTROSE:		
	2-1/2% in water:		
70	250 ml:		
	McGaw #S1002.	EA	.45
71	1,000 ml:		
	McGaw #S1000.	EA	.63
	Abbott #1508-05; 6 per case:		
	(a) 1 to 24 cases	CS	4.51
	(b) 25 to 84 cases.	CS	4.14
	(c) 85 or more cases.	CS	3.80
	5% in water:		
72	150 ml:		
	McGaw #S1103.	EA	.44
	Abbott #1522-01; 12 per case:		
	(a) 1 to 24 cases	CS	6.55
	(b) 25 to 84 cases.	CS	5.53
	(c) 85 or more cases.	CS	5.08
73	250 ml:		
	McGaw #S1102.	EA	.45
	Abbott #1522-02; 12 per case:		
	(a) 1 to 24 cases	CS	6.68
	(b) 25 to 84 cases.	CS	5.65
	(c) 85 or more cases.	CS	5.19
74	500 ml:		
	McGaw #S1101.	EA	.52
	Abbott #1522-03; 12 per case:		
	(a) 1 to 24 cases	CS	7.50
	(b) 25 to 84 cases.	CS	6.48
	(c) 85 or more cases.	CS	5.95
75	1,000 ml:		
	McGaw #S1100.	EA	.65
	Abbott #1522-05; 6 per case:		
	(a) 1 to 24 cases	CS	4.41
	(b) 25 to 84 cases.	CS	3.83
	(c) 85 or more cases.	CS	3.52
	10% in water:		
76	250 ml:		
	McGaw #S1202.	EA	.52
	Abbott #1530-02; 12 per case:		
	(a) 1 to 24 cases	CS	7.25
	(b) 25 to 84 cases.	CS	6.65
	(c) 85 or more cases.	CS	6.11
77	500 ml:		
	McGaw #S1201.	EA	.59
	Abbott #1530-03; 12 per case:		
	(a) 1 to 24 cases	CS	8.35
	(b) 25 to 84 cases.	CS	7.28
	(c) 85 or more cases.	CS	6.68
78	1,000 ml:		
	McGaw #S1200.	EA	.72
	Abbott #1530-05; 6 per case:		
	(a) 1 to 24 cases	CS	5.23
	(b) 25 to 84 cases.	CS	4.55
	(c) 85 or more cases.	CS	4.18
79	20% in water; 500 ml:		
	McGaw #S1251.	EA	.75
	Abbott #1535-03; 12 per case:		
	(a) 1 to 24 cases	CS	11.13
	(b) 25 to 84 cases.	CS	9.97
	(c) 85 or more cases.	CS	9.15
80	50% in water; 500 ml:		
	McGaw #S1281.	EA	1.03
	Abbott #1536-03; 12 per case:		
	(a) 1 to 24 cases	CS	14.17
	(b) 25 to 84 cases.	CS	13.21
	(c) 85 or more cases.	CS	12.12
81	2-1/2% in 1/2 strength normal saline, 250 ml:		
	McGaw #S2052.	EA	.46
	Abbott #1509-02; 12 per case:		
	(a) 1 to 24 cases	CS	6.70
	(b) 25 to 84 cases.	CS	5.95
	(c) 85 or more cases.	CS	5.46
	5% in 1/2 strength normal saline:		
82	250 ml:		
	McGaw #S2122.	EA	.47
	Abbott #1526-02; 12 per case:		
	(a) 1 to 24 cases	CS	6.86
	(b) 25 to 84 cases.	CS	6.08
	(c) 85 or more cases.	CS	5.58

SUPPLIES OR SERVICES - Continued

INDEX NO.	SUPPLIES OR SERVICES	UNIT OF PURCHASE	PRICE (DOLLARS)
83	500 ml:		
	McGaw #S2121.	EA	.55
	Abbott #1526-03; 12 per case:		
	(a) 1 to 24 cases	CS	7.94
	(b) 25 to 84 cases.	CS	6.87
	(c) 85 or more cases.	CS	6.31
84	1,000 ml:		
	McGaw #S2120.	EA	.69
	Abbott #1526-05; 6 per case:		
	(a) 1 to 24 cases	CS	4.96
	(b) 25 to 84 cases.	CS	4.33
	(c) 85 or more cases.	CS	3.98
	5% in normal saline:		
85	250 ml:		
	McGaw #S2102.	EA	.47
	Abbott #1527-02; 12 per case:		
	(a) 1 to 24 cases	CS	6.81
	(b) 25 to 84 cases.	CS	5.78
	(c) 85 or more cases.	CS	5.31
86	500 ml:		
	McGaw #S2101.	EA	.55
	Abbott #1527-03; 12 per case:		
	(a) 1 to 24 cases	CS	7.94
	(b) 25 to 84 cases.	CS	6.87
	(c) 85 or more cases.	CS	6.31
87	1,000 ml:		
	McGaw #S2100.	EA	.69
	Abbott #1527-05; 6 per case:		
	(a) 1 to 24 cases	CS	4.72
	(b) 25 to 84 cases.	CS	4.13
	(c) 85 or more cases.	CS	3.79
	10% in normal saline:		
88	500 ml:		
	McGaw #S2201.	EA	.62
	Abbott #1534-03; 12 per case:		
	(a) 1 to 24 cases	CS	7.94
	(b) 25 to 84 cases.	CS	6.87
	(c) 85 or more cases.	CS	6.31
89	1,000 ml:		
	McGaw #S2200.	EA	.78
	Abbott #1534-05; 6 per case:		
	(a) 1 to 24 cases	CS	5.47
	(b) 25 to 84 cases.	CS	4.80
	(c) 85 or more cases.	CS	4.41
	NORMAL SALINE SOLUTION:		
90	150 ml:		
	McGaw #S4403.	EA	.43
	Abbott #1583-01; 12 per case:		
	(a) 1 to 24 cases	CS	6.40
	(b) 25 to 84 cases.	CS	5.41
	(c) 85 or more cases.	CS	4.97
91	250 ml:		
	McGaw #S4002.	EA	.44
	Abbott #1583-02; 12 per case:		
	(a) 1 to 24 cases	CS	6.49
	(b) 25 to 84 cases.	CS	5.53
	(c) 85 or more cases.	CS	5.08
92	500 ml:		
	McGaw #S4001.	EA	.50
	Abbott #1583-03; 12 per case:		
	(a) 1 to 24 cases	CS	7.06
	(b) 25 to 84 cases.	CS	6.07
	(c) 85 or more cases.	CS	5.57
93	1,000 ml:		
	McGaw #S4000.	EA	.59
	Abbott #1583-05; 6 per case:		
	(a) 1 to 24 cases	CS	3.99
	(b) 25 to 84 cases.	CS	3.46
	(c) 85 or more cases.	CS	3.18
	LACTATED RINGERS INJECTIONS:		
94	250 ml:		
	McGaw #S3502.	EA	.49
	Abbott #1553-02; 12 per case:		
	(a) 1 to 24 cases	CS	6.91
	(b) 25 to 84 cases.	CS	5.95
	(c) 85 or more cases.	CS	5.46
95	500 ml:		
	McGaw #S3501.	EA	.61
	Abbott #1553-03; 12 per case:		
	(a) 1 to 24 cases	CS	8.61
	(b) 25 to 84 cases.	CS	7.53
	(c) 85 or more cases.	CS	6.91
96	1,000 ml:		
	McGaw #S3500.	EA	.70
	Abbott #1553-05; 6 per case:		
	(a) 1 to 24 cases	CS	5.09
	(b) 25 to 84 cases.	CS	4.42
	(c) 85 or more cases.	CS	4.06
	RINGERS INJECTIONS:		
97	500 ml:		
	McGaw #S3801.	EA	.55
	Abbott #1582-03; 12 per case:		
	(a) 1 to 24 cases	CS	7.98
	(b) 25 to 84 cases.	CS	6.93
	(c) 85 or more cases.	CS	6.36
98	1,000 ml:		
	McGaw #S3800.	EA	.69
	Abbott #1582-05; 6 per case:		
	(a) 1 to 24 cases	CS	4.99
	(b) 25 to 84 cases.	CS	4.36
	(c) 85 or more cases.	CS	4.00
99	FRUCTOSE 10% INJECTION, 1,000 ml:		
	McGaw #S1600.	EA	1.16
	Abbott #1537-05; 6 per case:		
	(a) 1 to 24 cases	CS	8.79
	(b) 25 to 84 cases.	CS	7.70
	(c) 85 or more cases.	CS	7.07
100	SODIUM BICARBONATE 5% INJECTION, USP; 500 ml:		
	McGaw #S4981.	EA	1.34
	TRIFLUOPERAZINE HYDROCHLORIDE:		
101	CONCENTRATE; 2 fl. oz. 12 units per container	CO	A/P
		CO	
	INJECTIONS, NF; M/D vials, 10 cc:		
102	1 vial.	VI	A/P
103	20 vials.	VI	A/P

SUPPLIES OR SERVICES - Continued

INDEX NO.	SUPPLIES OR SERVICES	UNIT OF PURCHASE	PRICE (DOLLARS)
	TABLETS, NF:		
	1 mg:		
104	100 tablets	BT	A/P
105	1,000 tablets	BT	A/P
106	5,000 (carton of 5 bottles, 1,000 tablets per bottle)	CT	A/P
	2 mg:		
107	100 tablets	BT	A/P
108	1,000 tablets	BT	A/P
109	5,000 (carton of 50 bottles, 100 tablets per bottle)	CT	A/P
110	5,000 (carton of 5 bottles, 1,000 tablets per bottle)	CT	A/P
	5 mg:		
111	100 tablets	BT	A/P
112	1,000 tablets	BT	A/P
113	5,000 (carton of 50 bottles, 100 tablets per bottle)	CT	A/P
114	5,000 (carton of 5 bottles, 1,000 tablets per bottle)	CT	A/P
	10 mg:		
115	100 tablets	BT	A/P
116	1,000 tablets	BT	A/P
117	5,000 (carton of 50 bottles, 100 tablets per bottle)	CT	A/P
118	5,000 (carton of 5 bottles, 1,000 tablets per bottle)	CT	A/P
	PROCHLORPERAZINE EDISYLATE:		
	INJECTIONS, USP; 2 cc, 10 mg:		
119	6 per box:		
	Smith, Kline & French (Compazine)	BX	4.25
120	100 per box:		
	Smith, Kline & French (Compazine)	BX	61.63
121	500 per box:		
	Smith, Kline & French (Compazine)	BX	239.70
	LIQUID, ORAL; 10 mg/ml:		
122	1 - 4 fl. oz. bottle:		
	Smith, Kline & French (Compazine Concentrate)	BT	4.68
123	36 - 4 fl. oz. bottles:		
	Smith, Kline & French (Compazine Concentrate)	CS	141.10
	INJECTIONS, USP; 5 mg/ml; 10 ml:		
124	1 vial:		
	Smith, Kline & French (Compazine)	VI	3.19
125	20 vials:		
	Smith, Kline & French (Compazine)	BX	55.46
126	100 vials:		
	Smith, Kline & French (Compazine)	BX	213.35
	PROCHLORPERAZINE MALEATE CAPSULES:		
	10 mg:		
127	50 capsules:		
	Smith, Kline & French (Compazine Spansule)	BT	5.70
128	500 capsules:		
	Smith, Kline & French (Compazine Spansule)	BT	53.98
129	1,500 (package of 3 bottles, 500 capsules per bottle):		
	Smith, Kline & French (Compazine Spansule)	PG	137.70
	15 mg:		
130	50 capsules:		
	Smith, Kline & French (Compazine Spansule)	BT	7.40
131	500 capsules:		
	Smith, Kline & French (Compazine Spansule)	BT	70.13
132	1,500 (package of 3 bottles, 500 capsules per bottle):		
	Smith, Kline & French (Compazine Spansule)	PG	181.90
	30 mg:		
133	50 capsules:		
	Smith, Kline & French (Compazine Spansule)	BT	8.33
134	500 capsules:		
	Smith, Kline & French (Compazine Spansule)	BT	79.26
135	1,500 (package of 3 bottles, 500 capsules per bottle):		
	Smith, Kline & French (Compazine Spansule)	PG	206.55
136	75 mg; 50 capsules:		
	Smith, Kline & French (Compazine Spansule)	BT	9.95
	PROCHLORPERAZINE SUPPOSITORIES, NF, 12 suppositories per box:		
137	2.5 mg:		
	Smith, Kline & French (Compazine Suppositories)	BX	2.13
138	5 mg:		
	Smith, Kline & French (Compazine Suppositories)	BX	2.38
139	25 mg:		
	Smith, Kline & French (Compazine Suppositories)	BX	2.98

