SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6541–6580

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man and contained a quantity of peyote or other named narcotic or hypnotic substance, or a chemical derivative of such substance, which derivative had been by regulations designated as habit forming, and its label failed to bear the name, and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(l), the article was composed wholly or in part of a kind of penicillin, or streptomycin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6541. Dexules timed disintegration capsules. (F.D.C. No. 44602. S. No. 8–880 R.)

QUANTITY: 6 display ctns., containing 12 btls. each, at Buffalo, N.Y.

SHIPPED: 4–15–60, from Hoboken, N.J.

LABEL IN PART: (Btl.) "30 Timed Disintegration Dexules All Day Appetite Suppressant * * * Approved Pharmaceutical Corp. Syracuse * * * New York

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."