

significant new products. And, in general terms, I would have to agree with you, yes.

Mr. GORDON. What page of your statement were you on doctor?

Dr. GODDARD. Page 6, good manufacturing practice.

There are 20,000 firms registered with the FDA as engaged in the drug business, but 13,000 of these are in medicated feeds. Of the remaining 7,000 firms, some are in veterinary drugs, and some are repackers, leaving close to 2,000 companies who engage primarily in the manufacture of prescription or nonprescription drugs for human use.

Senator NELSON. When they register with the FDA do they describe the size of their operation, number of employees, things like that?

Dr. GODDARD. No, they just register the name of the corporation and the legal address.

Senator NELSON. That is all?

Dr. GODDARD. That is all of them, 900 of these, by actual count, Senator, 861 as of July 1, are principally manufacturers of prescription drugs. We are obliged by law to physically inspect each register firm no less than once every 2 years.

Senator NELSON. All 2,000?

Dr. GODDARD. Yes.

During inspection of the plants, we check the manufacturing and quality control procedures to see if the general regulations establishing Current Good Manufacturing Practices are being followed in actual production. For the most part, this is the case; however, as in any other manufacturing situation, there can be a tendency for those on the line and in quality control to deviate from approved guidelines. To do so is a violation of Current Good Manufacturing Practices. Our field investigations reveal numerous deviations from Current Good Manufacturing practices. These deviations are of varying degrees of importance and may be found in plants of every size and description.

Senator NELSON. In the first line of this section, you referred to 13,000 of these drug manufacturers engaged in manufacturing medicated foods for animals, livestock and so on?

Dr. GODDARD. Yes.

Senator NELSON. What kind of surveillance do you perform over them?

Dr. GODDARD. Very poor.

Let me clarify that by telling you the situation is this: Many of these medicated feed manufacturers are completely mobile now and they operate in trucks. We cannot carry out inspections of many of these establishments. With those that are fixed operators, so to speak, what you might call fixed base operators, we do inspect their establishment and try to determine that they are using the proper quantities of antibiotics in mixing a feed to be used specifically to prevent infection or to promote weight again in certain animals.

Senator NELSON. As you know—we did not, when I was on the farm, feed them anything but what they could find in the yard. There were no medicated feeds. What concern do you have about the problem of an excessive accumulation of these drugs in fatty tissue of the animals—sheep, beef, chicken, turkey—which are then consumed by the human being at the end of the food chain?

Dr. GODDARD. Senator, besides commenting on this, may I submit for the record a brief statement that I made at a meeting that was con-