

the treatment of scabies in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "Directions Apply with cotton or gauze on to affected parts."

*Sulfur ointment.* Misbranding, Section 502 (f) (1), the article was offered for the treatment of scabies, and the directions for use in such treatment, "Directions Apply directly to affected parts," appearing on the label of the article, were not adequate directions for use in the treatment of scabies.

**DISPOSITION:** April 18, 1946. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$50 on each of counts 1 through 5 of the information and suspended sentence on count 6, which related to the misbranding of the *sulfur ointment*.

### NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

**1853. Adulteration and misbranding of Bacratrycin Antibiotic Ointment. U. S. v. 32 Jars of Bacratrycin Antibiotic Ointment. Default decree of condemnation and destruction.** (F. D. C. No. 17335. Sample No. 6350-H.)

**LIBEL FILED:** September 11, 1945, Southern District of New York.

**ALLEGED SHIPMENT:** On or about July 26, 1945, by the Wallace Laboratories, Inc., from New Brunswick, N. J.

**PRODUCT:** 32 jars of *Bacratrycin Antibiotic Ointment* at New York, N. Y.

**NATURE OF CHARGE:** Section 505, the article was a new drug in that its composition was such that, as a result of investigations to determine its safety for use, it had become recognized as safe for use under the conditions prescribed, recommended, and suggested in its labeling, but it had not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; it was not, prior to June 25, 1938, subject to the Food & Drugs Act of 1906; and no application had been filed pursuant to the law which was effective with respect to the article.

Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented by the following statements to possess, since the article contained no significant proportion, if any, of gramicidin and therefore no significant proportion, if any, of tyrothricin: (Labels) "Bacratrycin Antibiotic Ointment containing Tyrothricin Each gram contains 0.30 mg. Tyrothricin (gramicidin and tyrocidin)"; and (enclosed circular) "Ointment containing Tyrothricin Bacratrycin \* \* \* utilizing the gram-positive bacteria-killing properties of tyrothricin \* \* \* employing both fractions of tyrothricin (gramicidin \* \* \*) Activity: Tyrothricin, the active ingredient in Bacratrycin \* \* \* Potency: Each gram of Bacratrycin contains 0.30 mg. tyrothricin."

Misbranding, Section 502 (a), certain statements in the circular enclosed in each package of the article were false and misleading since they represented, suggested, and implied that the article contained a significant proportion of gramicidin; that it exhibited an appreciable antibiotic activity such as would characterize a gramicidin-containing ointment; and that the article would be effective in the treatment of impetigo, pustular dermatitis, infective dermatitis, various types of ulcers, abscesses, infected wounds, and similar surface lesions caused or complicated by streptococci, staphylococci, pneumococci, or other gram-positive organisms. The article contained no significant proportion, if any, of gramicidin; it exhibited no appreciable antibiotic activity such as would characterize a gramicidin-containing ointment; and it would not be effective in the treatment of the conditions stated.

**DISPOSITION:** September 13, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

### DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

**1854. Action to enjoin and restrain the misbranding of drugs in interstate commerce. U. S. v. I. James Hendelberg (Southeast Pharmacy). Injunction granted.** (Inj. No. 138.)

**COMPLAINT FILED:** March 29, 1946, District of Columbia, against I. James Hendelberg, trading as the Southeast Pharmacy, Washington, D. C.

\*See also Nos. 1851, 1852.

**NATURE OF CHARGE:** That prior to December 20, 1945, and until the time the complaint was filed, the defendant had been holding quantities of *sulfadiazine tablets*, *sulfathiazole tablets*, and *Nembutal (pentobarbital sodium) Capsules* which had been shipped in interstate commerce in containers labeled in accordance with the law; and that within the period of December 20, 1945, to January 17, 1946, the defendant had repacked a portion of the drugs into unlabeled containers, which act of repacking resulted in the misbranding of the drugs in the following respects: Section 502 (b) (1), the drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they failed to bear labels containing accurate statements of the quantity of the contents; Section 502 (e), they failed to bear labels declaring their common or usual name; Section 502 (d), the *Nembutal Capsules* failed to bear a label containing the name and quantity or proportion of barbituric acid contained in the product and, in juxtaposition therewith, the statement, "Warning—may be habit forming"; and, Section 502 (f) (2), the drugs were without labeling bearing adequate warnings against use in those pathological conditions, or by children, wherein the use of the drug might be dangerous to health, or against unsafe dosage or methods or duration of administration.

The complaint charged further that the drugs were made for use by or under the supervision of physicians or dentists and were exempted from the requirements of the law that their labeling bear adequate directions for use; but that the acts of the defendant had caused the exemption to expire, resulting in the misbranding of the drug in violation of Section 502 (f) (1) for failure to bear such directions for use.

**PRAYER OF COMPLAINT:** That a temporary restraining order issue; that, after due hearing, a preliminary injunction be granted; and that, after due proceedings, the preliminary injunction be made permanent.

**DISPOSITION:** April 5, 1946. The defendant having consented to the entry of a decree, the court entered an order permanently enjoining the defendant from the commission of the acts complained of.

**1855. Misbranding of sulfathiazole tablets. U. S. v. Emmons Blane Coffee (Coffee's Drug Store). Plea of guilty. Defendant fined \$500 and placed on probation for 2 years. (F. D. C. No. 16597. Sample Nos. 34410-F, 64238-F.)**

**INFORMATION FILED:** January 2, 1946, Middle District of Georgia, against Emmons Blane Coffee, trading as Coffee's Drug Store, Columbus, Ga.

**INTERSTATE SHIPMENT:** On or about November 8, 1944, from Kalamazoo, Mich.

**LABEL, IN PART:** "1000 Compressed Tablets Sulfathiazole Upjohn 7 7/10 Grains (0.5 Gm.) 2-Sulfanilyl Aminoethiazole \* \* \* Caution: To be used only by or on the prescription of a physician."

**NATURE OF CHARGE:** On or about November 22 and December 14, 1944, the defendant removed a number of *sulfathiazole tablets* from the bottles labeled as above, repacked them into unlabeled boxes, and sold them without a prescription.

The information charged further that the acts of the defendant resulted in the misbranding of the drug in the following respects: Section 502 (f) (1), the boxes containing the drug bore no labeling containing directions for use; and, Section 502 (f) (2), they bore no labeling containing warnings against use in those pathological conditions wherein use of the drug might be dangerous to health, or against unsafe dosage and methods and duration of administration.

**DISPOSITION:** March 4, 1946. A plea of guilty having been entered, the defendant was sentenced to pay a fine of \$500 on count 1 of the information and to serve 2 years on probation on all counts, on condition that he pay the fine.

**1856. Misbranding of sulfathiazole tablets. U. S. v. Henry C. Smith, Sr. (H. C. Smith's Drug Store). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 16598. Sample Nos. 34415-F, 64095-F.)**

**INFORMATION FILED:** January 2, 1946, Middle District of Georgia, against Henry C. Smith, Sr., trading as H. C. Smith's Drug Store, Columbus, Ga.

**INTERSTATE SHIPMENT:** Between the approximate dates of February 15 and November 20, 1944, from Bristol, Tenn.

**LABEL, IN PART:** "1000 Tablets Sulfathiazole 0.5 Gm Grooved Each tablet contains Sulfathiazole (2 Sulfanilyl Aminoethiazole), 0.5 Gm. (7.7 grs.) \* \* \* Caution: To be used only by or on the prescription of a physician."

**NATURE OF CHARGE:** That on or about December 14 and 15, 1944, the defendant removed a number of *sulfathiazole tablets* from the bottles labeled as above,