*SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5481–5500*

*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, and its quality and purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess; and 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), 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 and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol, and the name, and quantity or proportion of atropine, hyoscine, and hyoscyamine contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; 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 packaged as prescribed therein; Section 502(i)(3), the article was a drug 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; Section 502(l)(2), the article was, or purported to be, or was represented as, a drug composed wholly or partly of penicillin; and it was from a batch with respect to which a certificate issued pursuant to Section 507 was not in effect; 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.

## DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

**5481. Castor oil and hydrogen peroxide solution.** (F.D.C. No. 40474. S. Nos. 24–038 M, 50–722 M, 50–821 M.)

INFORMATION FILED: 2–10–58, S. Dist. Calif., against Norton Chemical Co., Inc., t/a Norton Products Co., Los Angeles, Calif.

ALLEGED VIOLATION: During the year of 1956, while a quantity of turpentine was being held for sale at Los Angeles, Calif., after shipment in interstate commerce, the defendant caused the turpentine to be repacked into bottles labeled,

in part, as "Norco Castor Oil," which act resulted in the article being adulterated and misbranded as described below.

In addition, between 1–15–57 and 1–24–57, the defendant caused to be introduced into interstate commerce, at Los Angeles, Calif., for delivery to Phoenix, Ariz., a quantity of an article labeled, in part, "Enterprise Solution of Hydrogen Peroxide U.S.P. 10 Volume ¼ Lb. (4 Oz. Av.) Enterprise Drug & Chemical Company Los Angeles, Calif.," which was adulterated as described below.

CHARGE: *Castor oil.* 501(d)(2)—turpentine had been substituted for *castor oil*, which the article was represented to be; 502(a)—the label statement "Castor Oil" was false and misleading; 502(i)(3)—the article was turpentine, and it was offered for sale under the name of another drug, namely, *castor oil;* and 502(j)—the article was dangerous to health when used in the dosage prescribed, recommended, and suggested in its labeling, namely, "Dose: Children, one to two teaspoonfuls. Adults, one to two tablespoonfuls."

*Hydrogen peroxide solution.* 501(b)—the quality and purity of the article fell below the standard for *hydrogen peroxide solution* set forth in the United States Pharmacopeia since the article contained isopropyl alcohol, which is not permitted in such standard.

PLEA: Guilty.

DISPOSITION: 4–21–58. $1,500 fine.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**5482. Royal jelly capsules and royal jelly cream (2 seizure actions).** (F.D.C. Nos. 41270, 41271. S. Nos. 73–114/7 M.)

QUANTITY: 71 btls., each containing 18 50-mg. capsules; 50 btls., each containing 60 50-mg. capsules; 24 btls., each containing 100 50-mg. capsules; 41 btls., each containing 15 75-mg. capsules; 30 btls., each containing 30 75-mg. capsules; 19 btls., each containing 15 125-mg. capsules; and 20 btls., each containing 30 125-mg. capsules, of *royal jelly;* and 43 1-oz. jars and 16 2-oz. jars of *royal jelly cream*, at Denver, Colo.

SHIPPED: Between 8–30–57 and 10–24–57, from Bayonne, N.J., by Continental Honey Products, Inc.

LABEL IN PART: (Btl.) "Imperial Royal Jelly Capsules * * * Continental Honey Products, Inc., Dist. N.Y."; (jar) "Imperial Royal Jelly Cream Continental Honey Products, Inc., Dist. N.Y." and "Imperial Royal Jelly Cream Queen Bee Royal Jelly and Lecithin."

ACCOMPANYING LABELING: Circulars entitled "Facing New Horizons With Imperial Royal Jelly."

LIBELED: 12–12–57, Dist. Colo.

CHARGE: 502(a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that the articles would cure the ill, aid in the treatment of cancer, lengthen life, be beneficial in sexual deficiencies and ailments, be effective in the treatment of diseases of children, and increase intellectual activity; and that they were effective in treating liver ailments, arthritis, leukemia, and ulcers; and 505(a)—the articles were new drugs within the meaning of the law, and applications filed pursuant to the law were not effective with respect to the drugs.

DISPOSITION: 2–12–58. Default—a portion of the articles was delivered to the Food and Drug Administration, and the remainder was destroyed.