

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.