SUPPLIES OR SERVICES - Continued

65, I - C

INDEX NO.	SUPPLIES OR SERVICES	UNIT OF PURCHASE	PRICE (DOLLARS)
140	PROCHLORPERAZINE EDISYLATE SYRUP, USP; 5 mg. per 5 ml., 4 fl. oz.:		
	Smith, Kline & French (Compazine Syrup).	BT	1.66
	PROCHLORPERAZINE MALEATE TABLETS, USP:		
	5 mg:		
141	100 tablets:		
	Smith, Kline & French (Compazine Tablets).	BT	6.04
142	1,000 tablets:		
	Smith, Kline & French (Compazine Tablets).	BT	57.38
143	5,000 (package of 5 bottles, 1,000 tablets per bottle):		
	Smith, Kline & French (Compazine Tablets).	PG	245.65
	10 mg:		
144	100 tablets:		
	Smith, Kline & French (Compazine Tablets).	BT	7.82
145	1,000 tablets:		
	Smith, Kline & French (Compazine Tablets).	BT	74.38
146	5,000 (package of 5 bottles, 1,000 tablets per bottle). . . .	PG	275.40
	25 mg:		
147	100 tablets:		
	Smith, Kline & French (Compazine Tablets).	BX	9.18
148	1,000 tablets:		
	Smith, Kline & French (Compazine Tablets).	BX	87.13
149	5,000 (package of 5 bottles, 1,000 tablets per bottle)	PG	335.75

65, I - C

10

LIST OF CONTRACTORS

CONTRACTS AWARDED AS A RESULT OF NEGOTIATION PURSUANT TO SECTION 302 (C)(7) & (10) OF THE FEDERAL PROPERTY ADMINISTRATIVE SERVICES ACT OF 1949, 63 STAT. 393, AS AMENDED [41 U.S.C. 252 (C)(7) & (10)]

BUSINESS SIZE: Listed in the column CONTRACT NUMBER V797P- is the business size indicator of "s" for small business and "o" for other than small business.

TELEPHONE NUMBERS: Listed in the column CONTRACTOR, ADDRESS, TELEPHONE under each address, the commercial phone number (Com) is listed first followed by the Federal Telecommunications System number (FTS).

DOLLAR VOLUME DISCOUNT COLUMN: Discounts shown were offered by the contractors based on the dollar volumes displayed.

MINIMUM ORDER COLUMN: Listed is the smallest order the contractor stated he would accept.

MAXIMUM ORDER COLUMN: Listed is the maximum limitation of any order.

CONTRACT NUMBER V797P-	CONTRACTOR ADDRESS & TELEPHONE	DOLLAR VOLUME DISCOUNT	PROMPT PAYMENT DISCOUNT	MINIMUM ORDER (DOLLARS)	MAXIMUM ORDER (DOLLARS)	TIME OF DELIVERY (DAYS)
o 5094c	ABBOTT LABS, DEPT 346 14TH & SHERIDAN RD NORTH CHICAGO, IL 60064 Com: (312) 688-7901 FTS: (312) 353-4400	NONE	NET	ANY	5,000	10
a 5056c	AMERICAN QUININE HOSPITAL DIV ONE FAIRCHILD CT PLAINVIEW, NY 11803 Com: (516) 931-3300 FTS: (212) 460-0100	$5,000 - 10,000: 3% 10,001 - 15,000: 5% 15,001 - 20,000: 7% 20,001 - 25,000: 10%	1/10	50.00	25,000	10
o 5057c	ARMOUR PHARMACEUTICAL CO 111 W CLARENDON PHOENIX, AZ 85077 Com: (602) 248-5331 FTS: (602) 261-3900	NONE	NET	ANY (Case lots only)	5,000	3 to 5
o 5058c	ASTRA PHARMACEUTICAL PRODUCTS INC NEPONSET ST WORCESTER, MA 01606 Com: (617) 852-6351 FTS: (617) 791-2251	NONE	1/20	ANY (Case Quantities)	5,000	5 to 21
o 5059c	BEECHAM-MASSENGILL PHARMACEUTICALS DIV OF BEECHAM INC 501 - 551 FIFTH ST BRISTOL, TN 37620 Com: (615) 764-5141 FTS: (901) 534-3011	NONE	NET	ANY	5,000	3 to 5
o 5060c	BRISTOL LABORATORIES DIV OF BRISTOL-MYERS CO BOX 657 SYRACUSE, NY 13201 Com: (315) 470-2865 FTS: (315) 473-3350 Send remittances to the contractor at Box 7251, Church Street Station, New York, NY 10049.	NONE	2/30	ANY	5,000	10
o 5061c	ELI LILLY & CO PHARMACEUTICAL DIV 307 E McCARTY ST INDIANAPOLIS, IN 46206 Com: (317) 261-2318 FTS: (317) 633-7000	NONE	2/30	50.00	5,000	10
o 5088c	McGAW LABORATORIES 1015 GRANDVIEW AVE GLENDALE, CA 91201 Com: (213) 246-6521 FTS: (213) 247-2202	NONE	2/30	ANY	5,000	2 to 10

LIST OF CONTRACTORS - Continued

CONTRACT NUMBER V797P-	CONTRACTOR ADDRESS & TELEPHONE	DOLLAR VOLUME DISCOUNT	PROMPT PAYMENT DISCOUNT	MINIMUM ORDER (DOLLARS)	MAXIMUM ORDER (DOLLARS)	TIME OF DELIVERY (DAYS)
o 5062c	PARKE-DAVIS & CO BOX 118 GPO DETROIT, MI 48232 Com: (313) 567-5300 FTS: (313) 226-6000	NONE	NET	50.00	5,000	10
o 5063c	PFIZER LABORATORIES DIV PFIZER INC 235 E 42ND ST NEW YORK, NY 10017 Com: (212) 573-2679 FTS: (212) 460-0100	NONE	NET	ANY	5,000	3 to 5
o 5064c	PHILIPS ROXANE LABORATORIES INC 330 OAK ST COLUMBUS, OH 43216 Com: (614) 228-5403 FTS: (614) 469-6600	NONE	1/30	ANY	5,000	10
o 5065c	RIKER LABORATORIES INC 19901 NORDHOFF ST NORTHRIDGE, CA 91324 Com: (213) 341-1300 FTS: (213) 688-2000	NONE	1/30	ANY (5% Service Charge for orders less $50.00)	5,000	10
o 5066c	SMITH, KLINE & FRENCH LABORATORIES DIV OF SMITH/KLINE CORP 1500 SPRING GARDEN ST PHILADELPHIA, PA 19101 Com: (215) 564-2400 FTS: (215) 597-3311	NONE	2/30	ANY	5,000	10
o 5067c	E R SQUIBB & SONS INC BOX 4000 PRINCETON, NJ 08540 Com: (609) 921-4080 & 921-4081 FTS: (201) 645-3000	NONE	NET	ANY	5,000	10
o 5068c	THE UPJOHN CO 7000 PORTAGE RD KALAMAZOO, MI 49001 Com: (616) 381-1010, EXT 76 FTS: (616) 962-6511	NONE	NET	ANY	5,000	10

CROSS REFERENCE TO RELATED SCHEDULES

FSC	PART	SECTION	RELATED ITEMS
65	I	A	DRUGS AND PHARMACEUTICAL PRODUCTS
65	I	B	DRUGS AND PHARMACEUTICAL PRODUCTS

12
ALPHABETICAL INDEX

-0-

GSA DC 74-5756

Senator NELSON. Please proceed.

Dr. LEE. In your item 2 which has to do with actions on the Comptroller General's report, it proposes a number of changes in the management of our drug procurement program. We have indicated our general agreement with this report and our intention to implement those recommendations which relate to the VA. The current status of each recommendation involving us is as follows:

A study led by OMB with representatives of GSA, DOD, VA and HSW, has been completed and is currently being circulated to the heads of the departments and agencies concerned for final decision. The study and report relate to other medical items as well as drugs, and proposes the consolidation of requirements, the use of both VA and DOD central systems to purchase and distribute all Federal agencies' medical requirements, the authorization to field installations of VA and DOD to use the central purchase and distribution facilities of either agency. I note this was a point made by General Hayes this morning.

We anticipate that the final positions and a Government policy will be developed on this report shortly. In the meantime, discussions have already begun between DOD and VA officials on the methods and procedures necessary to achieve central purchasing facility.

We have, for several years, checked with the Defense Personnel Support Center prior to initiation of purchase action from our Marketing Center. If DPSC has the item in stock at a favorable price, we requisition from them rather than purchase from commercial suppliers. Our current level of procurement of drugs from DPSC is $800,000 annually. We also acquired over $400,000 in drugs from the medical emergency stockpile in fiscal year 1973. Altogether in fiscal year 1973, our sales of drugs to other Federal Government agencies from our own central supply system amounted to $3,500,000. We awarded contracts valued at $54 million, which they used.

The GAO report contained a recommendation that the VA should develop specifications for all new drugs which VA decides to manage centrally. We have implemented this recommendation to the extent we feel it appropriate. That is, 175 items which can be procured competitively. We have developed specifications for those items which can be procured competitively. We feel it is unnecessary to develop specifications for those drug items for which we know there can be no competition because of patents, or if the drug is sufficiently prescribed in official compendia.

Another recommendation proposes that DOD and the VA should consider jointly developing specifications which would satisfy all Federal agencies' drug requirements. We are happy to go forward with this. As a matter of fact, we have used the DOD specifications in developing our own for drug products.

We accept this recommendation. We have for several years used DOD specifications, modified as required, in developing VA specifications for drug products. At the same time, we have made available our specifications to DOD. A control system would assure a more effective joint effort and, in most instances, would result in a

single specification which would be Federal rather than an agency specification. We will approach DOD to establish such a system.

Another recommendation was that the VA should make a number of changes in its existing system for reporting VA field station drug procurements, and should insist that Federal Supply Schedule contractors report detailed sales data when required by contracts.

We are currently improving our internal reporting system. This recommendation did not propose any change in data input, but rather that the data be consolidated into different report formats and that greater care be exercised in accurate reporting. We plan to supplement our current reports with summary reports as proposed by GAO. We expect to implement this summary reporting system for the period ending June 30, 1974. Our computer system is currently being programed to accomplish this.

We are working with the General Services Administration on the problem of reporting of vendor sales. That is not an easy thing, the impact of contractors' operating costs, this has a particular adverse effect on a small business firm.

If the Federal Government imposes detailed and complex reporting systems upon contractors, this impacts the contractor's operating costs. This has a particularly adverse effect upon the small business firm. Our past practice has been to rely upon the amount and type of data available from each firm's existing internal reporting process. This has resulted in a lack of uniformity of data and the inability to assess its validity. In some instances, we feel firms tend to understate the volume of sales to the Federal Government. Others appear to have overstated such sales in order to retain marginally justified contracts. Few firms maintain records of sales both by individual item and individual Federal activity in a readily retrievable form.

