

DPSC - File

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September 30, 1969

Mr. Thomas C. Filicecia
Drug and Chemical Unit
Technical Services Branch
Defense Personnel Support Center
2800 South 20th Street
Philadelphia, PA 19101

Dear Mr. Filicecia:

I am responding to your communication dated August 8, 1969, (DPSC-ATTN-24) with which you enclosed a draft, which, when published in final form, would become part of Federal Standard No. 142a.

While your letter requested that our reply be sent within 30 days, I would note for the record that my associate in the NF office, Mr. Durward Dodson, has telephoned you and Mr. Cutler on this matter several times during the past month. During these discussions, he was informed that our comments would be welcomed and duly taken into account even though they did not reach you until this date.

A principal reason for the delay in our response can be attributed to our effort to edit or revise your draft based upon our knowledge of the NF monographs involved, the pertinent NF General Test chapters involved, and the basis for each of these as well as their proper application and interpretation. Our efforts in this regard have not been particularly successful, however, since we are not certain that our redraft of your proposed specification will necessarily achieve the precise results which you intend. Consequently, we are forced to conclude that it would be simplest to provide you with an explanation of the basis of the NF standards and leave it to you to utilize or apply this information as you see fit in developing your own specifications.

The basic approach of the NF with respect to sterile solids is comparable and consistent with our approach to other dosage forms including tablets and capsules.

In the case of sterile solids having diluents present (these are identified by monograph titles reading "_____ for Injection"), the sterile solid is required to comply with the monograph rubric tolerance which provides limits, compliance with which is determined through the Assay utilizing a pooled sample of a number of containers. In the case of these monographs, moreover, the article must comply with a specification in the monograph concerning either weight variation or content uniformity.