DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5387. Digitoxin powder. (F. D. C. No. 40334. S. No. 62–192 M.)

QUANTITY: 1 100-gram btl. at New York, N. Y.

SHIPPED: 1–15–57, from Paris, France, by Expandia.

LABEL IN PART: "Digitoxin U. S. P."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 54.1 percent of digitoxin.

LIBELED: 7–5–57, S. Dist. N. Y.

CHARGE: 501 (b)—the strength of the article, when shipped, differed from the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of digitoxin, the minimum permitted by the standard.

DISPOSITION: 10–17–57. Default—destruction.

5388. Digitoxin powder. (F. D. C. No. 39889. S. No. 59–018 M.)

QUANTITY: One ctn. containing 100 grams at Philadelphia, Pa.

SHIPPED: 1–28–57, from New York, N. Y., by Desmo Chemical Corp.

LABEL IN PART: "Net 100 gms. * * * Digitoxin U. S. P. * * * Assay: Digitoxin 99.1 percent Loss on drying: 0.62 percent."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 79 percent of digitoxin.

LIBELED: 3–19–57, E. Dist. Pa.

CHARGE: 501 (b)—the strength of the article, when shipped, differed from the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin, the minimum permitted by the standard.

DISPOSITION: 8–28–57. Default—destruction.

5389. Vitamin capsules. (F. D. C. No. 40198. S. No. 62–186 M.)

QUANTITY: 162 100-capsule btls. at Bronx, N. Y.

SHIPPED: 1–8–57, from Newark, N. J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin B_{12}.

LIBELED: 5–29–57, S. Dist. N. Y.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 10 micrograms of vitamin B_{12}; and 502 (a)—the label statement "Vitamin B–12 10 Mcgms." was false and misleading.

DISPOSITION: 7–16–57. Default—destruction.

5390. Halazone tablets. (F. D. C. No. 40318. S. No. 67–482 M.)

QUANTITY: 25 cases, containing 2,575 btls., at Falls Church, Va.

SHIPPED: Prior to 10–7–55, from North Chicago, Ill.

LABEL IN PART: (Btl.) "100 Water Purification Tablets for Purifying Drinking Water in Canteens Halazone N. N. R. * * * Each tablet contains: 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."