On the two most widely used commodities by VA—drugs and food —we have relied upon our own internal reporting of field station purchases and orders rather than upon vendors' sales records. This is an alternative, but might prove too costly if extended Governmentwide. We will continue to work with the General Services Administration, which has regulatory responsibility in this matter, to improve existing vendor sales reporting systems.

Another recommendation proposes that the DOD and VA consider using a standardized coding system, such as the National Drug Code. The VA has already decided to use the National Drug Code for identifying drug purchases. We cannot fully implement this decision until HEW completes the assignment of National Drug Codes to virtually all items. We have already begun input of the NDC where available into our records, so that we can begin its use when the system is complete. Our information is that it is about 75 percent completed. It is a responsibility of the HEW and one over which we have not sought nor do we seek any control.

The final GAO recommendation affecting the VA was that the DOD, HEW and VA should review the frequency and types of inspections required and the related changes needed to facilitate the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies.

I would like to discuss this if you wish, in some detail, because I know it is a point of interest to the committee.

This is your third issue, consolidation of quality assurance in FDA. The truth is we have substantially relied upon the FDA for quality assurance in our drug procurement program for many years. Our position is—and has consistently been—that we are willing to rely upon FDA for a comprehensive quality assurance program, providing FDA makes the necessary information available to us in a reliable and timely manner.

Senator NELSON. Do they?

Dr. LEE. They have in many instances. In some they have not, and we have had discussions with FDA officials in recent weeks to indicate our VA requirements. It looks as though we can have them met in each instance, yes, sir.

For the past 15 years, we have relied upon the FDA laboratories to perform drug assay and testing of those drugs VA procures. Those items we identify as requiring testing before issue to our hospitals are received at our supply depots and placed in quarantine. Random samples are selected by VA personnel from each lot or batch and sent to FDA laboratories, usually the one in Cincinnati, Ohio, for assay and testing. After the results are reported to us, we either remove the drug from quarantine and place it in stock for issue, or, if the report is unfavorable, return the drug to the vendor as rejected merchandise. We also select random samples from items delivered under Federal Supply Schedules and submit them for test in a similar manner. Currently, we are sending about 1,400 items a year to FDA for laboratory testing. We reimburse the FDA for this service.

We rely on both FDA and DOD inspections made by those agencies for their own purposes where feasible. We attempt to determine from them or from prospective contractors if either of these two agencies has inspected the contractors' plants within the past 12 months. We receive copies of inspection reports from DOD, but not from FDA. Current discussions will, we believe, develop increased information exchange with FDA that has not been routine up to now. To supplement FDA and DOD information, we employ two pharmacists at our Marketing Center, each of whom devotes approximately one-half his time to performing plant inspections and quality control.

If neither FDA nor DOD has inspected a facility in which we are interested in the past 12 months, we conduct our own inspections, using the inspection guidelines developed from material obtained from DOD and from Good Manufacturing Practices published by FDA. In addition, we also review the vendor's capacity, performance and delivery capability as well as other matters related to contract administration. During the first 4 months of the current fiscal year, VA officials inspected 23 plants. We declined to contract with six firms because of our findings. We did not find evidence in these cases of production of adulterated or dangerous drugs. We would, of course, have reported any such instances to the FDA had we encountered them.

I previously stated that if we are assured of adequate and timely information, we can accept GAO's recommendation to rely upon FDA for quality assurance—both for plant inspections and laboratory testing. We mentioned preliminary discussions with HEW and FDA officials to accomplish this. We expect the discussions to result in early implementation.

In 1973, VA did 130 inspections and our rejection rate was 32 percent.

Senator NELSON. For failure to meet manufacturing requirements?

Mr. COOK. For a variety of reasons, for contractual requirements as well as those reasons going to the heart of the drug; quality. Some of them were what we felt were not adequate good manufacturing practices. We did not find any that were gross violations of manufacturing practices.

Senator NELSON. When you say contract reasons, they could not meet the contract schedule?

Mr. COOK. In some instances we felt they were unable to meet the delivery schedule they had said they could meet.

Senator NELSON. Do you have a breakdown of the reasons that could be submitted for the record?

Mr. COOK. It will be submitted for the record.

[The information referred to follows:]

REASONS FOR REJECTION OF CONTRACTORS' FACILITIES BY VA INSPECTORS FISCAL YEAR 1973

1. Two firms failed to demonstrate operation capacity to produce in accordance with VA delivery requirements.

2. Forty firms were rejected for the following reasons. Most of the firms were rejected for more than one reason:

QUALITY CONTROLS

(*a*) Commingling of processed materials with raw materials and/or tested and quarantined items—23
(*b*) Incomplete listing of chemical components of raw and finished materials—14
(*c*) Lack of labelling controls—9
(*d*) Equipment not calibrated—8
(*e*) Stability program lacking—8

HOUSEKEEPING

No specific requirements for cleaning processing equipment—10
Inadequate air exhaust—1
Floors encrusted with materials and peeling paint in processing area—2
Lack of screening of windows and doors—2

Mr. GORDON. Do you have any problems which are considered serious?

Mr. COOK. We had a few that we considered serious, one a couple of weeks ago on the west coast in which we found that there were capsule problems in this case. They were contaminated.

Mr. GORDON. What company was that?

Mr. COOK. Syntex, I believe.

Mr. GORDON. What about your other serious problems?

Mr. COOK. And recent problem with Abbott Laboratories which we felt were serious.

Mr. GORDON. Both members of the Pharmaceutical Manufacturers Association, by the way.

Mr. COOK. I do not know.

Mr. GORDON. How about small firms?

Mr. COOK. Yes, one small firm inspected within the last couple of weeks. I do not remember—it is in Chicago, in which they had a number of deficiencies we felt which indicated we should not contract with them.

Mr. GORDON. You have reported that incident to the FDA, I take it?

Mr. COOK. Yes.

Dr. LEE. Every reasonable effort must be made to treat all VA patients with the most effective therapeutic agents indicated, which will be procured at the most favorable price that can be obtained.

Since there are differences of opinion on the effectiveness of many drug products and valid differences in approach to the selection of therapeutic regimens, we cannot rigidly restrict professional practices by administrative direction.

We will rely upon our therapeutics agents and pharmacy reviews committees at each of our field stations to carefully screen all drugs approved for use at their stations to assure the most effective products are selected for inclusion in the local formulary each hospital maintains.

Mr. COOK. We do not feel that the violations were violations of the law, of the Pure Food and Drug Act. We felt they were practices we did not feel were those we wanted the firms supplying us the product at that time under those conditions.

Mr. GORDON. You are not talking about the three serious ones you mentioned before?

Mr. COOK. Yes, sir. They had not used these capsules. They were there but they were not used on our product.

Senator NELSON. Are you saying that these discrepancies or whatever you wish to call them, did not violate the standards of good manufacturing established by the FDA?

Mr. COOK. Senator, I am not sure that I am prepared to even judge that. I am saying I did not, in the case, for example, of one of the firms where there were capsules contaminated, we had no evidence they were using them. We decided we would wait until those capsules were out of the plant before we contracted with the firm, in any event.

Dr. LEE. Your fourth issue in the questions which were given to us is the use of formularies.

The VA adopted the American Hospital Formulary Service as our agency-wide formulary. We have required for many years that each hospital maintain a formulary for those drugs which are approved for use at that hospital. The formulary consists of monographs on those drugs selected by the station therapeutics agents and pharmacy review committee. Through peer review of the prescribing practices of our staff physicions, we are assured that the knowledge and information of those responsible for patient treatment are combined in determining which drugs will be in the station formu-

lary. Committee members raise questions as to the safety and efficacy of specific drugs and combine their knowledge to evaluate and select the best agent. Both staff physicians and fee basis physicians are expected to prescribe only those drugs in the station formulary. For our in-patient program, exceptions are made when the individual physician determines he will accept only the specific item prescribed. Physicians desiring to continue to use items not in station formularies are required to submit to the station committee their reasons, and to justify their inclusion in the station formulary or substitute the necessity for a continuing exception. This formulary system we currently use is the one which we feel most effectively meets the widespread and diverse VA needs.

Senator NELSON. Because of the time situation I want to be sure to raise one issue with you, which shocks me. It has nothing to do with VA, but with one of your suppliers, the Merck Co., and the drug is Aldomet, an anti-hypertensive. I raise this because it seems to me to be a very important policy question for the Government. As you know, Merck synthesized this drug in 1953 and secured a patent. They could find no use or value for the drug. The National Heart Institute (NHI) took the drug and did some experimenting and created the use for the drug at the expense to the taxpayer.

I shall read from the Senate Appropriations Committee hearings on HEW appropriations for 1965. It says here on page 1310 that:

> However, for several years after its synthesis in 1953, alpha-methyl DOPA (which is Aldomet), was of interest only as a research tool for studies on amine metabolisms, since neither it nor any of its chemical relatives demonstrated any effect whatsoever on blood pressure in animal studies. Despite evidence of any demonstrable blood-pressure effects in animals, the National Heart Institute scientists became interested in alpha-methyl DOPA in 1958. They felt that it might possibly be useful for the treatment of pheochromocytoma or malignant carcinoid. . . . So the NHI scientists cautiously tested the drug in some patients with pheochromocytoma or malignant carcinoid. Parallel biochemical studies were also undertaken in several patients with hypertension. . . . Had this drug not been tested in humans, it might even today be considered simply another research tool for studies in amine metabolism. Instead, under the trade name Aldonet, the drug has proved to be a valuable new addition to the physician's arsenal of drugs against hypertension.

Also, in hearings before the House Appropriations Committee for 1966 HEW appropriations, NHI testified that:

> It is probable that Aldomet would never have made the grade if NHI scientists had not tried it in human subjects despite its lack of hypertensive action when tested in laboratory animals. The near accidental discovery of its effectiveness in hypertensive patients resulted in a valuable new drug. In long-term clinical trials at NHI, Aldomet has effectively controlled blood pressure in about two-thirds of hypertensive patients in which it has been tried.

So the use of the drug was discovered and developed by scientists at the National Heart Institute. It is interesting to note that in 1970 the sales of this drug were $33,200,000. One year later in 1971 it had jumped to $42 million, which would make it one of the top-selling drugs in the country.

I also note, and correct me if I am wrong, that VA spends more money on this drug than on any other drug, is that correct?

Dr. LEE. We need to go back a little in history before we can answer that question.

Senator NELSON. Let me finish the question. I am only reciting the facts thus far.

I understand that, though this was developed by the Government as it clearly was, and is a big seller, when VA seeks to purchase the drug, Merck refuses to give any discount, well, only 3 percent which is not enough to warrant buying it through your central purchasing system.

Dr. LEE. It is correct. We are purchasing approximately a million dollars worth of that drug a year at the present time. The historic study of hypertension and control of mild hypertension thereby controlling severe hypertension and stroke and so forth, was initiated in VA by Dr. Freis. He demonstrated that early treatment of hypertension did prevent the frequency of cardiovascular attacks, both coronary and stroke. As a matter of fact, he won the Lasker Award 4 years ago for that particular finding. Having done so, we felt that his findings demonstrated to the Veterans Administration that we had best see if we could not apply this in patients.

Senator NELSON. Which drug was this?

Dr. LEE. This research finding was the fact that treatment for hypertension will sustain these people longer. There are several drugs which can be used in this area.

