OLEOVITAMIN A&D, NF, 50CC (DRUG)—DEWEY PRODUCTS CO., GRAND RAPIDS, MICH.

After the lot was rejected because the vitamin D assayed above the allowable specification ranges it was returned to the Charles A. Pfizer plant at Groton, Conn. The lot is currently under quarantine at the plant pending a final decision on disposition.

SODIUM WARFARIN TABLETS—ENDO LABORATORIES, GARDEN CITY, N.Y.

This drug was recalled as a result of analysis performed by FDA in the course of a survey of anticoagulant drugs. Information regarding the drug's deficiency was supplied to the Defense Department and other Federal agencies as a routine Food and Drug Administration procedure under the IPAD agreement. The recalled material was destroyed by the firm.

This we knew about in advance of your letter. We had acted upon it and notified the appropriate agencies through the IPAD mechanism.

DIIODOHYDROXYQUIN TABLETS—PANRAY DIVISION OF ORMONT DRUGS & CHEMICAL CO., ENGLEWOOD, N.J.

The lot was rejected at the plant. A sample analyzed by FDA contained iron particles. Since the drug had not moved in interstate commerce, we have advised State authorities of the situation and the lot has been placed under embargo.

Mr. ROSENTHAL. In this instance do you know how many bottles or how much is involved?

Dr. GODDARD. I would have to supply that for the record, Mr. Chairman, if I may.

Mr. ROSENTHAL. Yes.

(See p. 10 for this information.)

Dr. GODDARD. I will go on.

BELLADONNA ALKALOIDS WITH PHENOBARBITAL TABLETS—KETCHUM LABORATORIES, BROOKLYN, N.Y.

The drug was voluntarily destroyed under the supervision of the FDA on March 27–28, 1968.

As you know, Mr. Chairman, the FDA administers various statutory requirements relating to truthful and informative labeling and packaging of food and drugs. A food or drug rejected by the Government, but labeled in such a manner as to indicate or suggest that the article meets Government specifications, would be misbranded and subject to appropriate sanctions.

But rejection by a Federal agency, in itself, as you pointed out in your opening statement, does not necessarily indicate that FDA action is necessary. Government purchasers impose various standards and specifications upon suppliers because of their unique needs. Some of these are of little or no significance to the ordinary consumer. Many products are procured for prolonged storage, some may be subjected to extreme conditions, or they may be intended for special use, such as civil defense stockpiles. Certain items may be rejected because there is too great a variance in portion size; likewise products may be re-