exempting the drug from bearing adequate directions for use in its labeling; 502 (l)—the article was composed wholly or partly of tetracycline, a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law; and 503 (b) (4)—the article was subject to the provisions of 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 4–14–55. Default—delivered to the Food and Drug Administration.

4744. Achromycin capsules and terramycin capsules. (F. D. C. No. 37927. S. Nos. 21–805/6 M.)

QUANTITY: 1 300-capsule btl. of *Achromycin capsules* and 2 250-capsule btls. of *terramycin capsules* at Philadelphia, Pa.

SHIPPED: 8–4–54, from Franklin Square, Long Island, N. Y., by Economy Buying Service, Inc.

RESULTS OF INVESTIGATION: Analyses showed that the *Achromycin capsules* contained 250 milligrams of tetracycline hydrochloride per capsule and that the *terramycin capsules* contained 250 milligrams of oxytetracycline hydrochloride per capsule.

LIBELED: 4–7–55, E. Dist. Pa.

CHARGE: 502 (b) (1)—the labels of the articles when shipped failed to bear the name and place of business of the manufacturer, packer, or distributor; 502 (f) (1)—the labels of the articles failed to bear adequate directions for use; 503 (b) (4)—the articles were subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 502 (l)—the *Achromycin capsules* purported to be and were represented as a drug composed wholly or partly of a derivative of chlortetracycline, and the capsules were not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: 7–27–55. Default—destruction.

4745. Nasal hydrocortisone, nasal solution, and Aureomycin capsules. (F. D. C. No. 37954. S. Nos. 13–661/3 M.)

QUANTITY: 7 ½-oz. vials of *nasal hydrocortisone*, 7 ½-oz. vials of *nasal solution*, and 1 100-capsule btl. of *Aureomycin capsules*, at Philadelphia, Pa.

SHIPPED: During January 1955, from Franklin Square, Long Island, N. Y., by Carl H. Kaplan, t/a Economy Buying Service, Inc.

LABEL IN PART: (Vial) "'Vasocort' Hydrocortisone Nasal" and "Drilitol Nasal Solution"; (btl.) "100 * * * Lederle Aureomycin Hydrochloride Crystalline Capsules 250 mg."

RESULTS OF INVESTIGATION: The *Aureomycin capsules* were shipped in a bulk container and were placed by the shipper in the above-described bottle when he delivered the capsules to the consignee, who supplied the bottle.

Partial analyses disclosed that the *nasal hydrocortisone* contained hydrocortisone and Paredrine; that the *nasal solution* contained thenylpyramine hydrochloride, Paredrine, and polymyxin B; and that the *Aureomycin capsules* contained about 155 milligrams of chlortetracycline per capsule.

LIBELED: 4–29–55, E. Dist. Pa.; amended libel filed 6–2–55.

CHARGE: 501 (b)—the *Aureomycin capsules* purported to be and were represented as a drug, the name of which is recognized in the United States Pharma-

copeia, and the strength of the article when shipped and while held for sale differed from the official standard;

502 (b) (1) and (2)—the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents;

502 (e) (2)—the labels of the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear the common or usual name of each active ingredient;

502 (f) (1)—the labeling of the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear adequate directions for use;

502 (f) (2)—the labeling of the *nasal solution* when shipped failed to bear such adequate warnings against unsafe methods and duration of administration, in such manner and form, as are necessary for the protection of users;

502 (l)—when shipped and while held for sale, the *Aureomycin capsules* purported to be and were represented as a drug composed wholly or partly of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law;

503 (b) (4)—the *nasal hydrocortisone* was a drug subject to 503 (b) (1), and its label when shipped failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–27–55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

4746. Glutamic acid tablets and wheat germ oil capsules. (F. D. C. No. 37655. S. Nos. 9–323 M, 9–325/6 M.)

QUANTITY: 24 100-tablet btls. of *glutamic acid tablets* and 44 400-capsule btls. and 36 100-capsule btls. of *wheat germ oil capsules* at West Los Angeles, Calif.

SHIPPED: Between 4–23–54 and 11–23–54, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Btl.) "100 Tablets Glutamic Acid 7.7 gr. Use: Anticonvulsant in petit mal. Caution: Federal law prohibits dispensing without a prescription. Dose: Eight tablets 3 times daily" and "Wheat Germ Oil Each capsule contains Wheat Germ Oil . . . 3 Minums (A refined cold pressed oil from Wheat Embryo.) The need for Wheat Germ Oil in human nutrition has been established. Dose: 1 or 2 capsules daily or prescribed by a physician. Caution: Federal law prohibits dispensing without a prescription."

LIBELED: 2–14–55, S. Dist. Calif.

CHARGE: *Glutamic acid tablets.* 502 (a)—the statement on the label of the article when shipped contained false and misleading representations that the article when taken as directed was effective as an anti-convulsant in petit mal; and 502 (f) (1)—the article failed to bear adequate directions for use, and it was not exempt from such requirement because of the label statement "Caution: Federal law prohibits dispensing without a prescription" since the article was not in the possession of a firm or person lawfully entitled to dispense prescription drugs.

Wheat germ oil capsules. 503 (b) (4)—the article was not a drug subject to 503 (b) (1), and its label when shipped bore the statement "Caution: Federal law prohibits dispensing without a prescription."

The *wheat germ oil capsules* were alleged also to be misbranded under the

*See also Nos. 4742–4745.