Senator NELSON. No.

Mr. FEINBERG. Well, what I was pointing out, sir, was you made reference to FDA inspection. FDA does inspect. They apparently tell the companies what it is that is wrong and then await the action of the company during which time the company does produce on the market place.

In our case, if the company is not in compliance with the required pharmaceutical practices, they are not qualified to get—to be awarded a contract for that item.

Senator NELSON. Are your required manufacturing practices different from the FDA?

Mr. FEINBERG. Well, the FDA has just come out with its new good manufacturing practices which become effective this month and we have reviewed that and I would say that there are some areas of differences but there are none of much magnitude.

If you would like, I can review for you some of the differences.

Senator NELSON. What are the differences that you consider might be significant?

Mr. FEINBERG. The FDA good manufacturing practices do not require written procedures covering the receipt of new material, quality control, packaging, and inspection of raw material.

Senator NELSON. They do not require written what?

Mr. FEINBERG. Written procedures for this, whereas we do.

Senator NELSON. What is a written procedure for this? What do you mean?

Mr. FEINBERG. Well, this is where the quality control officials in this case would identify in writing what it is that their employees have to do, sort of like a check list. When material comes in, you sample by some specific sample procedure. You send it to the laboratory for testing. You await the report from the laboratory. These are systems methods and procedures that become necessary in order to continually produce in a uniformly satisfactory manner.

Senator NELSON. Now, what else is on that list that the FDA does not require?

Mr. FEINBERG. They do not require written procedure in this respect.

Senator NELSON. Does that mean that the company doesn't have a list of written procedures or that the company doesn't follow these procedures?

Mr. FEINBERG. It means that the company has not established—there is no doubt that many companies do have written procedures. It is just that as a minimum that the FDA is asking for, they are not saying that you have to have it. And for inspection purposes and to produce on a uniform consistent basis, particularly where you have people who are out sick, who go on vacation, you should have procedures so that the people in these various areas of manufacture know precisely what has to be done.

Senator NELSON. And you would not purchase from any company that didn't have these enumerated written procedures? Is that what you are saying?

Mr. FEINBERG. If they did not have these procedures, they would not be qualified. However, they would be asked if in fact they want to do this, and give them the opportunity to do so.