My point is at the present time, we have screened well over 100,000 patients who have other than hypertensive problems and find that approximately one-third of these people have what by definition is a hypertensive level that needs to be followed. Of that one-third, half of them need treatment. What I am saying is that this is a big problem, that it is increasing and that there will be a lot more purchases of these anti-hypertensive drugs. A policy needs to be developed not only on the Heart Institute's finding on the Aldomet itself but we are all getting into this problem of early hypertension and stroke. This is a problem.

Senator NELSON. Well, now that I realize NHI developed the use, it shocks me that they would not get a use patent for this drug. It bothers me more that they have given the Merck Co. a very valuable drug, and the company would not even give VA a break on the purchase price; what is your observation about that?

Mr. COOK. Senator, this is the largest single drug item which we procure from our Federal Supply Schedule. It is not the largest use item in the Agency.

Senator NELSON. It is the largest item on the Federal Supply Schedule, and it is $1 million a year?

Mr. COOK. Yes, sir.

Senator NELSON. And as Dr. Lee just testified, it will be larger?

Mr. COOK. Yes.

Senator NELSON. And it amounts, to about—what do you say are the total purchases?

Mr. COOK. Last year it was $86 million. It will be $112 million this year.

Senator NELSON. It is a large item. I just wonder what your reaction is or what does Merck tell you when you negotiate with them

and they do not give you a discount sufficient to make it worthwhile to put it into your depot system?

Mr. COOK. Merck has given us a discount for the product over the commercial price in placing it on the Federal Supply Schedule. They have not given us sufficiently greater discount to make it worth our while to offset the cost, as a matter of fact, of placing it in our central depot system.

The current price which they have offered us, I think the schedule price is a little higher, for the 250 milligram 100 tablet bottle is $5.01. I believe that is below—certainly it is below the retail market price. I can personally attest to that because I use the product. I know what I pay for it.

Senator NELSON. What do you pay for it retail?

Mr. COOK. $8.

Senator NELSON. So they are giving the Government the magnificent break of selling it for $5. I would guess, then, that the retailer is buying it about as cheaply as the Government.

Mr. COOK. That is possible, sir.

Dr. LEE. You asked our reaction, sir, and our reactions are two.

The first is we would like to negotiate a better price. The other is something we have been following through repeatedly and are doing so in this particular instance, and that is to seek through research in the VA drugs which are equally effective, perhaps less in price.

Senator NELSON. You say you get it from the Federal Supply Scehdule for $5——

Mr. COOK. The Federal Supply Schedule.

Senator NELSON. You are able to purchase it at retail for $8?

Mr. COOK. Yes, sir.

Senator NELSON. It would surprise me if the Government is getting it any cheaper than the retailer because it has to go to the wholesaler and from there to the retailer, each one getting a markup. The average retail markup around the country has been about 66-2/3 percent. If that is so, the Government is paying as much to Merck as the retailer. But it shocks me that a company would take the benefit of the research of the Federal Government, the drug then becoming one of its largest sellers—a drug for which the use was discovered, developed, proven by a Federal institution—and then turn around and not give them a break on the price. If NHI had taken a use patent on it as we should have, we would have been able to get a fair break on it.

Mr. COOK. We intend continuing to negotiate with them.

Senator NELSON. Let us know how you come out. I will check the price that is supplied to the retailer.

Please proceed.

Dr. LEE. We are coming to the conclusion of our statement, Mr. Chairman.

Every effort is made to assure that VA does not expend more than necessary for drug products. The problem is both simple and complex. It appears simple, since the mechanisms are available for

determining the reasonable price of a drug product. It is complex in that the selection of which drugs to use must be made from among thousands of possible choices, relying upon the memory, ready reference and experience of many persons making these choices. We feel the need for education of physicians on those prescribing practices which will result in minimizing the cost of drugs is an area where we can assist; but it is one which can best be met through the combined efforts of the Federal Government, the medical academic community, those responsible for providing support to health care delivery programs, and the Congress in its deliberations upon national health programs. We believe the soundest approach to rational selection of suitable drugs at reasonable costs is through education of physicians, patients, and support personnel, and that we should promote the widest dissemination of information on the relative quality and efficacy of drug products marketed in this country. Where reasonable doubt exists on the relative quality and efficacy of competing products, it should be resolved by appropriate research and clinical testing, and our staff is exceedingly active in a great deal of this, including the hypertensive drugs. We are engaged in a VA effort internally and are ready to utilize the resource in assisting, if you like, in a wider Federal program to achieve these goals, the education, obviously the dissemination of the various drug usages, the purchases and controls, and we are happy to go forward with this committee and think there has been a good deal of progress made in the past few years.

Senator NELSON. Thank you very much, Doctor.

I have one final question. I note from your statement that $34 million out of the $41 million central purchasing are sole source items. The question I would be interested in is how many different compounds does this represent? This is what I am getting at. Panels of the National Academy of Sciences-National Research Council concluded that tetracycline—I do not want to present this as a quote—would be the drug of choice of that particular family of antibiotics. There might be some exceptions. But you have a whole list of analogs of tetracycline, such as oxytetracycline (trade name: Terramycin) which is much more expensive, chlortetracycline, (trade name: Aureomycin), and as you look at the price schedules of those drugs they are much more expensive. A number of other distinguished witnesses, clinicians who say tetracycline is the drug that ought to be used, although there may be some circumstances when another tetracycline may be helpful. How much of this sole source purchasing is due to the purchase of one of the tetracycline family other than tetracycline itself? Do you have any notion about that? If you do not, could you supply us an example?

Mr. COOK. It is not among these 369. It is purchased by us on a competitive or generic basis. I cannot tell you specifically——

Senator NELSON. You say you purchase tetracycline on a competitive basis?

Mr. COOK. Yes, sir, and we do not have the others in our system.

Senator NELSON. You do not have them in your system?

Mr. COOK. No.

Senator NELSON. Are there other examples of the kind I am thinking of? We have seen many times on some DOD purchasing that the specs were drafted in such a way that one of the analogs of one of the classes of drugs ends up being purchased on a negotiated sole source basis simply because that was the specification that was drafted to fit that particular brand of that particular class of drug.

Do you have any notion whether that occurs in any percentage amount of this $34 million that you buy?

Mr. COOK. I can try to provide that for the record later. I will state from general information I am sure there are some of this $34 million that are similar analogs of each other. None of them, I hope, are there because of the specification that made them sole source.

[The information referred to follows:]

ITEMS OF SIMILAR ANALOGS CARRIED IN VA DEPOT STOCKS

Of the 369 items in VA Depot stocks as sole source, 6 items representing a total of 17 different analogs are stocked. The remaining 352 are unique products not duplicated in the system. Three analogs of cephalosporin account for 8% or $3.3 million of the total Depot sales volume. The remaining 14 analogs account for 2% or $99,000 of the total Depot sales.

Mr. GORDON. Actually you are buying in dollar terms only 17 percent of your drugs on a competitive basis; is that correct?

Mr. COOK. On the basis of dollars, yes.

Mr. GORDON. That is a pretty small percentage, wouldn't you say?

Mr. COOK. On the basis of dollars it is. If generic drugs are cheaper your dollar value has to be less.

Senator NELSON. On that point, if you are taking bids on a drug, the brand name that is selling at a very high price at the retail market may out-compete a generic drug in a bid.

Mr. COOK. Many times they do.

Senator NELSON. We have seen drugs which are as much as 20, 30, or even 40 times as much in the retail marketplace as the same manufacturer's bids to DOD or the city of New York. If you take a bid it isn't just for a generic drug, it is a bid by the generic name, asking for the drug from any reliable source?

Mr. COOK. That is correct.

Senator NELSON. And a brand name may out compete?

Mr. COOK. In many instances they do.

Mr. GORDON. I brought to your attention the fact that in Canada you can get the same drugs, not necessarily by the same company, the same drugs that are sold here. In Canada they are much less. Why can't the VA buy in Canada?

Mr. COOK. Mr. Gordon, we approached 11 Canadian firms concerning specific products, and inquired of them if they were interested in selling to the Veterans Administration in the United States. The responses that we got initially were no, for two reasons. One reason was in some cases they were operating under a license that did not permit sale or export from Canada to any place, not just the United States.

Their second reason was they did not have NDA's to market and sell the product in the United States. We suggested they might perhaps apply. So far none have, so we cannot purchase the drug unless they hold some type of NDA for its marketing in the United States.

Mr. GORDON. Well, they can get an NDA if it is worth their while.

Mr. COOK. If they wish.

Mr. GORDON. But it is the patent problem that is troubling you.

Mr. COOK. Probably.

Mr. GORDON. How about pentaerithratol tetranitrate? You can buy that domestically at a much lesser price. How come you are paying such high prices for it? You paid $9.44 under direct purchase; $27.41 from FSS; and a high of $27 and a low of $24.65 through local purchase. You could get it in Canada for a much, much lower price, and even in the United States for as low as $1.65 under its generic name.

Mr. HARDING. May I respond?

This happens to be one of those drugs which is on the "possibly effective" list on which we are awaiting the final decision of the NAS–NRC studies.

Senator NELSON. I thought you had removed everything on the "possibly effective" list.

Mr. HARDING. No, sir. If there is nothing in the higher categories that the doctor is sure will work then we will still maintain that "possibly effective." We don't have too many of those left, but a few. This is true of all the Government agencies, not only the VA.

But the reason that we have had to do this, this is a drug where many patients became upset when they heard this drug was going to be removed from the market. This is still under study and until studies are completed we are holding——

Senator NELSON. Do I understand correctly that you do continue to stock drugs classified by the National Academy of Sciences-National Research Council as "possibly effective," and "probably effective"?

Mr. HARDING. We do not stock those classified "ineffective." The others we stock only if there is nothing appropriate in a higher category.

Mr. COOK. To put that in perspective, Senator, there are less than three dozen "possibly effectives" our people have identified where no drug of greater effectiveness than this classification on the market.

Mr. GORDON. But you are paying $9.44 for a thousand tablets of 10 milligram pentaerithratol tablets, is that correct?

Mr. HARDING. That happens to be one of those very well marked items and a heart patient is not very happy to have his drugs switched around. As long as there is a study—I have stood at the window many, many times and tried to tell someone the other drug was the same thing, but with that type of patient I am very reluctant to do that. So we have kept that drug for that reason.

Mr. GORDON. You mean the patient demands the higher priced drug?

Mr. HARDING. The patient demands the drug he has been getting. It is identified as such.

By the way, I might add one other statement. All drugs have a generic name. The brand name is only the name the company has attached to it. When only one company manufactures a drug that is still generic purchasing. If someone else comes along——

Senator NELSON. I understand that. I wanted to be sure we weren't talking only about a generic manufacturer v. a brand name.

Mr. GORDON. Just one question.

Is it possible within a specified time, let's say 6 months, to bring that 17 percent bought on a competitive basis up to 25 percent?

Mr. HARDING. I would say on that, sir, yes, if there is enough competition in the sole source drugs or also if there are enough of the generic products at high enough cost go into the generic competition.

Mr. COOK. It is possible. I can't tell you whether it will be 25 or something less than that or greater than that. One of the things we do know, in quite recent times there have been a number of drugs previously patent protected, on which the patents have expired and the number of firms obtaining NDAs' to make these drugs have been substantial within the last 2 or 3 months.

Senator NELSON. Thank you very much, gentlemen.

The hearings will open again tomorrow with Dr. Edwards.

[Whereupon, at 12:00 p.m., the committee recessed, to reconvene at 10:10 a.m., Wednesday, March 6, 1974.]

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

WEDNESDAY, MARCH 6, 1974

U.S. SENATE,
SUBCOMMITTEE ON MONOPOLY OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10 a.m., in room 6202, Dirksen Senate Office Building, Senator Gaylord Nelson [chairman of the subcommittee] presiding.

Present: Senators Nelson and Beall.

