

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.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM
OFFICIAL OR OWN STANDARDS**

2918. Adulteration and misbranding of chorionic gonadotropic hormone. U. S. v. 54 Cartons, etc. (F. D. C. No. 27279. Sample Nos. 11292-K, 11293-K.)

LIBEL FILED: June 6, 1949, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 14 and February 20, 1948, from Philadelphia, Pa.

PRODUCT: 54 cartons and 75 cartons, each carton containing 1 unlabeled vial, of *chorionic gonadotropic hormone* at Richmond Hill, N. Y. Each lot was accompanied by sticker labels on the shipping cartons which represented that the 54-carton lot contained 500 International Units of *chorionic gonadotropic hormone* per vial and that the 75-carton lot contained 1,000 International Units of *chorionic gonadotropic hormone* per vial. The vials and the 1-vial cartons were labeled after shipment in interstate commerce.

Analyses showed that the product (both lots) contained less than half of the declared amounts of *chorionic gonadotropic hormone*.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to the article, which contained less than half of the declared amounts of *chorionic gonadotropic hormone*: (54-carton lot) "Each 1 cc will contain 500 international units of chorionic gonadotropic hormone when 10 cc of triple distilled water is added to this vial" and (75-carton lot) "Each 1 cc will contain 100 international units of chorionic gonadotropic hormone when 10 cc of triple distilled water is added to this vial."

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 9, 1949. Default decree of condemnation and destruction.

2919. Adulteration and misbranding of surgical dressings. U. S. v. 126 Packages, etc. (F. D. C. No. 28341. Sample Nos. 33682-K, 33683-K.)

LIBEL FILED: November 22, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about October 4, 1949, by Surgical Dressings, Inc., from Boston, Mass.

PRODUCT: 126 packages, each containing 1 roll, of bandage 1½" x 12" and 114 packages, each containing 1 roll, of bandage 2" x 24" at Sacramento, Calif. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "Sterilastic Dressing Bandage."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements appearing on the package labels of the article were false and misleading as applied to an article which was not sterile: (1½" x 12" size) "Sterilastic * * * First Aid Wound Protection * * * Both the Sterilastic and the Gauze in this Package have been sterilized * * * Surgical Dressing" and (2" x 24" size) "Sterilastic First Aid Bandage * * * Surgical Dressing * * * The gauze supplied with Sterilastic may be used in an emergency."

DISPOSITION: December 8, 1949. Default decree of condemnation and destruction.