SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6661–6700

Adulteration, Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below, that which it purported to possess; Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear, 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(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not labeled as prescribed therein; Section 502 (i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended, or suggested in the labeling thereof; and Section 502(l), the article was composed wholly or in part of a kind of penicillin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6661. Hypodermic syringes. (F.D.C. No. 45536. S. No. 3–211 R.)

QUANTITY: 7 ctnd. syringes at Atlanta, Ga.

SHIPPED: 1–9–61, from Long Island City, N.Y., by Propper Mfg. Co., Inc.

LABEL IN PART: (Syringe) "2 cc. * * * 40 Units * * * 80 Units * * * Propper Trophy" and (ctn.) "One 2 cc. Propper TROPHY Hypodermic Syringe Short Insulin 40/80 Propper Mfg. Co., Inc."

ACCOMPANYING LABELING: (Insert leaflet) "Certificate of Accuracy Propper Trophy Hypodermic Syringes. This syringe is made in Japan to conform to standards of accuracy described in Federal Specifications. * * * Propper Mfg. Co., Inc."

RESULTS OF INVESTIGATION: Examination showed the article to be a conventional insulin-type glass hypodermic syringe of 2 cc. size, with graduations marked on one side with a scale reading up to a maximum of 40 units, and marked on the opposite side with a scale reading up to a maximum of 80 units. The syringe was not marked to show that the first scale was to be used for administering insulin from a solution having a potency of 20 units per cubic centimeter, and that the other scale was to be used for administering insulin from a solution having a potency of 40 units per cubic centimeter.

LIBELED: 3–28–61, N. Dist. Ga.

CHARGE: 502(f)(1)—when shipped, the labeling (syringe) failed to bear adequate directions for use of the article as a means of self-administration of insulin; and 502(j)—the article was dangerous to health when used according to the dosage scales inscribed on its label.

DISPOSITION: 6–19–61. Default—destruction.

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

6662. Penicillin G potassium tablets. (F.D.C. No. 45896. S. Nos. 83–301/23 R.)

QUANTITY: 578 100-tablet btls. of 50,000 unit *penicillin G potassium tablets* and various drums, cartons and bottles of 50,000, 100,000, 200,000, 250,000, 400,000, and 500,000 unit tablets of penicillin G potassium, totaling 3,369,913 tablets in all, at New York, N.Y., in possession of Pure Laboratories, Inc.

SHIPPED: During 1960 and 1961, from various manufacturers in the State of New York.

RESULTS OF INVESTIGATION: The tablets were repacked by the dealer from *penicillin G potassium tablets* received from various manufacturers who manufactured the tablets from penicillin powder received in interstate commerce.

LIBELED: 5–22–61, S. Dist. N.Y.

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

DISPOSITION: 6–27–61. Consent—claimed by Pure Laboratories, Inc., and released to be brought into compliance with the law.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6663. Amphetamine sulfate tablets and dextro-amphetamine sulfate tablets. (F.D.C. No. 46116. S. Nos. 31–132/6 R.)

QUANTITY: 2 50,000-tablet drums, 1 btl. of 1,498 tablets, 1 btl. of 2,497 tablets, and 1 can of 6,445 tablets of amphetamine sulfate; 1 btl. of 365 tablets of dextro-amphetamine sulfate, at Mobile, Ala.

SHIPPED: Prior to 7–10–61, from Woodside, Long Island, N.Y., and thereafter transported from Moss Point, Miss., to Mobile, Ala., by Jonathan Mead.

LIBELED: 7–17–61, S. Dist. Ala.

CHARGE: 502(f)(1)—while held for sale by Jonathan Mead, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were prescription drugs which were not and would not be lawfully used nor lawfully dispensed by a practitioner licensed by law to administer such drugs in the course of his professional practice.

DISPOSITION: 8–16–61. Default—destruction.

6664. Sea brine. (F.D.C. No. 45845. S. No. 54–441 R.)

QUANTITY: 8 cases of 24 8-oz. btls. each at Minneapolis, Minn.

SHIPPED: 1–18–61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

*See also No. 6661.