

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.