

**NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION**

**3341. TB-One tablets. U. S. v. 2 Cases \* \* \*. (F. D. C. No. 29786. Sample No. 86304-K.)**

**LIBEL FILED:** October 5, 1950, Southern District of California.

**ALLEGED SHIPMENT:** On or about September 13, 1950, by the Cosmos Chemical Corp., from New York, N. Y.

**PRODUCT:** 2 cases, each containing 44 boxes and each box containing 12 50-tablet bottles, of *TB-One tablets* at Los Angeles, Calif.

**RESULTS OF INVESTIGATION:** This drug was a new drug within the meaning of Section 201 (p) (1) of the law since the name "TB-One," together with the label statement "Caution: To be used only by or on the prescription of a physician," suggested that it was for use in the treatment of tuberculosis in the dosage which had been recommended for the disease in published reports by some physicians, namely 2 to 8 tablets per day for six months or longer; and it was not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under these conditions.

**LABEL, IN PART:** (Bottle) "TB-One Para Acetylaminobenzal Thiosemicarbazone 25 Mg. Caution: To be used only by or on the prescription of a physician."

**NATURE OF CHARGE:** Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

**DISPOSITION:** November 27, 1950. Default decree of condemnation and destruction.

**DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED**

**3342. Adulteration and misbranding of Dr. Merrick's Ear Canker Creme. U. S. v. 33 Cartons \* \* \*. (F. D. C. No. 30261. Sample No. 93094-K.)**

**LIBEL FILED:** November 30, 1950, Southern District of Florida.

**ALLEGED SHIPMENT:** On or about September 20, 1950, by the Brookfield Laboratories, from Chicago, Ill.

**PRODUCT:** 33 retail cartons, each containing 1 tube, of *Dr. Merrick's Ear Canker Creme* at Tampa, Fla.

**LABEL, IN PART:** (Retail carton) "Dr. Merrick's Ear Canker Creme Active Ingredients: Aureomycin, Tyrothricin, 2-Mercaptobenzothiazole, Bismuth Subnitrate, Bismuth Subgallate \* \* \* Net Contents 1/2 Ounce."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess since it contained but an inconsequential trace, if any, of aureomycin.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to the article, which contained but an inconsequential trace, if any, of aureomycin: (Display carton) "contains \* \* \* Aureomycin," (retail carton) "Active Ingredients: Aureomycin," and (leaflet in retail carton) "Aureomycin and Tyrothricin