(e) Provision for the maintenance of the results of any assays, including dates and endorsement of analysts. Such records, together with records of analyses reported by any State feed control official shall be retained in the possession of the manufacturer or in the possession of a consulting laboratory operating in his behalf. Such records shall be maintained for a period of at least 1 year after distribution of the medicated feed has been completed.

§ 133.109 Distribution records.

Complete records shall be maintained for each shipment of medicated feeds in a manner that will facilitate the recall, diversion, or destruction of the medicated feed, if necessary. Such records shall be retained for at least 6 months after the date of the shipment, and shall include the name and address of the consignee, the date and quantity shipped, and the manufacturing dates, control numbers, or marks identifying the medicated feed shipped. If the medicated feed is held under control of the manufacturer for further shipment at establishments other than where produced, records as outlined in this section shall be maintained at these establishments.

§ 133.110 Complaint files.

The medicated-feed manufacturer shall evaluate by responsible key personnel each complaint received by him on a feed that is manufactured or distributed by him and, where indicated, make such further investigations or take such appropriate action as appears to be warranted in the circumstances. A record of complaints and the action taken by the feed manufacturer shall be maintained for a period of 2 years. If the medicated feed is the subject of an approved new-drug application held by the feed manufacturer, he shall make such reports as are required by § 130.13 of this chapter.

Dr. GODDARD. We are at this time reevaluating the current good manufacturing practices regulations for prescription drugs. Frankly, we are going to have to make them more definitive, much as the drug industry requested in regard to prescription drug advertising regulations. We had expected that the present regulations would assure adequate quality control by all manufacturers, large and small. But the increasing recalls indicate that we must provide more detailed specifications to be followed and precautions to be observed to cut down the risk of failure of drug products to perform properly when they are administered to the patient.

Senator NELSON. How many firms had drug recalls last year?

Dr. GODDARD. 584 in fiscal 1967.

Senator NELSON. How many of those were products marketed by members of the Pharmaceutical Manufacturers Association?

Dr. GODDARD. 131 were members of the PMA and 471 were non-PMA members.

Let me make certain these statistics are right. Let me go back over those.

There were 584 drug recalls for all reasons. One hundred thirteen of these involved PMA members.

Mr. GORDON. We are talking about firms having recalls.

Dr. GODDARD. There were 46 PMA firms that were responsible for the 113 recalls. One hundred eighteen firms were responsible for the 471 recalls of drug products manufactured by non-PMA members.

Senator NELSON. So 32 percent of PMA's members had recalls last year?

Dr. GODDARD. Now, in order that there will not be any argument about the numbers at a later date. Senator, may I submit a table for the record, because we did exclude from our published recall list in preparing for this hearing 38 investigator determinations, six veterinary vitamin preparation recalls, 20 veterinary drug recalls, two diagnostic agents, and one medicated feed recall. So the numbers would