Briefly, if an item is pronounced to be "ineffective," we suspend it from issue and delete it from the catalog. If an item is pronounced to be "possibly effective," we issue existing assets until exhausted providing the customer submits a requisition with advice code 2F indicating that the item is known to be possibly effective and it is still desired.

6. Discuss the implementation of the Buy American Act and balance of payments procedures in relation to comparison of foreign and domestic bids.

Under departmental regulations we artifically raise the foreign supplier's bid price by "evaluating" it to give an edge to the domestic producer. To the bid price, inclusive of duty and transportation to depot, we add 6% (12% if the low domestic bidder is a small business or labor surplus area concern). Then we take the price *minus* duty, but including transportation and add 50% to the foreign bid. Whichever of those two calculations result in a higher figure is the "evaluated" foreign bid. If this "evaluated" price is still lower than the low domestic bid, the foreign bidder gets the award if the firm is otherwise qualified.

7. The need for requiring a specification prior to introducing an item into the supply system where (1) competition is restricted due to a patent, an NDA, or form 6 which relates to antibiotics, and (2) the item is monographed in the USP and NF.

When time is of the essence, which is almost always the case in the introduction of a newly-standardized drug item into the system, we buy under "accelerated procurement procedures" which in effect permit making the initial procurement by brand name, without specifications. This gives us time to prepare a specification for following procurements. We agree that the preparation of an exhaustive specification is wasted effort if the items is available only from one source, but we do not agree that no specification at all is required. In order to insure that we make only wise expenditures of public monies we need to specify what it is that the Government intends to buy and expects to get. A brand name is an advertisement, not a recipe or warranty. We need to make sure that what we are buying on contract comes up to the quality of the item which originally led to standardization. To assume that this will automatically be the case is a naive disregard of some disappointing experiences. Further, we need to develop firm specifictions during the period of restricted procurement, to be ready to go into a competitive market when patents expire, when we buy around patents under the patent indemnity clause, or when additional NDA's are approved.

During the course of the past year the General Accounting Office has intensively studied the need for specifications which go beyond USP/NF requirements for monographed items. They alluded briefly to their findings in the hearings before this subcommittee on 10 May 1972. ". . . additional requirements are often included to provide assurance that items manufactured will have needed characteristics for such requirements as potency and purity, from the time of manufacture to use."

I am sure they would be happy to report their findings in greater detail. DPSC has been the national leader in developing specific drug standards, and many of their supplementary requirements have been adopted in subsequent revisions of the official compendia. These added requirements include such specifications as: pH compatibility with route of intended administration; objective standards for limits of color loosely described in compendia: particle size, bacterial limits, and liquefaction of ophthalmic ointments; biological effectiveness of hormone preparations; and maximum limits for potentially toxic breakdown products. There is ample testimony to indicate that conformance with the criteria of the monographs in the compendia is not sufficient alone to guarantee the safety and efficacy of a drug product.

8. The actions taken to centralize plant inspection and drug testing under one agency.

The Department of Defense has taken no action to centralize plant inspection and testing under a single government agency. It has no objection to such centralization, so long as the agency can and does provide effective inspection and testing. We do rely on the Food and Drug Administration for the inspection and certification of antibiotics. However, we have found that inspection of a company, a plant, or a process at intervals of one to several years is no assurance whatsoever that the result will be a satisfactory product on a specific procurement. We cannot risk public funds in the volume we expend without positive