We understand that a second edition of the manual is scheduled for publication shortly and will include changes designed to make it more useful including dosage guidelines, ingredients of over-the-counter drugs, and additional trade name items.

One requirement of an efficient supply system for prescription drugs is the development of specifications which can be used to encourage competition and assure controlled quality production of drugs with the desired therapeutic effect.

Both DPSC and VA develop specifications for items they intend to buy competitively. These items account for about 25 percent of all VA centrally managed drug items and 99 percent of all DPSC centrally managed drug items. The remaining items procured centrally by the agencies are designated for purchase from preselected sole sources. Data for preparation and development of DPSC specifications is obtained primarily from the manufacturers of drug products.

Although DPSC attempts to purchase virtually all of its drug items competitively, it has been able to do so for only about 51 percent of its approximately 1,100 drug items. The remainder, about 535 items, have been supplied by single sources.

Senator NELSON. What is the explanation for that? Is it because the specifications are drawn in such a way that, though there may be several of the same compounds in the market for the same purpose, the competition is eliminated because of the way the specifications are drafted?

Mr. STAATS. Well, we cover that a little bit later. I believe it will be partially answered.

Senator NELSON. All right.

Mr. STAATS. Of these, competitive procurement of 386 is limited by patents or by FDA regulatory requirements which preclude marketing without an approved New Drug Application or antibiotic certification. The remaining 149 items have no apparent legal or regulatory restrictions that would preclude interested firms from submitting bids on DPSC requirements. That narrows the field down, as you see.

In 1969 and 1971 DPSC made a widespread effort to develop competition on a large number of drug items but the responses were few and disappointing.

Basically DPSC's specifications require full compliance with the product standards and requirements set forth in the U.S. Pharmacopeia (USP) or National Formulary (NF). But additional requirements are often included to provide assurance that items manufactured will have needed characteristics for such requirements as potency and purity, from the time of manufacture to use.

Senator NELSON. I do not quite understand that. The U.S. Pharmacopeia sets a potency standard. The National Formulary sets a potency standard. Are DPSC's standards more narrow, that is, they allow a more narrow variation? I do not quite follow that.

It says "But additional requirements are often included to provide assurance that items manufactured will have needed characteristics for such requirements as potency and purity, from the time of manufacture to use."

Mr. STAATS. We have several examples here, Mr. Chairman, of requirements which are additional to the compendia to provide assurance that drug items manufactured have the necessary characteristics from the time of manufacture to use. For example, there are color standards.