

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN
VIOLATIONS REPORTED IN D.D.N.J. 5981-6000**

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 Pharmacopoeia), and its strength differed from 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 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(e) (2), the article was a drug not designated solely by a name recognized in an official compendium, and it was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each 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 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(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; 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**

DRUG FOR HUMAN USE

5981. Alcorem. (F.D.C. No. 41476. S. Nos. 13-268/9 P.)

QUANTITY: 260 btl. of fluid extract of ipecac root and 264 kits, each containing 1 btl. of fluid extract of ipecac root and 1 btl. of vitamin capsules at Chicago, Ill., in possession of Midwest Health Aids.

SHIPPED: (Fluid extract of ipecac root), 9-11-57 and 2-12-58, from New York, N.Y., and (vitamin capsules), from Chicago, Ill., on an unknown date.

LABEL IN PART: (Kit) "Alcorem Kit * * * Contains bottle of Alcorem with dispenser, 21 Pinkies for Vitamin Deficiency, Weight Chart and Complete Instructions for home use," (btl.) "½ Ounce ALCOREM Emetic Brand of Fluid Extract of Ipecac - Alcohol 30%" and "21 Capsules Special PINKIES Capsules Natural Fortified Vitamin B Complex * * * Each Capsule Contains: Vitamin B-1 1,000 U.S.P. Units Vitamin B-2 3,000 Micrograms Vitamin B-6 125 Micrograms Calcium Pantothenate 3,000 Micrograms Niacin Amide 10,000 Micrograms."

ACCOMPANYING LABELING: Circulars entitled "Instructions For the Use of Alcorem for the Relief of Drunkenness," "Alcorem Weight Chart for Men and Women," "Housewife Praises Pinkies," "Important Read Carefully," "Special Quick Action Order Blank," and "Live Longer."

RESULTS OF INVESTIGATION: The fluid extract and the capsules had been repackaged into kits by the dealer from bulk stock which had been shipped as described above. The circulars were printed locally on order of the dealer.

LIBELED: 3-19-58, N. Dist. Ill.; amended libel 5-27-58.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for drunkenness; 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling; and 503(b)(4)—the article was a drug to which 503(b)(1) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-1-59. Default—destruction.

DRUG FOR VETERINARY USE

5982. Giles veterinary medicine. (F.D.C. No. 43171. S. Nos. 58-465/6 P.)

QUANTITY: 4 1-gal. cans and 4 1-qt. btls. at Denver Colo.

SHIPPED: (Cans) 5-5-58, and (btls.), some time prior to 1955, from Oak Park, Ill., by Giles Remedy Co.

LABEL IN PART: (Can and btl.) "The Great 'Giles' Veterinary Medicine Oleum Lini-Aether Sulphuricus Ten Per Cent — Camphora * * * A Veterinary Compound for Internal and External Use * * * prepared for Horses and Cattle * * * Made only by Giles Remedy Co. of Illinois."

RESULTS OF INVESTIGATION: Examination showed that the article was a yellow-colored, oily liquid, having odors of ether, camphor, and linseed oil.

LIBELED: 6-10-59, Dist. Colo.

CHARGE: 502(a)—the label of the article contained false and misleading representations and suggestions that the article was an adequate and effective treatment in horses and cattle for preventing or correcting "layups," loss of appetite and stamina, chills, colds, colic, and bloat, and for preventing and relieving shipping fever, and ailments caused by exposure; 502(e)(2)—the label of the article failed to bear the common or usual name of each of the active ingredients contained therein; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use where its use may be dangerous to health and against unsafe dosage and methods and duration of administration or application; and 502(j)—the article was dangerous to health when used in the eyes, and internally, as directed in its labeling.

DISPOSITION: 7-22-59. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5983. Bee Royale Capsules. (F.D.C. No. 39873. S. No. 50-245 M.)

QUANTITY: 42 jars at Cambridge, Mass., in possession of Nature Food Centres, Inc.

SHIPPED: 1-23-57, from New York, N.Y.

LABEL IN PART: "Bee Royale Capsules * * * Contents 30 Capsules Each Capsule Contains: Royal Jelly 5 mg. Thiamine Hcl 10 mg. Pyridoxin 0.5 mg. Nucleic Acid 2 mg. *Calcium Pantothenate 10 mg. *Biotin 0.5 mcg. Directions: Adults: One Capsule daily with principal meal."

LIBELED: 2-13-57, Dist. Mass.; amended libel 4-10-57.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for delaying old age, restoring sexual vigor, rejuvenating impaired glands, restoring vigor, eliminating a chronic feeling of tiredness, growing hair, restoring youthful sex functions to women in meno-