Also present: Chester H. Smith, Staff Director and General Counsel; Benjamin Gordon, Staff Economist; and John O. Adams, Minority Counsel.

Senator NELSON. Our witness this morning is Dr. Charles Edwards, Assistant Secretary for Health, Department of Health, Education, and Welfare. I don't know in what order your associates are seated. If you would have them identify themselves for the record for the reporter, Dr. Edwards.

STATEMENT OF CHARLES C. EDWARDS, M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY JOHN JENNINGS, M.D., ASSOCIATE COMMISSIONER FOR MEDICAL AFFAIRS, FOOD AND DRUG ADMINISTRATION, DHEW; KEITH WIEKEL, M.D., ASSOCIATE ADMINISTRATOR FOR PLANNING AND EVALUATION, LEGISLATION, HEALTH SERVICES ADMINISTRATION, DHEW; MARK NOVITCH, M.D., DEPUTY ASSOCIATE COMMISSIONER FOR MEDICAL AFFAIRS, FOOD AND DRUG ADMINISTRATION, DHEW; VINCE GARDNER, CHIEF, DRUG STUDIES BRANCH, SOCIAL SECURITY ADMINISTRATION, DHEW; AND FRANK SAMUEL, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH) DHEW

Dr. EDWARDS. Thank you, Mr. Chairman, Senator Beall.

Let me identify my colleagues. On my right, whom you know well, Dr. John Jennings, Associate Commissioner of the Food and Drug Administration. Dr. Mark Novitch, who is the Deputy Associate

Commissioner for Medical Affairs of FDA. On my left, at the far end, is Mr. Vince Gardner, the Chief of the Drug Studies Branch of the Secial Security Administration. Next to him is Mr. Frank Samuel, Deputy Assistant Secretary for Legislation. And on my immediate left is Dr. Keith Wiekel, the Associate Administrator for Planning, Evaluation and Legislation of the Health Services Administration.

Senator NELSON. Go ahead, Doctor. Present your statement however you desire.

Dr. EDWARDS. Thank you, Mr. Chairman. We are delighted to have the opportunity to discuss with you this morning the issue of our drug quality assurance programs and the effect these may have on Federal procurement policy. We are also pleased to have this opportunity to update the Congress on the implementation of the revised drug reimbursement policy that was announced by Secretary Weinberger in December.

Your most recent investigation of the first of these issues began February 20 when Dr. Alexander Schmidt of the Food and Drug Administration outlined the quality control and other regulatory activities of the Department of Health, Education, and Welfare which serve to guarantee the safety and efficacy of pharmaceutical products sold throughout the United States. These include many different programs—inspection of drug manufacturers, monitoring of marketed drugs, batch certification, adverse reaction reporting, to mention only a few. I will not add further to that testimony except to restate our belief that these activities have served and continue to serve the quality control needs of all drug purchasers in this country.

As you know, Mr. Chairman, the GAO report of December 1973 recommended that separate quality assurance activities of the Defense Department, Veterans Administration and the Food and Drug Administration be consolidated into one organization. We believe this is an excellent recommendation and that the FDA is the appropriate and the obvious organization to carry this out. The FDA has already begun discussions with representatives of the Defense Department and the Veterans Administration. These discussions will continue, and we expect that positive actions can be taken in the very near future.

Senator NELSON. This will involve all the agencies of Federal Government that procure drugs?

Dr. EDWARDS. Yes, sir.

Senator NELSON. Mainly DOD and VA?

Dr. EDWARDS. Primarily VA and DOD.

Senator NELSON. If I recall the testimony correctly, the other day Dr. Lee of the VA said that they do rely or intend to rely or will be relying, I believe, exclusively upon FDA. Is that correct?

Dr. EDWARDS. That is correct. We have more and more taken over this function for the VA and I think for all practical purposes it is fairly complete at this point in time.

Senator NELSON. Do you have any target date on reaching this arrangement with the DOD?

Dr. EDWARDS. I am not just sure. Dr. Jennings, do you have any——

Dr. JENNINGS. I don't think any specific target date has been established as yet, Senator. We are in the exploratory phase at the present time. I think if this comes to pass, it will probably be a gradual acquisition of these responsibilities.

Senator NELSON. Well, as I recall it, the FDA has something over 800 inspectors now in the field, is that correct?

Dr. EDWARDS. Yes, sir.

Senator NELSON. And DOD has about 20?

Dr. EDWARDS. I think it is between 20 and 30.

Senator NELSON. Would that mean that ultimately those 20 would be assigned to FDA or——

Dr. EDWARDS. I think that is one of the issues that we are currently debating with the Department of Defense. In assuming these responsibilities we would obviously like to have the resources that they have been utilizing move over to the FDA and become part of the Food and Drug Administration's operation. I think this can be worked out but some of the details have not yet been. I would certainly hope, Mr. Chairman, that this isn't something that is prolonged over an extended period of time but rather that we can get this accomplished literally within the next couple of months.

Senator NELSON. Is my memory correct? Are additional inspectors for FDA recommended in the current budget?

Dr. EDWARDS. In the 1975 budget?

Senator NELSON. Yes.

Dr. EDWARDS. There are some. I can't give you right offhand the exact number. But the FDA budget has gone up in the order of magnitude of $200 million with some additional provisions.

Senator NELSON. You are familiar, of course, with the continual argument that there are inadequate inspections in order to assure the physicians that in fact the drugs being put into the market do meet USP and NF standards. I don't know the merit of that. As I recall, your testimony of a short time ago was that you have a program which guarantees now that you will at least get around to every plant at least once every two and a half years. How many more inspectors would you need to have an optimum assurance that good manufacturing practices are being met by those who put drugs in the marketplace?

Dr. EDWARDS. Mr. Chairman, I think it is not just a matter of inspectors. I think the drug listing law, because we didn't always have the kind of information we needed, is going to help a great deal. I am not sure we can give you the exact number of new positions we need.

Dr. Jennings, you might want to speak to that.

Dr. JENNINGS. No, sir. I don't think we can state at this time how many new positions it would require to give assurance that we would cover every drug firm every 2 years in the way that we would like to.

Now, inspection means different things to different people. We have all levels of inspections. We inspect a plant when, for instance,

a New Drug Application is filed and is close to approval. We inspect the plant specifically for its capability to produce that drug.

Senator NELSON. You inspect the plants before they in fact produce that drug or before it is put into the marketplace, right?

Dr. JENNINGS. Yes, sir.

Senator NELSON. As to their capacity to produce that drug and meet USP standards?

Dr. JENNINGS. USP or NDA standards, whichever is in existence for that particular drug. Of course, in the course of such an inspection there will be a general appraisal of the plant's capabilities to produce other drugs. So, I think to say that we are aiming for only a visit, a housekeeping type of inspection of every plant every two years, is an oversimplification of the problem. There are different levels of inspection that are required for different purposes. I think we certainly could use more inspectors because as you are fully aware, the problems of drug quality control seem to become more complicated as time goes on. The more we know about drugs and possibilities for things going awry, the more complicated and the more intensive our inspection efforts must be. But I think the thing to remember is Dr. Schmid't testimony of a few weeks ago that as of now the prescription drug production inspection is essentially up to date. That is, something like 97 percent of the plants producing 95 percent of the prescription drugs in this country are currently in inspection.

Senator NELSON. I realize some plants you inspect very frequently, others not. Is it your view that once every 2 years or so is a fair assurance that a plant is in compliance or continues to be in compliance with good manufacturing practices?

Dr. JENNINGS. I would think that as a minimum a general inspection for the general capabilities of manufacturing every 2 years would provide adequate assurance, but I think, estimating manpower requirements, we would have to remember that there would be need for interim inspections.

Senator NELSON. There would be what?

Dr. JENNINGS. There would be a requirement for inspections between those biennial visits for special requirements, either because a new drug was to be produced and the capabilities for that particular production would have to be assessed, or because there was some indication that there might be a problem because of a complaint, because our surveillance activities had uncovered a defect. So that it isn't simply a matter of a rotation or inspections every 2 years. There is a need for capability for special, and sometimes very exhaustive, inspections in addition to the routine every-2-year visit.

Senator NELSON. Please go ahead.

Dr. EDWARDS. Just in conclusion on this particular issue, Mr. Chairman, we feel very strongly and Dr. Schmidt and the FDA certainly have the Secretary's and my support in their effort to move ahead rapidly on this pulling the inspectional capabilities of the Federal Government together.

As you know, the Department has also recently submitted to Congress a legislative proposal—the Food, Drug and Cosmetic Amend-

ments of 1974—to significantly assist the FDA in carrying out its vital mission. These amendments for the first time would provide FDA with subpoena authority, full factory inspection authority for all drugs and other products subject to their jurisdiction, and broad authority to require pertinent records to be maintained and records to be submitted to the agency. These authorities and others contained in the bill will assist FDA in obtaining the information they need to fully and we believe effectively administer the Federal Food, Drug and Cosmetic Act. We would certainly urge Congress to act on these amendments as quickly as possible and believe they will serve not only to assure a higher level of equality for all drugs but also the other products—foods, cosmetics and medical devices—which FDA has the responsibility for.

Senator NELSON. Doctor, when you say the Department has recently submitted to Congress the legislative proposal, is it in bill form and has it been introduced?

Mr. SAMUEL. Yes, it has. I would be happy to give you the bill numbers.

Senator NELSON. I introduced a bill a year ago last February, S. 960, that does the same thing. Are you familiar with that?

Mr. SAMUEL. No, sir, I am not.

Dr. EDWARDS. I am, yes.

Senator NELSON. You may be able to save yourself a lot of time by just endorsing my bill.

Mr. SAMUEL. Or perhaps you can endorse ours.

Dr. EDWARDS. It certainly is a possibility.

Senator NELSON. Well, look at it a little more carefully and see——

Dr. EDWARDS. We will.

Senator NELSON (continuing). If it might turn into a new classification of a probability.

Dr. EDWARDS. I think that certainly you and I are in agreement as to what we would like to have.

Senator NELSON. I haven't read the bill recently, but as I recall we cover in S. 960 every area you mention in your remarks and some more, too.

Dr. EDWARDS. As a matter of fact, you go a little further than we do in several areas. I haven't compared the two bills recently but I have in the past. I think you have gone a little further than we propose to go.

Senator NELSON. Then you could just endorse those parts you agree with.

Dr. EDWARDS. I think that again is a possibility.

Senator NELSON. Please proceed.

Dr. EDWARDS. Mr. Chairman, I would like to now turn to—to discuss the issues of our Federal drug procurement policy. As you know, and I mentioned earlier, in December 1973, Secretary Weinberger announced a policy to limit drug reimbursement under programs administered by the Department to the lowest cost at which the drug is generally available unless there is a demonstrated difference in therapeutic effect. We believe this policy could possibly result

in savings of 5 to 8 percent in the overall HEW reimbursements for prescription drugs and in addition have a beneficial impact on drug pricing throughout the country. I would like to take this opportunity to certainly reaffirm the Department's commitment to this policy and assure this committee that regulations to implement this policy are being developed.

Senator NELSON. I guess this question would fit just about any place. As to that policy, I have a list of drugs here. One drug is Polycillin, which has the generic or official name of ampicillin.

Now, Polycillin wholesales, 100 capsules, 250 milligrams, at $14.85 under the brand name price. Under the generic price, wholesale, ampicillin is $4.70.

I have a whole list here. Ampicillin again, under the trade name of Penbriten, 100 capsules, 250 milligrams, $14.54, ampicillin, generic price, $4.70. Here is Pentids 400, 100 tablets, $10.04. Under the generic name of penicillin G, $1.45, wholesale.

Will it be your policy, then, that you will reimburse at the ampicillin generic price, at the penicillin G, generic price, and that price only?

