These aid in detecting deterioration and resolving differences of opinion over color acceptability.

There is a time limit for solubility of dry powder in a vial. This is to assure that the powder will go into solution within the desired time.

There is a potential hydrogen, or ph, range. This is to assure greater stability over the shelf life.

The fourth example is consistency test requirements, to be sure that the item has the proper consistency at the anticipated use and storage temperature.

There are some other examples of this type that have been given to us to explain these additional specifications.

Senator NELSON. I would like to get this clear: Is the suggestion here that drugs that are procured meet USP standards at the factory or the manufacturer, but for some reason or another, by the time they are sent to wherever they will be used, they do not meet USP standards? Or are we talking about some additional specifications?

Mr. STAATS. Just the latter, Mr. Chairman. I think if I understand it correctly, what the USP and the NF will do is set the standards for public use. There are additional requirements which the military feels that they need for their own special requirements.

Senator NELSON. Are these requirements that the military feel they need or are these specifications submitted to the procurement agency by the drug company?

Mr. STAATS. I cannot answer that question.

Mr. CROWTHER. Generally, these are requirements that the military needs in order to maintain a particular consistency, potency, color, whatever it is, for a shelf life for a period of time at a particular location. Their concern is the point in time that the particular drug will be used, and it may take quite a length of time, either shipment or storage, before actual use.

Senator NELSON. I just want to be clear about what we are talking about here. The Defense Department testified on that point about a year and a half ago.

If you are talking about the question of being sure that it is appropriately packaged and protected for handling in Africa or such places as a jungle, which puts the drug to a different test than in this climate, that is one item. But I am trying to get at a question which we raised once before. We raised the question in the hearings in January and February of 1971, and we read at that time a quote from a speech which was given at the 21st annual meeting of the Defense Supply Association and was printed in the Review for November-December 1968. The speech is by Col. W. V. Breyfogle, Chief, Division of Medical Materiel, Defense Personnel Support Center, Defense Supply Agency, in which he addresses himself to the question you raised in your remarks here. I would like to read them for the record:

> The first problem that has been bothering us for some time is our inability to procure competitively. The policy of the Department of Defense, as it has been for many years, is that we will obtain competition on our procurements to the maximum extent possible. The major problem in our failure to procure competitively is the nature of the specifications that we are using. It has been said in the past that our specifications are too restrictive in nature and thereby restrict competition. There is some validity in the statement. Before you can understand why we have a problem of procuring competitively, however, you must understand how items are selected for standardization and stockage in our DSA depot system. The items that are standardized by the Defense Medical