Each Capsule Contains: Phenylpropanolamine Hydrochloride 75 mg. Protein Hydrolysate 15 mg. specially prepared to disintegrate over an 8 to 10 hour period for continuous appetite suppression."

ACCOMPANYING LABELING: Display carton, reading in part, "Now! Just One-A-Day Reduce . . . 5–10–20 Pounds Eat All You Want With Dexules * * * Suppresses Appetite All–Day Long"; leaflet entitled "One Week Sample Diets * * * Safe and Sane Reducing Plan."

RESULTS OF INVESTIGATION: Analysis showed that the article contained the labeled amount of phenylpropanolamine hydrochloride. The article had been shipped from Hoboken, N.J., to Syracuse, N.Y., as bulk stock. In Syracuse, N.Y., the article was repacked and then shipped to Buffalo, N.Y.

LIBELED: 6–1–60, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was effective as an appetite suppressant, that it would suppress appetite all day long, and that it was a scientific modern method for losing weight through control of appetite; and 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 3–23–61. Default—destruction.

6542. Barthro injection. (F.D.C. No. 45406. S. No. 46–533 R.)

QUANTITY: 17 boxes, 7 ampules each, at Cleveland, Ohio.

SHIPPED: 11–22–60 and 11–29–60, from Detroit, Mich., by Barry Laboratories, Inc.

LABEL IN PART: (Box) "Barthro (Guanido-Amino-Peptidase) Product No. 2294–5 7 ampules 5 ML. size 2 Q units per 5 ML. each 5 ML. contains enzyme activity not less than 2 "Q" units (Benzyl Alcohol 1.5% as preservative) in water for injection * * * Barry Laboratories, Inc., Detroit 14, Michigan * * * Composition: Barthro is a biocatalyst derived from natural animal material having a direct enzymatic relationship to the substrate of guanine, a purine found in nucleic acid * * * indications: rheumatoid arthritis, osteoarthritis, acute gouty arthritis."

ACCOMPANYING LABELING: Booklet entitled "Barthro Report of Dr. Joseph Fisher, Chelsea, Michigan" and leaflet entitled "Barthro."

LIBELED: 2–1–61, N. Dist. Ohio.

CHARGE: 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 3–3–61. Default—destruction.

6543. Laetrile (Formula L). (F.D.C. No. 45170. S. Nos. 31–106/7 R.)

QUANITITY: 50 vials of *Laetrile* and 14 vials of *Formula L* at Dallas, Tex., in possession of Taylor Clinic.

SHIPPED: Between 9–30–60 and 10–21–60, from Los Angeles, Calif., by Hale Laboratories, Inc.

LABEL IN PART: (Vial) "Laetrile 500 mg. Sodium 1-mandelonitrile-beta-glucuronoside. Caution: * * * New Drug * * * Hale Laboratories, Inc. * * * Los Angeles 64, California 1423" and "Formula L: Mix with 10 cc sterile water. Give 5 cc each injection. Note: Injections 3 times weekly."

RESULTS OF INVESTIGATION: The 14-vial lot was the "*Laetrile*" product which had been relabeled by the dealer as "*Formula L.*"

LIBELED: 12–28–60, N. Dist. Tex.

CHARGE: 505(a)—the article was a new drug which may not be introduced into or delivered for introduction into interstate commerce since it was sold for investigational purposes and was not being so used, and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 2–7–61. Default—delivered to the Food and Drug Administration.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

6544. Penicillin G tablets. (F.D.C. No. 45448. S. No. 26–857 R.)

QUANTITY: 43 100-tablet btls. at Los Angeles, Calif.

SHIPPED: 8–16–60, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LIBELED: 3–8–61, S. Dist. Calif.

CHARGE: 502(l)—when shipped, the article was composed in whole or in part of penicillin and was from a batch with respect to which a certificate or release had not been issued pursuant to 507 in that effective exemption or supplemental certification of the batch had not been obtained.

DISPOSITION: 3–30–61. Default—destruction.

DRUG FOR VETERINARY USE

6545. Dihydrostreptomycin tablets. (F.D.C. No. 45511. S. No. 61–028 R.)

QUANTITY: 3 drums, each containing 11,500 tablets, 1 drum containing 600 tablets, and 125 100-tablet btls., at St. Joseph, Mo., in possession of United Pharmacal Co., Inc.

SHIPPED: 7–30–58, from Buffalo, N.Y.

LABEL IN PART: (Drum) "Special Formula S/F Tablets—Uncoated Expiration Date July 1960 7–30–58 Manufactured for United Pharmacal Co. * * * St. Joseph, Missouri * * * Formula No. 159,700 Lot 1 UPC–1 * * * Each tablet contains: Dihydrostreptomycin Base (as Sulfate) 50 mg. Pectin 37 mg. Kaolin 417 mg. Hydrated Alumina Powder 126 mg. For treatment of gastroenteritis, enteritis and diarrhea (due to dihydrostreptomycin sensitive organisms) in cats and dogs" and (btl.) "UPCO * * * 'K.P.S.–630' Dihydrostreptomycin Sulfate with Kaolin, Alumina, and Pectin. Each tablet contains * * * Distributed by United Pharmacal Company, St. Joseph, Mo."

RESULTS OF INVESTIGATION: The article in the bottles was repacked and labeled by the dealer after shipment as described above.

LIBELED: On or about 3–16–61, W. Dist. Mo.

CHARGE: 502(l)—while held for sale, the article purported to be and was represented as a drug composed in part of dihydrostreptomycin and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 5–5–61. Default—destruction.