

Shortly thereafter, DSA and FDA made a joint inspection of the firm. Following this inspection, the company initiated a recall of the improperly sealed ampoules in the civilian market. At the same time, the military sent telegrams to all of their installations ordering them to discontinue the use of ampoules found defective.

In another instance, the FDA was advised by DSA that a drug firm had submitted a sample of petrolatum which failed to meet the USP standards. In addition, a mineral oil sample furnished by the firm had a foreign odor. The FDA made an immediate follow-up inspection and learned that the firm was repacking mineral oil, glycerine, and petrolatum with the same equipment used to pack a variety of insecticides. Laboratory examination of the firm's repacked drug items showed they were contaminated with several insecticides, including malathion, lindane, and DDT. Results of our findings were teletyped to the VA, the firm's only drug customer, which placed an immediate embargo on all of the firm's products. Needless to say, DSA was also advised of our findings. On another occasion, the local DSA representative contacted one of our district offices to report that several local dairies were supplying two military installations with slack-filled or short-weight containers of milk. FDA investigated and subsequently issued notices of hearing to the offending dairies. Following the hearings, the firms corrected their short-weight practices.

In another case, a Post Veterinarian at an Army base advised another FDA district that horse radish which he had examined contained glass particles and both live and dead insects. FDA's examination confirmed the Army's findings that the lot was adulterated with filth and the goods were removed from the market by seizure.

These are by no means isolated examples of cooperation between the military and the FDA. Our files contain many other instances where we have exchanged information to the mutual benefit of both agencies and the public. Mr. Chairman, you have also requested a status report on the disposition of eight specific drug items which were rejected by DSA. Except for the sodium warfarin tablets, which were recalled as a result of analysis performed by FDA in the course of a survey on anticoagulant drugs, we had not been notified about these prior to receiving the subcommittee's letter of February 2, 1968.

Let me briefly report our findings in regard to each of these drugs:

*Endo broth membrane filter, a product of Millipore Corp.*—This product is not subject to the F. D. & C. Act. However investigation reveals that this lot was returned by DSA and destroyed by the manufacturer.

*Ascorbic acid tablets—Chase Chemical Co., Newark, N.J.*—The five rejected lots were voluntarily destroyed under supervision of the FDA on March 22, 1968.

*Antiserum, C-reactive protein, 1cc (diagnostic reagent)—Difco Laboratories, Detroit, Mich.*—Investigation reveals that the lot was destroyed by the firm on September 7, 1967.

*Reserpine tablets—Anabolic Inc., Glendale, Calif.*—The drug failed the USP tablet disintegration test. The firm has advised our Los Angeles office that it has asked DSA to destroy the drug at military installations.

*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 Chas. 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.

*Diiodohydroquin 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.

*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.