

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 5461-5480**

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; and 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.

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(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, including the proportion of alcohol contained therein; Section 502(f) (1), the labeling of the article failed to bear adequate directions for use; Section 502(f) (2), the labeling of the article failed to bear 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(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; Section 502(l), the article was, or purported to be, or was represented as, a drug composed partly of chlortetracycline, bacitracin, or any derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b) (4), the article was subject to Section 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**

5461. Coron tablets. (F.D.C. No. 40677. S. No. 53-624 M.)

QUANTITY: 368 btl. at Bellaire, Tex.

SHIPPED: 7-31-57, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

LABEL IN PART: "100 No. 501 Tablets Coron Each Tablet contains: Cobalt Gluconate 25 mg. Ferrous Gluconate 200 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 2.91 mg. of cobalt (equivalent to 24 mg. of cobalt gluconate) per tablet.

LIBELED: 10-3-57, S. Dist. Tex.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Dosage: One or two tablets after each

meal"; and 503(b)(4)—the article was a drug subject to 503(b)(1)(B), and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-17-57. Consent—claimed by Savage Laboratories, Inc., Belaire, Tex., and relabeled.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5462. Pega Palo vine. (F.D.C. No. 40676. S. No. 81-078 M.)

QUANTITY: 9 pieces of vine packaged separately in Pliofilm bags at Washington, D.C.

SHIPPED: 1-15-57, from Chicago, Ill., by A-1 Importing Co.

LABEL IN PART: (Bag) "Pega Palo Vine."

ACCOMPANYING LABELING: Reprints of an article, from the January 1957 issue of "Confidential" magazine, entitled "The Vine That Makes You Virile."

RESULTS OF INVESTIGATION: Examination showed that the article consisted of pieces of fibrous, woody material, 4 to 6 inches in length, which obviously were part of a plant stem.

LIBELED: 10-7-57, Dist. Columbia.

CHARGE: 502(f)(1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the article was intended; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 11-1-57 and 11-26-57. Default—delivered to the Food and Drug Administration.

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

5463. Achromycin capsules. (F.D.C. No. 40513 S. No. 68-277 M.)

QUANTITY: 2 jars containing about 123 capsules at Ridgefield, N.J.

SHIPPED: 3-7-57 and 4-4-57, from New York, N.Y., by Re-Ly-On Drug Co.

RESULTS OF INVESTIGATION: The jars containing the article were shipped unlabeled, and after receipt of the article, one of the jars was labeled with the words "Achromycin V."

LIBELED: 7-15-57, Dist. N.J.

CHARGE: 502(b)(1) and (2)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e)(1)—the label of the article failed to bear the common or usual name of the article; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and the labeling failed to bear the information necessary to exempt the article from such requirement; 502(1)—the article contained tetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law; and 503(b)(4), the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9-4-57. Default—destruction.