Dr. EDWARDS. Well, I think that is exactly what we are trying to come to grips with right now. We obviously are not going to pay the excessive price or the high price. There are a number of issues that have to be taken into consideration when one is considering the lowest price and whether or not, first of all, the drug is generally available. We are trying to establish in what range we should establish this lowest price generally.

Senator NELSON. But you would agree that ampicillin is generally available, right?

Dr. EDWARDS. That is right.

Senator NELSON. And penicillin G?

Dr. EDWARDS. Penicillin G, both would be generally available, that is right.

Senator NELSON. Let us take the antihistamine chlorpheniramine. Under the trade name of Chlor-Trimeton, a thousand tables, 4 milligrams, the price is $21.65. Under its generic name it is available at $1.05.

Dr. EDWARDS. There is no question that it is generally available but not necessarily generally available at the lowest price. In other words, manufactured at the lowest cost doesn't necessarily mean it would always be generally available. In other words, we have got to be certain that when we develop a price on a drug that is truly available at that price in interstate commerce and you can buy that drug for the same price in Washington as you could in Los Angeles. It is conceivable that a small manufacturer in the State of California could sell the drug at a price that was lower than it could be found any place else in the country and that would not be at the lowest price generally available.

Senator NELSON. Well——

Dr. EDWARDS. What I am saying, we have got to be certain that we come down at a level that truly is representative—that is one which would be available throughout the country. And I don't think

this is going to be a problem, but we have been playing with a number of different formulations that would allow us to do this.

Senator NELSON. Well, Chlorpheniramine, maleate is 21 times higher under the brand name than it is under the generic name. When you say available in interstate commerce, do you mean available in every State and every community when you use the phrase generally available? What do you mean precisely?

Dr. EDWARDS. Well, I think it would have to be generally available at that price throughout the United States.

Dr. WIEKEL. Our position is that it should be available at that price or lower, whatever we set. In determining what the maximum reimbursement level should be, we don't believe we can establish that maximum reimbursable level at a price which some pharmacies in the country will not be able to purchase it at. We think that presents an inequity and that it is possible unless we factor in the criteria of availability on a national basis, and unless we factor in the ability of the firms to supply the products on a national basis, that some pharmacies would not be able to purchase it at the lowest published price.

Senator NELSON. Well, I don't think the law is strictly honored by all the companies but isn't it correct that the law requires that a company must sell a drug at the same price to all the pharmacies, all the druggists, excepting for legitimate quantity discounts?

Dr. EDWARDS. Yes, certainly. According to the Robinson-Patman Act which you are referring to that is the case. We are saying that in a given situation some manufacturers may not in fact have national distribution, even though their price is published in the Red Book or Blue Book or some other reference. We don't think, therefore, we can simply take the lowest possible price which is published. We have to add some additional criteria of availability on a national basis to insure that all pharmacies can purchase it at that level.

Senator NELSON. Well, suppose it is regionally available?

Dr. EDWARDS. Well, Senator, we have looked at this in terms of some of the medicaid programs where they have a criteria of reregional availability. In those States they still end up in the majority of cases using the price levels of national manufacturers that have positive national distribution. I think that the use of nationally available prices will still allow us to take advantage of the cost savings that can be acrued through this policy.

I guess one additional point on that. We have analyzed the additional cost savings, for example, in the multiple source products. If we were to use a median price of the generic the differential between that and the lowest possible published price would only acrue an additional savings to the Federal Government in the neighborhood of 10 percent. That is because of the base which is provided by the dispensing fee, that you have an average of a $1.85 dispensing fee plus the cost of the product.

Senator NELSON. Does the Department of HEW have a policy on dispensing fees?

Dr. EDWARDS. Well, in fact, under the medicaid program the policy is that we will allow the States to use either usual and customary or a professional and dispensing fee.

Senator NELSON. Usual and customary markup?

Dr. EDWARDS. Right, at the retail level, or the dispensing fee. Thirty-five of the States which have drug programs in the medicaid program use dispensing fees.

Senator NELSON. You mean 35 percent required dispensing?

Dr. EDWARDS. 35 of the States, of the medicaid States, have the cost of the product plus a dispensing fee.

Senator NELSON. And those States will not permit the use of the ordinary markup?

Dr. EDWARDS. That is correct.

One other point that I would want to make, Mr. Chairman, our policy doesn't mean that a supplier has to have national distribution to provide his product, but the price that we go with has to be a price that is available nationally. A local supplier certainly can supply a drug but he has to supply it at a price that is a national price, not a regional price. If we don't go that way, the problem, of course, becomes very evident that we are going to have to get into the establishment of prices regionally and all of the administrative and bureaucratic things that have to go with the establishment. We just feel it is a much more efficient way to try to do it on a national basis.

Senator BEALL. Doctor, on that point when you say the regional supplier must supply it at a nationally available price, you don't mean to say he must raise his price.

Dr. EDWARDS. No, no; not at all. He can certainly have it lower than that price.

Senator NELSON. I discussed this with a generic manufacturer the other day who supplies drugs to a well-known brand name company. His own company also sells the same drug generically for one-fifth or one-sixth. He has a hard time getting the doctors to prescribe it. So then he photographs the two, assures them that they are made by the same process, same plant, same day. He says doctors still won't prescribe it. So, now he is inclined to put a trade name on it and raise the price up to where the brand names are because even though he is manufacturing both of them, one at one-fifth the price of the other, they won't buy the less expensive version.

Dr. EDWARDS. I have heard situations similar to that.

One of the proposals of the Pharmaceutical Manufacturers Association is that they provide doctors with more up to date drug price information. Of course, we are very hopeful that they will pursue this rather vigorously.

Continuing, we mentioned some of the rather numerous and rather complex issues that are involved in the establishing of such a policy. In fairness to all those affected by these new policies, these issues we believe must be addressed prior to the publication of our proposed regulations.

At this juncture, however, I think we can say that we believe none of these issues warrant any further delay.

I do, however, believe that the committee could benefit from a discussion of these issues and what we have done with respect to the legitimate concerns which have been raised by interested parties.

We must insure that this policy will in no way adversely affect the quality of drugs. As you know, the Department's firm position in this regard is that in terms of quality and therapeutic equivalence, with few exceptions, no significant differences between chemically equivalent drugs have been shown. We, therefore, do not believe that allegations of inequivalency can or should stand in the way of this drug reimbursement policy. We do, however, have some concern that particular manufacturers, be they large or small—and they can be either—may not be constantly producing high quality drugs. We, therefore, believe that the regulations should provide a mechanism to assure that all drugs covered by the policy meet compendial and other quality standards. The regulations will contain such provisions.

Second, we must insure that this policy in no way restricts the availability of needed drugs to a recipient. As we have just mentioned and as the Secretary pointed out, we want to peg the reimbursement level to the lowest cost for which the drug is "generally available." It has never been this Department's position that the reimbursement level should be established at the absolutely lowest cost drug. The regulations must insure that at the established reimbursement level a continuing supply of the drug will be available to all pharmacies.

Third, we must determine whether or not we are going to establish a maximum reimbursement level for all available drugs. Clearly, such an exercise would be futile if there is only one source of that drug. Additionaly, we do not believe it to be administratively advisable or practical to establish a reimbursement level for all multisource drugs, especially those that are not frequently prescribed.

Therefore, at this time, the regulations will be targeted to the top 200 drugs; that is, those 200 prescription drugs most often prescribed. We believe this makes good sense, will ease the administrative burden, and will produce the savings that the Secretary indicated would result. At a later time we would hope to perhaps extend this policy to other drugs.

The fourth issue that I would like to address briefly today concerns the source which should be used to determine the prices at which drugs are available. As you know, many of the publications which list prices are not exact and do not include promotional discounts and other marketing devices such as bulk sales. One alternative we are considering is requesting accurate price information from the manufacturers. If such information is not forthcoming, we will simply use the best and most reliable sources we can obtain.

Fifth, the procedures and criteria to be used in developing the reimbursement levels will also be set out in the regulations. The exact mechanisms to be used remain to be designed. We have, however, tentatively decided to spell out the criteria, including, among other factors, availability of the drug, disparity of prices among

equivalent products, demand for the product, and ability of the manufacturer to produce quality drugs.

Sixth, it should be recognized that the price of a prescription at the retail level is composed of two parts: cost of the drug and the cost of the overhead and profit of the drug dispenser. Both parts account for approximately equal portions of the final price of the prescription to the consumer. Maximum cost savings can only be achieved by controlling both elements. Therefore, the regulation will have to address ways to deal with both of these problems.

Seventh, in discussing the implementation of the Maximum Allowable Cost (MAC) policy, apprehension has been expressed with regard to the possibility that, in the event that the physician, for valid medical reasons, insists that a drug be used which is priced above the MAC level, his patient receiving services under the medicare or medicaid programs would have to pay the difference between the MAC price and the cost of the drug he prescribed. In this regard it should be noted that Title XIX, Section 1902(a)(14) of the Social Security Act stipulates that individuals receiving benefits under the medicaid programs cannot now be required to pay additional costs resulting from, in this instance, the use of drugs costing more than the MAC price. In view of the legal prohibitions against passing the cost to the patient, we believe that, in those instances where an exception is requested for medically valid reasons, the program should pay the added cost. We believe it would also be appropriate for the medicare program to pay these added costs for its beneficiaries.

Senator NELSON. How do you determine whether it is for a valid reason? How do you handle a matter like this: Somebody prescribes Darvon as an analgesic, although aspirin is more effective and much cheaper. Will the doctors have to tell you that the reason is the patient is allergic to aspirin or some special medical reason? How do you handle that?

Dr. EDWARDS. As I will note later in my statement, the physician would be required to state on an appropriate form why the patient needs a specific brand of product and this form would accompany the prescription and it would be retrospectively reviewed.

Senator NELSON. Please proceed.

Dr. EDWARDS. As I said, the physician would be required to state on an appropriate form why the patient needs a specific branded product. This form would accompany the prescription. The pharmacist would file one copy with the prescription and the other would be submitted with his request for payment to the Federal prgram. These would be reviewed retrospectively and enforcement would be by utilization review committees or PSROs. In those instances where no medical justification has been presented, these programs will not pay the additional cost.

Senator NELSON. Wouldn't that present a complicated paperwork problem?

Dr. EDWARDS. I don't know, Mr. Chairman. I think this is one of those things we are going to have to try. I think just the fact that they have to fill out a form will probably eliminate most doctors

requesting special brands of a particular drug. If it doesn't, then we might have to go to a prospective rather than a retrospective review of the claim or the request.

But I would hope we could avoid that because if we had to set up a prospective kind of review, I think that is the kind of review that would require a fairly sizeable staff and organization.

We also plan that those exemptions to Maximum Allowable Cost will be defined very narrowly. We do not expect many physicians will find it necessary to specify that their patient can only tolerate a specific brand. If the exemptions are abused we will, of course, appropriately, as I mentioned, alter the policy.

Other issues involving package size, dosages and a host of other problems have to be taken on. The Department has been working diligently to determine the most equitable way to devise these regulations and to anticipate all relevant issues. I hope from this discussion of these very complex issues that it will be fully realized that this policy is a tremendous undertaking on the part of the Department which has required the expenditure of considerable effort. It is a challenge that we have welcomed and one that we are hopeful we are meeting rather rapidly.

We are now at the stage in the preparation of the regulations when we can begin to consult with various interested groups regarding the issues we have discussed today. We feel this is only fitting when one considers the impact that these regulations will have. Again, I would like to emphasize that by undertaking such consultation we are not in any way attempting to further delay the regulations. We believe it will be useful and productive to provide the many interested groups with an opportunity to informally comment on our proposal as now developed. We believe this consultation can be conducted within a period of 2 to 3 weeks and, furthermore, we believe that the regulations can then be issued shortly thereafter.

