

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.)

QUANTITY: 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."