

It must be recognized that military needs frequently involve requirements which transcend those of some commercial products on the market. For example, military medical materiel is subjected to worldwide distribution under adverse conditions. Product stability is, therefore, a very essential element in assuring that the product is suitable when it is ultimately consumed. As a result, the standards described in DPSC specifications are at times more stringent than commercial standards in anticipation of adverse storage and transportation, and long-term storage.

Senator NELSON. May I ask a question there? The first sentence is, "It must be recognized that military needs frequently involve requirements which transcend those of some commercial products."

As I read your statement, you seem to be referring to packaging here, not composition of the finished product. Am I correct?

Admiral ETTER. The stability of the product itself for long-term storage, and this can come particularly in the tablet form of certain drugs. Tablets must be made in a particular fashion so that they will remain stable longer under high temperatures or high humidities or freezing or cold. Packaging is certainly part of that, too.

Senator NELSON. Fine.

Admiral ETTER. It will be noted that the method of specification preparation is responsive to the rapidly changing need of the medical services. The division operates closely with the procurement personnel and obtains rapid feedback from industry on recent technological advances. Technical reviews and evaluations of such data permit updating and upgrading medical specifications. Valuable information is obtained via the complaint reporting system which involves evaluation of complaints, classification of the types of complaints, and determination of whether specifications require modifications in order to circumvent further complaints of a similar nature.

DPSC procures approximately 1,100 drug items, of which about 560 are monographed in the current issue of USP XVIII and NF XIII. About 50 percent of these items include standards that exceed those of the official compendia.

Senator NELSON. In what way do you exceed the standards of the official compendia? It is the position of the USP and NF that these standards are as high as they can be for any useful medical purpose.

Admiral ETTER. For example, it is my understanding that with some of the antibiotic preparations, DPSC requires both high and low limit concentrations of the available active ingredients in that drug. NF and USP did not, and now I understand they have incorporated some of the higher standards as I indicated before, because of certain storage requirements and certain requirements which make them last over a longer period of time under adverse conditions.

Senator NELSON. Just so that it is clear in the record, you are not saying that because it has something that makes it store for a longer period, that that makes it a therapeutically more effective drug?

Admiral ETTER. No, sir.

Senator NELSON. I just wanted to get at the question of superiority, to be clear on what you mean by standards that exceed those of the official compendia and if you intend to say they exceed them in terms of therapeutic effectiveness.