

10212 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Honorable Gaylord Nelson

-2-

February 27, 1974

Subcommittee on February 21, I reviewed the NF articles included in this sample that they provided, and I offered my general conclusions. Later that same day, Dr. Daniel Banes testified on behalf of the USP, and he offered a very similar assessment and opinion with regard to the USP articles in that sample listing.

Based upon my review of the current material submitted by DOD as its second increment of information, I have concluded that the general assessment I presented on February 21, can be applied with little, if any, modification to the entire list of NF items which the DOD has just submitted.

- The overwhelming majority of so-called "additional requirements" are identified in the DOD list as "classification of defects," as defined and explained in the explanatory notes which accompanied their January 30 letter. This "requirement" is desirable or perhaps necessary for contractual purposes. This does not constitute a standard of quality in the usual sense; therefore, while such a requirement may be useful for administrative purchasing purposes, it should not be considered as, nor confused with, quality specifications.
- A very substantial number of the other "additional requirements" are of such a nature that they may contribute to the elegance or aesthetics of the product, but they have no apparent relevance from the standpoint of medical value or safety of the article.
- A very significant number of so-called "additional requirements" are already covered in the overall NF standards and specifications -- either in the pertinent monograph, related monograph for the active ingredient, or in some other section of the NF pertaining to general product specifications. (A list of selected examples, along with comments, is appended to this letter for illustrative purposes.)
- And finally, there are a few "additional requirements" which are not currently specified in the National Formulary for the pertinent drug items. In most of these cases, it is not apparent that such additional requirement is either necessary or serves a meaningful .