SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5701–5740

Adulteration, Section 501(a)(1), the article consisted in part of a filthy substance; Section 501(a)(2), the article had been prepared, packed, or held under insanitary conditions; 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 or National Formulary) and its strength differed from, and its quality and purity fell below, 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 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 contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative; 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) the drug was fabricated from two or more ingredients, and its label failed to bear 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; and (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 or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b)(4), the article was subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and, in another case, the article bore the caution statement quoted above, but the article was not one to which Section 503(b)(1) applies.

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.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5701. Vitamin capsules. (F.D.C. No. 41851. S. No. 35–361 P.)

QUANTITY: 171 btls. at Philadelphia, Pa.

SHIPPED: The capsules were shipped in bulk, on 3–19–58, from Detroit, Mich.

LABEL IN PART: (Btl.) "500 Capsules List No. 100 VITAL B-C THERAPEUTIC FORMULA Each capsule contains 25,000 units of Vitamin A * * * 1 mg. of Vitamin B_1 * * * 5 mg. Ascorbic Acid * * * Prepared for Daniel Cooperman."

ACCOMPANYING LABELING: Folder entitled "Directions for the use of Vital B-C Capsules.", reading in part: "Three capsules four times a day before meals and at bedtime."

RESULTS OF INVESTIGATION: The capsules in the above-described shipment were, after arrival at Philadelphia, Pa., repackaged into bottles and labeled as described above.

LIBELED: 6–4–58, E. Dist. Pa.

CHARGE: 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for acne; and 502(j)—the article, because of its content of vitamin A, was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Three capsules four times a day before meals and at bedtime," which were the recommended directions contained in the folder entitled "Directions for the use of Vital B-C Capsules."

DISPOSITION: 8–29–58. Consent—claimed by Daniel Cooperman Pharmacy, Philadelphia, Pa., and relabeled.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5702. Clarimycin (3 seizure actions). (F.D.C. Nos. 41607, 41608, 41609, 41610, 41677. S. Nos. 8–341 P, 11–763 P, 11–866/7 P, 16–789 P.)

QUANTITY: 1,912 display cards, each containing 1 btl., at Highland Park and Detroit, Mich.; 33 display cartons, each containing 6 btls., at Cleveland, Ohio; and 297 btls., at Pittsburgh, Pa.

SHIPPED: Between 12–12–57 and 2–24–58, from Jersey City, N.J., by Meritt Corp.

LABEL IN PART: (Btl.) "Contents 5 drams Clarimycin Anti-biotic Acne Lotion * * * Active Ingredients: Neomycin Sulphate, Allantoin."

LIBELED: Between 3–3–58 and 4–23–58, E. Dist. Mich., W. Dist. Pa., and N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling of the article in the Cleveland and Pittsburgh lots contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, and stubborn skin infections; and 505(a)—the article, in all lots, was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: Between 8–21–58 and 10–21–58. Consent—destruction.

5703. Meprobamate tablets. (F.D.C. No. 41895. S. No. 4–401 P.)

QUANTITY: 1 drum containing 25,000 tablets at Richmond, Va.

SHIPPED: 5–6–58, from Brooklyn, N.Y., by Hall Pharmacal Co., Inc.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 400 milligrams of meprobamate per tablet.

LIBELED: 6–27–58, E. Dist. Va.

CHARGE: 502(a)—the statement on the drum label "For Investigational and Export Use Only" was false and misleading as applied to the article; and 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.