Mr. Chairman, this concludes the formal parts of our presentation and we would be delighted to attempt to answer any questions that you have.

Senator NELSON. I have a couple of miscellaneous issues that have been raised in recent hearings. Dr. Schmidt testified on the bioavailability question when he was here a short time ago.

The industry itself keeps raising the question about the terrible problem of bioavailability, potential and real, and so forth. Just what do you think about the issue of bioavailability that continues to be raised respecting assurance of comparability of drugs?

Dr. EDWARDS. Mr. Chairman, I have said from the very beginning that I thought that bioavailability or equivalency as it relates to our pricing policy has no relevance. I think that it is being used more or less as a smoke screen by those who prefer not to have a pricing policy. I am not for a moment suggesting that bioavailability doesn't represent a potential problem, but, nevertheless, in reviewing the records of the Food and Drug Administration, I think the number of major bioequivalency or bioavailability problems has been small. It certainly is an issue to which the FDA is going to

have to be constantly alert but it has nothing to do per se, in my judgment, with the development of a pricing policy.

Senator NELSON. How many drugs have involved a bioavailability problem of consequence?

Dr. EDWARDS. If you don't mind, I would like to have Dr. Jennings address himself to that.

Dr. JENNINGS. I am not sure I can give you an exact figure, Mr. Chairman. I would say the number is within the range of a dozen —that is, where a problem has been identified under the rather strict criteria that we use to define generic inequivalence—that is, the same drug, the same dosage form, the same potency, and purported to have the same effect.

I think the problem of bioavailability is like any other problem of quality control. It requires on the part of the industry and the regulatory agency constant vigilance. We are apt to find different product effects from time to time and this is the whole reason for our system of surveillance and inspections and sample analysis.

Over the past several years I think we have become more sophisticated with respect to questions that relate to bioavailability and generic equivalence, the problems of dissolution and absorption, crystalization, and all that sort of thing.

There have been problems. There was a problem with chloramphenicol a couple of years ago that you are very familiar with, a problem which was resolved successfully. The smaller manufacturers, as you recall, after having the deficiency brought to their attention, by making a few changes in formula, were able to produce a product that was comparable to the originally approved product.

We more recently had a problem with digoxin and I think this one illustrates the growing sophistication on the part of the industry and the agency. Here the problem seemed to be related to the dissolution rate and there is good correlation between the dissolution time of the tablet and the amount of the drug that became biologically available. As a result of this finding, the USP has added a dissolution rate to their specifications and I feel this is the proper approach to the question of bioavailability—that is, one of quality control, including new and more sophisticated specifications as we become more and more familiar with the various aspects that contribute to problems of bioavailability.

Senator NELSON. Well, the record will speak for itself, but if I recall the testimony of the FDA on this issue, its position is that with respect to drugs which are composed of the same compound, in the same dosage form, meeting USP standards, the question of bioavailability is—these are my words—relatively insignificant in the whole drug picture.

Would you agree or disagree with that?

Dr. JENNINGS. Yes, sir, that is our opinion.

Senator NELSON. Let me turn to another issue. Yesterday I raised it with the Veterans Administration, though it is more properly within HEW. That was the question of the drug Aldomet.

That is the drug alpha-methyl DOPA, an antihypertensive.

Now, that drug was synthesized in 1953 by Merck and they found no useful medical purpose for it. Then NHI, specifically the National Heart Institute, started experimentation with it and discovered through careful scientific trials of their own that it was a very useful antihypertensive. It is pretty clear from the testimony in 1965 and 1966 before Senate and House Appropriations Committees that it was NHI, National Heart Institute, and their experiments that discovered a use for the drug that was very valuable.

Sales for this drug amounted to $33 million in 1970, up to $42 million in 1971. I don't know where it is now, but it certainly is one of the largest selling drugs in the country.

The company has until now refused to give a price break to VA sufficient enough to make it economically justifiable for them to purchase and centrally store it, which is an interesting commentary on the industry's attitude towards the Government that gave them a profitable market for the drug in the first place, by discovering a use for it.

If you have a philosophical comment you would like to make on that issue, I would like to hear it. My second question would be, why in heaven's name does the Federal Government, in this case the NHI, expend taxpayers' money and create a use for a drug with sales 3 years ago of $42 million, and be so neglectful as not to take out a use patent? What is the policy of our Government in protecting the taxpayer? Here they are being outrageously gouged by a company who got a profitable product through the taxpayers' efforts and through the efforts of the greatest research institute of its kind in the world which then turned around and gave the results of these efforts to Merck so they could gouge the taxpayer.

This seems to me just an outrageous business and what are you gentlemen doing about that?

Dr. EDWARDS. First, let me say I don't know that that really is the fault of the NHI. I suspect it is the fault of the Department generally and I must say I don't know anything that—I am not aware of this particular situation. I know we have had some very recent discussions on the whole subject of patents but as yet no definitive policy, at least that I am aware of, has been promulgated.

Senator NELSON. Well, it seems to me that the taxpayers' interest in this should be protected.

Dr. EDWARDS. I think your point is a very good one and I think that we should adopt a specific policy on this particular kind of issue.

Senator NELSON. This has occurred time after time, as you are aware, in all kinds of research and development of products by the Department of Agriculture, HEW, and any number of departments, and then suddenly the work of that department becomes the private preserve of one firm in the private sector with the public's interest not being protected at all.

Well, let me say this. We intend to have hearings on this specific issue, not only on this drug but the broad issue, because it is un-

fathomable to me how the Government can go ahead and do all this work and not at the very least get a use patent that protects the Government in purchases in behalf of its own people. So I don't expect you to comment on the current status of what the Government's position is, if any, but we will have hearings on it. We would hope that you would be prepared to explain what the policy is, if you have one, and whether there is an intention to change it.

Dr. EDWARDS. We certainly will.

Dr. NOVITCH. The general policy, the patent policy of the Department as I last understood it, was that only limited patent rights are granted to a manufacturer for a product that was developed with substantial Government support. Whether this drug was patented prior to any Government work on it would have a definite bearing on why they have an exclusive patent. But if it had been patented after Government contributions as I last understood the policy—I I am not familiar with it today—they would only have a limited patent.

Dr. EDWARDS. The specific product you are talking about as I understand it was actually produced by Merck Company and that the NHI did a lot of the clinical work involved. So that there is a little different light on it. I don't think our policy would apply at all in this particular case.

Senator NELSON. As I previously stated, Merck had synthesized the compound and secured a patent on it. According to testimony by NHI before the House and Senate Appropriations Committees the National Heart Institute experimented with it and discovered the use for it as an antihypertensive—not the company. The Department of HEW could have secured a use patent to protect the interests of the public and to prevent a private company from gouging the public with monopoly prices that would have been prevented if the Government had retained the patent.

Dr. EDWARDS. You well could be right.

Senator NELSON. It seems to me that at the very least there ought to have been some protection for the Government itself. But we shall raise this question at a later date.

Dr. EDWARDS. I think it would be certainly a worthwhile subject to talk about.

Senator NELSON. Well, thank you very much, gentlemen, for your presentation. We appreciate your taking the time to come before us.

(Whereupon, at 11 a.m., the committee recessed, subject to call of the Chair.)

APPENDIX

EXHIBITS PROVIDED BY THE UNITED STATES GENERAL ACCOUNTING OFFICE

UNITED STATES GENERAL ACCOUNTING OFFICE
Washington, D.C. 20548

For release on delivery
expected at 10 a.m. EDT
Wednesday, February 20, 1974

STATEMENT OF
ELMER B. STAATS, COMPTROLLER GENERAL OF THE UNITED STATES
BEFORE THE
MONOPOLY SUBCOMMITTEE
SELECT COMMITTEE ON SMALL BUSINESS
UNITED STATES SENATE

on

DIRECT AND INDIRECT EXPENDITURES
BY FEDERAL AGENCIES FOR PRESCRIPTION DRUGS

We are pleased to be here today to discuss our work related to procurement of and reimbursement for prescription drugs by the Federal Government and related matters.

Among the matters we will comment on are:

--The conclusions and recommendations contained in our recently issued report to the Congress entitled "How to Improve the Procurement and Supply of Drugs in the Federal Government" (B-164031(2), dated December 6, 1973).

--Status of Federal efforts to promote the use of formularies and encourage the use, where appropriate, of lower priced drugs, including generics.

--Status of actions taken by Federal agencies to assure that only effective drugs are procured with Federal funds.

It is estimated that direct Federal expenditures and reimbursements for prescription drugs amounted to about $1.6 billion in fiscal year 1973--an increase of more than $44 million over the expenditures in fiscal year 1972. This amount includes about $252 million in direct drug purchases by Federal agencies and reimbursements of over $1.3 billion under federally-sponsored health programs, such as Medicare and Medicaid.

Direct Procurements

The estimated $252 million in direct drug procurements represents a slight decrease from those in fiscal year 1972. Most of the direct procurements were made by the Defense Supply Agency (DSA) and the Veterans Administration (VA).

DSA's expenditures for its depot stocks amounted to about $91.4 million while VA spent about $38.1 million for its depot stocks. VA also administers Federal Supply Schedule contracts for drugs under which Federal agencies spent over $84 million. Purchases made by such agencies as the Public Health Service and the Agency for International Development and local purchases made by individual Federal

installations account for the remaining fiscal year 1973 expenditures for direct drug procurements.

Federal Expenditures for Drugs under Federally-Supported Health Programs

Available statistical data and agency estimates indicate that about 84 percent of the total Federal expenditures for prescription drugs during fiscal year 1973 were indirect in that they consisted principally of the Federal share of drug costs provided to beneficiaries of health programs supported by the Government. The Medicare and Medicaid programs administered by the Department of Health, Education, and Welfare (HEW) represent the major federally-supported health programs. The Federal Employees Health Benefits Program (FEP) and the Civilian Health and Medical Program for the Uniformed Services (CHAMPUS) are other large programs under which Federal expenditures for drugs are significant.

Federal expenditures for drugs under the Medicare program during fiscal year 1973 were estimated to be about $674 million--an increase of about $57 million over the program expenditures during fiscal year 1972. The Federal share of the cost of drugs provided during fiscal year

1973 to beneficiaries of the Medicaid program amounted to about $605 million--an increase of about $39 million over fiscal year 1972 Federal Medicaid drug costs. Federal expenditures for drugs under the CHAMPUS program were estimated to have exceeded $31 million in fiscal year 1973--an increase of over $5 million above fiscal year 1972 costs. Estimates of Federal expenditures for drugs under the FEP program for fiscal year 1973 were not available; however, expenditures for drugs under the program exceeded $40 million in fiscal year 1972.

Pending legislation pertaining to Federal participation in health care activities suggest that Federal expenditures for drugs may increase in the future--in some cases very substantially. For example, during the first session of the 93d Congress, numerous bills were introduced which dealt, in part, with drug purchases under the Medicare program. Most of these bills included provisions to extend Medicare to cover the costs of certain drugs to be dispensed to eligible recipients on an outpatient basis, and used to treat specified chronic illnesses. The Social Security Administration (SSA) estimates that such an extension of Medicare coverage would cost about $1.1 billion a year.

As you know, several legislative proposals concerning a national health insurance plan are currently under consideration by the Congress. The passage of a national health insurance plan would have a significant impact on Federal outlays for drugs.

