

retained for the time reasonably necessary for the distribution and use of drugs distributed; and

(p) Representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare are given free access to all records and controls pertaining to (1) the receipt of all raw materials or lots of drugs for manufacturing, processing, repacking, or relabeling; (2) the manufacturing, processing, repacking, or relabeling of all lots or batches of drugs; and (3) the distribution of all batches or lots of drugs whether interstate or intrastate, including, but not limited to, the records necessary to establish that adequate control systems have been installed embodying all of the herein listed safeguards for interstate commerce considered necessary to good pharmaceutical manufacturing practice.

**6176. Conjugated estrogen powder.** (F.D.C. No. 43181. S. No. 11-062 P.)

**QUANTITY:** 8 cans, each containing 2 kilograms, at Buffalo, N.Y.

**SHIPPED:** 5-2-58, from Montreal, Canada, by Steroid Laboratories, Ltd.

**LABEL IN PART:** "Product of Steroid Laboratories Limited Box 247 Montreal Canada 2 kilograms Conjugated Estrogens (Equine) Powder Each Gram Contains 17.1 Mg. Estrogens (as Conjugates)—Control No. 91497."

**RESULTS OF INVESTIGATION:** Analysis showed that total estrogen content corresponded to not more than 14.7 mgs. of estrone per gram.

**LIBELED:** 6-6-59, W. Dist. N.Y.

**CHARGE:** 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each gram contains 17.1 Mg. Estrogens" was false and misleading since the article contained not more than 14.7 mg. of estrone per gram.

**DISPOSITION:** 2-8-60. Consent—claimed by Steroid Laboratories, Ltd., and relabeled.

**6177. Conjugated estrogen granules.** (F.D.C. No. 44054. S. No. 86-566 P.)

**QUANTITY:** 4 cans containing a total of about 6,176 grams of estrogen (equine) granules at Buffalo, N.Y.

**SHIPPED:** 9-1-59, from Brooklyn, N.Y., by International Hormones, Inc., after having been imported during 1956, from Steroid Laboratories, Ltd., Montreal, Canada.

**LABEL IN PART:** (Can) "International Hormones, Inc. \* \* \* Brooklyn 1, N.Y. 1546 Grams Conjugated Estrogens (Equine) Granules 7.074 mg/gram Estrogens after Hydrolysis \* \* \* Control #79001."

**RESULTS OF INVESTIGATION:** Analysis showed the total estrogen content corresponded to not more than 4.61 mgs. of estrone per gram.

**LIBELED:** 2-4-60, W. Dist. N.Y.

**CHARGE:** 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "7.074 mg/gram" was false and misleading as applied to an article which contained 4.61 mgs. of estrone per gram.

**DISPOSITION:** 3-9-60. Default—destruction.