

The other incidents, we have examined the list of potential bidders, past bidders, and have looked at their quality record to see how close they have come to our standards, and we have specifically solicited a number of small business concerns that in the past have produced for us but have not bid recently, or in the past have been turned down on a preaward survey, but for a deficiency which is correctable without major capital investment.

Mr. GORDON. And you say the response has been disheartening?

Colonel LINDSEY. Yes, sir.

Mr. GORDON. Why is that?

Colonel LINDSEY. We only got about 20 percent replies of any sort from letters that we sent out to specific concerns. We sent back to these companies a copy of our latest issue of our drug standards booklet, our equivalent of FDA's good manufacturing practice document. In each instance, when they see what they have to do to meet our standards, why, they hold back. These are new small business concerns that we are looking for to add to our active list.

Senator NELSON. On the specifications, I take it the specifications required to be met are often beyond USP or NF standards, is that right?

Colonel LINDSEY. Yes, sir. This was mentioned in previous hearings and as a result, the General Accounting Office spent about a half a year on a special project, looking at 25 drug items which they selected. These were items which are monographed in the Compendia, either USP or the National Formulary, which have been limited for some time to a single supplier and in which our specifications have added something to the Formulary requirement. They thoroughly justify the additions which have been made as reasonable and necessary to insure value received to the Government. We have been a leader in many of these things and we expect to see many of these specifications added to later revisions of the Compendia. The things we have added, Senator, are simple. Color standards for an injectable solution so that there is no argument over what "light yellow" means in USP, or "straw colored;" pH limitations ophthalmic ointment, particle limitations on ophthalmic ointments. While the USP says there shall not be palpable particles, we specify particle size, bacterial limits, and melting range for an ophthalmic ointment. So we have requirements both for storage and the body surface for which it was intended.

I have here if you wish a summary of each of the 25 items that GAO studied, with notations on what the additions were in the specifications. I would be glad to answer any one of them.

Senator NELSON. Do you have an extra copy for the committee files?

Colonel LINDSEY. I can give you this copy. It is not an extra copy. The notations are in my handwriting. It is usable.

Senator NELSON. How large a document is it?

Colonel LINDSEY. Twenty-five pages, sir.

Senator NELSON. Are you going to duplicate that?

Colonel LINDSEY. I will leave it with you.

Senator NELSON. If you have an extra copy, we would like to have it.

Colonel LINDSEY. Will do.

Senator NELSON. Did not part of this problem arise—I think we raised this question last time—from the fact that, in some of the drugs