This would suggest to me that the specifications may, or must have been written from a draft that had a specific company's drug name in originally, and they forgot to delete it in one case.

Mr. GORDON. We are going to get those for the record, are we not?

Dr. FELDMANN. Yes.

I think that any doubt is removed when one goes to clomiphene citrate tablets, in which it states a trade name at the beginning of their bid specification: "shall be the William S. Merrell Company's Clomid tablets, and in addition shall comply with." I do not see how such a bid specification can go out to multiple bidders, or can be competitively bid upon.

Senator NELSON. That is one way to insure that you get only one bid.

Please go ahead.

Dr. FELDMANN. Going on with the four examples from the National Formulary that were cited in their response to you, Mr. Chairman, under propylhexedrine inhalant NF, they specify certain assay limits which they claim are higher or will insure greater adherence to a 100 percent of label claim. In fact, their specification does permit assay at not less than 93 percent up to 90 days, whereas the NF limits are a minimum of 90 percent for the entire shelf-life of the article.

Senator NELSON. What is the shelf-life?

Dr. FELDMANN. Whenever it is offered for dispensing to the patient—in other words, whenever it is in the channels of distribution.

Senator NELSON. How can you have a definition of shelf-life like that? There is some termination date.

Dr. FELDMANN. The manufacturer would need to state an expiration date if he is not confident or sure that it will maintain its potency under the normal conditions of storage—or as stated on the label, if there are special conditions of storage. If it will deteriorate to an extent that it would fall below the standard, then it is up to him to recall the product and remove it from the channels of distribution.

Senator NELSON. Well, does the manufacturer know what the shelf-life of the product is in all cases?

Dr. FELDMANN. I do not know whether he does or not, Mr. Chairman. This should be a factor in his being permitted to market a drug. In other words, this would be a responsibility which a manufacturer should assume.

Senator NELSON. Well, does the label show it, the shelf-life?

Dr. FELDMANN. Those products which are expected to possibly deteriorate or which might be expected to deteriorate would carry an expiration date, or should carry an expiration date, which would indicate a point or a date beyond which the integrity of the product could not be assumed.

Senator NELSON. Well, then, the specification, if I understood you correctly, of the compendia is higher than the specification of the DOD in this case.

Dr. FELDMANN. In our opinion, it is at least as good. That is correct.