

Lackzoom's New Blue Label Hi-B Complex Tablets.—"Nervousness Irritability. Loss of Pep Run Down Lackzoom Hi-B Complex Formerly * * * distinguished as the nerve and brain-food vitamin * * * Nervousness, loss of energy, constipation, indigestion, and neuritis are among the symptoms that may indicate Vitamin-B deficiency."

The above articles were misbranded while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the 14,000-tablet lot of the *Special Capsules* failed to bear adequate directions for use for the purposes for which the tablets were intended since the labeling failed to bear adequate directions for use for the conditions and diseases for which the tablets were offered in the booklet entitled "Lackzoom Hi-Lites," namely, nervousness, irritability, loss of pep, run-down condition, loss of energy, constipation, indigestion, and neuritis. The 14,000-tablet lot of the *Special Capsules* was misbranded when introduced into and while in interstate commerce.

The 25,000-tablet lot in the drum labeled "Special Tablets * * * Yeast Amino Acids" was alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 26, 1949. David B. Shakarian, claimant, having admitted that the allegations of the libel were true, judgment was entered ordering that the products be released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF THE PRESENCE OF A HABIT-FORMING NARCOTIC WITHOUT WARNING STATEMENT*

2916. Misbranding of Mothersill's Airsick Remedy and Mothersill's Seasick Remedy. U. S. v. 45 dozen Packages, etc. (F. D. C. No. 21680. Sample Nos. 43647-H, 43648-H, 71033-H.)

LIBEL FILED: November 26, 1946, Southern District of California; amended libel filed May 10, 1949.

ALLEGED SHIPMENT: On or about September 3 and 23 and October 11 and 14, 1946, by F. T. Hopkins & Son, from New York, N. Y.

PRODUCT: 45 dozen packages of *Mothersill's Airsick Remedy* and 272 dozen packages of *Mothersill's Seasick Remedy* at Los Angeles, Calif.

LABEL, IN PART: "Mothersill's Airsick Remedy * * * Each capsule contains 1½ grains of trichlor-tertiary-butyl-alcohol, a chloroform derivative, ¼₄₀₀ grain hyoscine hydrobromide, caffeine and suitable flavorings" and "Mothersill's Seasick Remedy * * * Each Capsule contains 2 grains of trichlor-tertiary-butyl-alcohol, a chloroform derivative, ¼₄₀₀ grain hyoscine hydrobromide, caffeine and suitable flavorings."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Guaranteed not to contain morphine, chloral, cocaine, opium, coal tar products or their derivatives," which appeared on the label of both articles, was misleading since it suggested and created the impression that the articles contained no injurious drugs, whereas the articles contained hyoscine hydrobromide and chlorobutanol, which are capable of producing injurious effects.

*See also No. 2912.

Further misbranding, Section 502 (c), the information required by law to appear on the label was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render such information likely to be read and understood by the ordinary individual under customary conditions of purchase and use since the statement of the quantity of the contents of the package appeared inconspicuously placed and in small type; since the name of the habit-forming ingredient, chlorobutanol, was declared by the name "trichlor-tertiary-butyl-alcohol," a designation which is not likely to be understood by the ordinary individual under customary conditions of purchase and use, and the quantity or proportion thereof, namely, 1½ grains and 2 grains, respectively, appeared inconspicuously in small type; and since the name and quantity or proportion of the ingredient, hyoscine hydrobromide, a derivative of hyoscine, and the name of the active ingredient, caffeine, appeared inconspicuously in small type on the label.

Further misbranding, Section 502 (d), the articles were drugs for use by man and contained chlorobutanol, a chemical derivative of chloral, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as habit forming; and the labels of the articles failed to bear immediately following the name of the article, the common or usual name of the article and in juxtaposition therewith, the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear such adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the articles contained hyoscine hydrobromide; and the labeling of the articles failed to warn that use of the articles should be discontinued if dizziness or blurring of vision occurred, and that use in excess of the recommended dosage may cause serious nervous disturbance.

DISPOSITION: F. T. Hopkins & Son appeared as claimant and, in accordance with the agreement of the parties, the libel proceedings were ordered removed to the District of New Jersey for trial. On November 29, 1949, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be destroyed.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2917. Adulteration of P & V Low Mallow (crude drug). U. S. v. 2 Drums
* * * (F. D. C. No. 27669. Sample No. 14195-K.)

LIBEL FILED: August 12, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 4, 1948, from Jersey City, N. J.

PRODUCT: 2 50-pound drums of *P & V Low Mallow* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 2, 1949. Default decree of condemnation and destruction.