Now, in those instances where the deficiencies are of a major nature and they could not possibly make these corrections within a timely fashion, or they may not have the desire to make the correction, then, of course, the company is disqualified for that particular procurement.

Senator NELSON. You say you make a product inspection. How is that done? Do you take a sample of something coming off the line and have it assayed to see whether it meets USP-NF standards?

Mr. FEINBERG. No, sir; we don't do that precisely. We inspect the plant for its total operation and this would include the personnel qualification, the plant arrangement, the line of equipment, the methods, systems and procedures used in manufacturing that item or proposed to manufacture that item, and, of course, the housekeeping and the stability that the company has developed for that product and, of course, stability is a very important point for us.

Senator NELSON. With respect to these items of inspection that you make, and that you have just recited, doesn't the FDA cover the same thing?

Mr. FEINBERG. Well, the FDA does, assumingly does, I don't know myself, but the FDA is in a different situation. They act from a point of view of regulation and the FDA by necessity, I assume, permits companies to manufacture in spite of the fact that they are not in compliance with the good manufacturing practices, and as I understand, in the testimony that Dr. Edwards gave before you, sir, he stated that there were—there was the intensified drug inspection for some 230-some-odd companies and that 147 I believe have gotten to the point now where they are willing to comply with the good manufacturing practices.

Well, during that period they were manufacturing but they were still not complying because FDA apparently cannot stop production within whatever regulations they operate.

Dr. Edwards also stated that there were 44 companies, and I believe he gave a list of the companies, that were presently under this intensified drug inspection and gave some statistics as to how many—what the categories were.

Well, we had an opportunity to review that list and of those 44, we had only contracted with one company and that one company contracted for us in a different location, different area, and which we had found at that time to be acceptable.

Senator NELSON. When you say only one out of 44, this 44 was in what category?

Mr. FEINBERG. Well, it is the one where Commissioner Edwards said:

> Since July 1968 FDA has initiated intensified inspection of 237 drug manufacturers and associated commercial testing laboratories. In 147 of the terminated cases, voluntary compliance with the GMP regulations was achieved through a dialogue between FDA district personnel and plant management. In the forty-four remaining cases are twenty-three which are now the subject of legal action and twenty-one firms which are going out of the drug business because of their inability to come into compliance.

Senator NELSON. Well, now this 21 and 23 are different firms. That makes your 44.

Mr. FEINBERG. That is right, sir. If I gave a different number, I was wrong.