Dr. FELDMANN. In other words, it makes a nice little piece of added window dressing, but it adds nothing to the integrity of the article.

Senator NELSON. Would you please explain what you mean, the content uniformity is assured? In what way is it assured?

Dr. FELDMANN. It is assured in this particular case because the assay provides—let me just—I will not read the three pages of the letter, but let me read just a couple of pertinent sentences from my response.

> In the case of the NF XIII sterile solids, the articles are all consistent with our policies, with the apparent exception of the monographs for Sterile Chymotrypsin and Hyaluronidase for Injection. However, there are special circumstances pertaining to each of these articles which require them to be exceptions to the general policies. These revolve about the fact that both are enzyme products, with peculiar problems associated with the non-homogeneity of enzymes.
>
> You will note that in each case the Assay directives call for conducting the Assay on individual vials of the article rather than pooled samples.

So the assay, as it is done in each particular case, is to take individual unit vials. Therefore, a content uniformity test, which is also to take individual unit vials, is simply duplicative of the assay.

Senator NELSON. I see.

Go ahead.

Dr. FELDMANN. Returning to page 9, Mr. Chairman.

If such as the case, pharmacists and physicians should be made aware of the facts in order that they might take appropriate professional action even before FDA takes legal action to remove such products from the marketplace. In APA's role of monitoring and disseminating such information, we have attempted to obtain specific details from DPSC as to which drug products have been rejected and the basis for rejection, as well as which drug manufacturers have been judged to be unsuited to manufacture products of acceptable quality.

Regrettably, our efforts in this regard have to date met with absolutely no success. In light of the fact that our informal requests for such information have been repeatedly rejected, this past September a formal request for such information was filed with the Defense Supply Agency of DOD under provisions of the regulation entitled Availability to the Public of Official Information, as it was promulgated in the Federal Register. Again, this effort failed to elicit the kind of information we seek.

And I have provided you, Mr. Chairman, with copies of our correspondence as exhibits F and G.

Mr. Chairman——

Mr. GORDON. Dr. Feldmann, this is rather puzzling in view of the statement the DPSC makes that: "A close working relationship exists between DPSC and the personnel of the FDA, the U.S. Pharmacopeia and the National Formulary." Here you are unable to get information from them, and they claim you have a very close working relationship.

What is the explanation?