15. QUESTION:

In the past several months Mr. Feinberg of the DPSC has publicized certain problems for which the Subcommittee is very anxious to secure additional information. His statement and our questions are as follows:

(e) "We develop definitive product specifications which often exceed official or commercial standards."

Please name each product for which such specifications have been developed; the significance for each product of these extra requirements; and the medical purpose served by these extra requirements.

ANSWER:

There are approximately 1200 drug items in FSC 6505 managed by DPSC. About 800 items are monographed in the USP or NF; the balance is not covered by official standards.

In preparing specifications for USP and NF items, the compendial standards are the focal point for the technical data. Additional standards are added in those instances where the need exists. Included are general requirements that exceed the standards of the USP and NF, such as Classification of Defects which are necessary for quality and contractual pruposes, limit on unrefrigerated shipping time for refrigerated items, and leakage testing for flame-sealed ampuls. Standards for individual items are added when problem areas are anticipated or complaint background develops. Such additional data may be obtained or developed from literature, industry, DMMB, DPSC staff, or DCAS Quality Assurance Representatives.

For those items that are not covered by the USP/NF, specification data are requested from those firms listed by the DMMB as the commercial reference. The Chemists/Pharmacists carefully review the submitted specifications, taking into account published information found in the literature, journals, handbooks, as well as their background and experience with similar items. There are times when a firm's submitted data do not contain sufficient requirements to insure a quality product. Other times, the methods are not entirely satisfactory.

The DPSC specifications are coordinated in house before a specification review board which consists of members of the Technical Services Branch, the Office of Counsel, the DPSC Medical Laboratory, and the Quality Assurance Branch.

Additional requirements for USP and NF items follow.