WAYS TO IMPROVE THE PROCUREMENT AND SUPPLY OF DRUGS IN THE FEDERAL GOVERNMENT

In our December 1973 report to the Congress, we discussed the effectiveness of Federal agencies' administration of programs and activities relating to the direct procurement and supply of drugs. This matter has been a subject of interest since at least 1963 when Federal agencies began studying the possibility of a single agency having Government-wide responsibility for managing pharmaceuticals, thereby eliminating unnecessary duplication between military and civil agencies. For example, in February 1971, the General Services Administration (GSA) and Department of Defense (DOD) agreed to assign medical material to DSA for integrated management, but the assignment was deferred pending the outcome of a comprehensive study proposed by the Office of Management and Budget (OMB) in June 1971. This study which was made by representatives of OMB, VA, DSA, GSA, and HEW was started in January 1972.

As of December 1973, no final agreement had been reached as to whether a single manager for drugs would be established. Our report supports the need for coordinated action in procuring and supplying drugs. I will briefly summarize our conclusions and recommendations and suggest that the report be included in the hearing record.

In summary, we concluded that:

--Significant savings and other advantages could result from greater cooperation and coordination between agencies in procuring drugs, such as consolidating requirements, making joint procurements, and reducing small-quantity local purchases by authorizing use by any Federal agency of any centralized Government supply source.

--Increased use of specifications for many drug products to encourage greater competition and central management of drugs should reduce costs.

--Better reporting of drugs bought locally and better use of related reports would improve selection of items for central management.

--Responsibility for all quality assurance activities relative to Federal purchases of drugs should be assigned to a single agency--the FDA.

To improve the direct procurement and supply of drugs by Federal agencies, we recommended that:

--The OMB lead in developing--with representatives of GSA, DOD, VA, and HEW--policies and procedures, including consolidating requirements, to increase agency cooperation in buying drugs and achieve substantial savings through large-volume buys. Field installations should be authorized to obtain their drug requirements from any centralized Government supply source.

--The VA should develop specifications for (1) all new drugs which VA decides to manage centrally, and (2) centrally-managed drugs for which it currently has no specifications.

--The Department of Defense should revise DOD policy to insure that drugs will be obtained centrally whenever savings would result.

--The Department of Defense and the VA should consider jointly developing specifications which would satisfy all Federal agencies' requirements.

--The Department of Defense should (1) develop, for reporting local drug purchases, a uniform reporting

system aimed at requiring all military activities with individual drug purchases exceeding specified criteria to report their purchases, and (2) require centrally-managed drugs purchased from other than a central manager to be reported.

--The VA should require that VA's Central Office Supply Service (1) prepare lists of summary and exception data from the information reported, (2) require local field stations to report their purchase data correctly and consistently, and (3) see that all vendors report detailed sales data when required by contracts.

--The Department of Defense and the VA should consider using a standardized coding system, such as the National Drug Code, for identifying local purchases of drugs not having Federal stock numbers.

--The Departments of Defense and HEW and the VA should review the frequency and type of inspections required and the related changes needed to facilitate the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies.

OMB, in commenting on our final report by letter dated January 14, 1974, stated that the study group has completed its report and has made recommendations which are currently under review by the principal agencies involved. OMB stated also that the findings and recommendations of the study closely parallel those set out in GAO's report.

In its letter commenting on our final report, DOD stated that it subscribes in general to the goals and principles set forth in the report. DOD stated also that, although agencies' actions to improve Federal coordination regarding specific aspects of drug procurement and management have been limited to informal coordination between agencies pending evaluation of the OMB report, advice as to positive actions concerning our recommendations would be furnished to us as they are implemented. Also, a clarifying DOD policy concerning adapting medical items for central procurement is expected to be released within 60 days.

In its letter dated January 16, 1974, VA indicated general agreement with the thrust of our report and discussed the status of actions to implement the recommendations. For example, VA:

--has authorized its marketing centers and supply depots to accept orders from DOD field installations;

--will initiate a control system with DOD to assure that drug specifications are either developed jointly or coordinated; and

--is willing to rely on FDA to provide quality assurance for VA drug purchases, provided that FDA makes the necessary data available in a timely manner.

HEW agreed with the rationale for consolidating all quality assurance responsibilities pertaining to purchases of drugs by the Federal agencies and stated that a single organization should inherently be more efficient and uniformly equitable in administering a quality assurance program.

HEW stated that, in view of the comments from other Departments on the draft report, it believes the immediate objective should be the development of a consolidated quality assurance program which satisfies the needs of all interested parties. The Food and Drug Administration is currently developing an initial concept for that consolidated program based on its assessment of quality assurance requirements.

STATUS OF FEDERAL EFFORTS TO PROMOTE THE USE OF FORMULARIES AND ENCOURAGE THE USE OF LOWER PRICED DRUGS

We will now discuss briefly Federal efforts to reduce drug costs by promoting the use of formularies and encouraging, the use of lower priced drugs, including generics.

Department of Defense

Military medical regulations require that Pharmacy and Therapeutic (P&T) Committees be appointed by the commanders of U.S. military hospitals. Among the primary functions of P&T Committees are the development and periodic review and revision of the hospitals' drug formularies. In making decisions concerning the addition or continuation of formulary items, the P&T Committees consider the relative costs of therapeutic alternatives.

In addition to the general use of formularies by the services, the Surgeons General and subordinate administrative levels issue monthly newsletters or special letters to health facilities highlighting comparative prices of drugs maintained in central inventories and encouraging the use of less expensive drugs when they are considered to be therapeutically equivalent to more expensive items. Prescriptions written

32-814 (Pt. 24) O - 74 - 38

by military physicians and filled in military hospitals for brand-name products may be filled with generic equivalent products except when the physicians specifically require that such substitutions not be made.

Under CHAMPUS, a DOD-supported program for providing medical care benefits from civilian sources to retired military personnel and military dependents, DOD has not established regulations requiring the use of formularies. Also, it has not encouraged the use of generic drug products for either the inpatient or outpatient portions of the CHAMPUS program.

Veterans Administration

VA requires that each of its medical facilities have a P&T Committee which develops and maintains a drug formulary. This formulary generally consists of monographs on those products selected by the P&T Committee for use in the facility. Generally, prescriptions will not be filled for drug items not included in the formulary. However, exceptions may be made with special permission. These monographs include the nonproprietary names of the drug, therapeutic classification, dosage, and instructions regarding product usage. VA has also instructed its physicians that generic identification of prescribed medications is preferred to the use of brand names.

Department of Health, Education, and Welfare

The HEW agencies that provide direct patient care, such as the Indian Health and Federal Health Program Services of the Public Health Service, require that all field installations be serviced by P&T Committees responsible for the development and maintenance of current formularies of accepted drugs. The formularies are required to list drug items by their official, generic or nonproprietary names and only formulary drugs are authorized for routine use by HEW installations providing direct patient care. Among the items the P&T Committees are required to consider in developing their formularies are comparative efficacy of formulary drugs with other drugs intended for the same use, evaluation of benefit/risk of formulary drugs and cost effectiveness.

Under Part A of the Medicare program, drugs are paid for by SSA--through fiscal intermediaries--as part of eligible recipients' total hospital bills. Under Part B of the program, Federal coverage for physicians and related services are provided through organizations known as "carriers." Coverage of drugs under Part B is limited to those drugs which are commonly furnished in physicians' offices and which cannot normally be self-administered.

The regulations for Medicare state that in order for a drug to be covered under Part A it must (1) represent a cost to the institution in rendering services to the beneficiary, and (2) either be included or approved for inclusion in specified drug reference volumes or approved by a P&T Committee (or equivalent) for use in the participating hospital. In order to be covered under Part B, costs of eligible drugs--like those of other medical services--must be accepted by the carrier as reasonable and necessary.

Under this system, SSA generally is not provided detailed information concerning the specific drugs that are being prescribed under Medicare. We were informed by an SSA official that there are currently no SSA regulations which encourage the use of generic drug products.

Under the Medicaid program, which is administered by State agencies with Federal guidance and reimbursed, in part, by the Social and Rehabilitation Service (SRS), the use of formularies and generic products is optional. The applicable Federal policy states that "where either is employed, there must be standards for quality, safety, and effectiveness under the supervision of professional personnel." Although SRS discusses the use of a formulary system as a means of reducing overall drug costs, the use of formularies is not

required. Presently 20 States use some type of formulary. SRS, in its Medical Assistance Manual, points out the arguments for and against the use of generic drugs but does not emphasize their use.

Although States generally accumulate data concerning the specific drugs being dispensed under the Medicaid program, the data is not normally provided to SRS.

As you know, Secretary Weinberger recently announced that HEW will be publishing regulations for public comment which, if adopted, would limit drug reimbursements under programs administered by the Department to the lowest cost at which the drug is generally available unless there is a demonstrated difference in therapeutic effect. The Secretary stated that this reimbursement policy will result in significant savings in the cost of providing prescription drugs under Medicare and Medicaid. The Secretary's announcement prompted the Chairman of the Senate Subcommittee on Health, Committee on Labor and Public Welfare, to hold another hearing on February 1, 1974, to provide representatives of the Administration and the drug industry the opportunity to clarify their positions concerning this significant new HEW policy. To date, the proposed regulations referred to by the Secretary have not been published.

STATUS OF ACTIONS TAKEN BY FEDERAL AGENCIES TO ASSURE THAT ONLY EFFECTIVE DRUGS ARE PROCURED WITH FEDERAL FUNDS

During our last appearance before this Subcommittee in May 1972, we commented on actions taken by DOD, HEW, and VA with respect to FDA's pronouncements regarding drug efficacy. As you are aware, FDA has categorized drugs as "effective," "probably effective," "possibly effective," and "ineffective" for one or more therapeutic indications claimed on the drug's labeling.

Legal action was brought against FDA in an effort to expedite FDA's completion of its determinations of drug efficacy under its Drug Efficacy Study Implementation (DESI). In October 1972, the Federal District Court for the District of Columbia:

--ordered FDA to meet specific target dates for various phases of DESI and to submit 6-month status reports to the Court concerning its progress.

--required FDA to make final determinations on drug efficacy or to rule on drug sponsors' request for hearings by October 1976.

As of January 1974, FDA's initial ratings on all but one of the more than 4,000 drug products included in the study have

been published in the Federal Register. However, in accordance with the procedures of DESI, FDA may--and has--revised its ratings for specific drugs as new information is submitted by the drugs' sponsors.

We inquired into the status of Federal agency actions to insure that only effective drugs are purchased with Federal funds and noted that, in general, definitive actions taken have been limited to direct Federal health care programs.

Actions Taken by the Department of Defense

We testified in May 1972, that as of November 18, 1971, the Defense Medical Materiel Board had initiated action to stop further procurement and to eliminate from the supply system all items that FDA had then pronounced "ineffective" or "possibly effective." Also, the Surgeons General of the military departments had emphasized through instuctions to medical organizations the DOD policy on such drugs, which became effective January 21, 1971. This policy provided that remaining stocks of "ineffective" drugs withdrawn from the market were to be destroyed or other appropriate action was to be taken to remove them from the inventory. For items categorized "ineffective," but awaiting final determination FDA, further use of remaining stocks was

suspended until the final status was announced by FDA. P&T Committees were required to question all prescriptions for "possibly effective" items, but local procurement of such items could be made if no alternative means of therapy was available.

On June 11, 1973, the Office of the Assistant Secretary of Defense (Health and Environment) announced a revised policy which is a bit less stringent with respect to the use of "ineffective" and "possibly effective" drugs. According to DOD, the original policy was revised because the completion schedule for the DESI had been substantially extended from that originally anticipated and because some of FDA's more recent drug classifications would be revised following only minor changes in labeling or formulation of certain widely-used items.

The revised policy provides that procurement of items classified by FDA as "ineffective" and ordered withdrawn from the market continues to be prohibited. However, for items which FDA has classified as "ineffective" but has permitted to remain on the market pending final resolution of the items' classification, the policy permits the Defense Medical Materiel Board, in conjunction with the Surgeons General, to determine whether centrally-procured stocks are