October 8, 1969

Mr. Max Feinberg
Defense Personnel Support Center
Directorate of Medical Material
2800 South 20th Street
Philadelphia, PA 19101

Dear Max:

On September 30, 1969, I sent a letter to Mr. Fileccia embodying an explanation of the NF approach to providing standards and specifications for sterile solids.

I have now received a copy of your letter dated October 1, 1969, addressed to Dr. Miller, in further connection with this subject (your reference DPSC-ATTH-24:kmc). By and large, the documents enclosed with your October 1 letter restate the DPSC viewpoint as previously expressed and as reflected in the draft document which Mr. Fileccia had transmitted for review and comment. As such, I will not reiterate the NF viewpoint in these areas, but would simply refer you to my September 30 letter.

There is, however, one new point which is introduced in the enclosures to your October 1 letter which had not arisen before and concerning which I have, therfore, not previously commented. This is the matter of sterile solids with added substances which are lyophilized in the final container and for which the NF provides an exemption from compliance with the Content Uniformity Test, as noted in the enclosure which accompanied your letter.

Please note that there are several conditions embodied in the NF exemption which are not specifically mentioned in your discussion of this exemption. These conditions are: (a) that the article was prepared from a true solution; (b) that the lyophilization process be performed in the final container; and (c) that the label must carry a statement to this effect in order for the exemption from this Content Uniformity requirement. Finally, while an article meeting these three conditions is then exempt from the Content Uniformity requirement, you will note that the NF specification then states that the preparation is required to meet the Weight Variation Test for sterile solids.

This exemption was adopted only after careful consideration by the NF Board and appropriate study of the manufacturing procedures utilized within the pharmaceutical industry. This study convinced the National Formulary that such an exemption would be entirely appropriate and would adequately assure suitable potency, homogeneity, and related standards of quality. If the conditions exist which would qualify a product for this exemption, one is