

4326. Misbranding of sulfathiazole tablets and sulfadiazine tablets. U. S. v. Standard Drug Co. and Ottice H. Blankenship. Pleas of guilty. Fine of \$200 against company and \$150 against individual. (F. D. C. No. 34829. Sample Nos. 46553-L to 46555-L, incl.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against the Standard Drug Co., a partnership, Sheffield, Ala., and Ottice H. Blankenship, a partner in the partnership.

NATURE OF CHARGE: On or about July 30 and August 12 and 15, 1952, while a number of *sulfathiazole tablets* and *sulfadiazine tablets* were being held for sale at the Standard Drug Co., after shipment in interstate commerce, the defendants caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: April 2, 1954. The defendants having entered pleas of guilty, the court fined the partnership \$200 and the individual \$150.

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

4327. Misbranding of Tryptacin tablets. U. S. v. 38 Dozen Bottles * * *. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 33948. Sample No. 19876-L.)

LIBEL FILED: October 20, 1952, District of Minnesota.

ALLEGED SHIPMENT: On or about October 8, 1952, by Rhodes Pharmacal Co., Inc., from Cleveland, Ohio.

PRODUCT: 38 dozen bottles of *Tryptacin tablets* at St. Paul, Minn.

RESULTS OF INVESTIGATION: An advertisement in a Minneapolis Sunday newspaper for September 28, 1952, announced the availability of "New Tryptacin An Achievement of Science" at various drug stores in the area. The advertisement consisted of a full page ad reading, in part, as follows: "We have proved it! In actual clinical X-ray tests patients showed almost complete healing in 4 weeks * * * New Tryptacin relieves Acid Pain of Diagnosed Stomach Ulcers, Acid Indigestion, Gas, After-Eating Distress * * * X-Rays revealed that a number of ulcer patients tested showed almost complete healing in 4 weeks."

LABEL, IN PART: (Bottle) "Tryptacin Rhodes For the Temporary Relief of Excess Gastric Acidity 100 Tablets Sole Distributors Rhodes Pharmacal Co., Inc., Cleveland, Ohio * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in that its label failed to state the conditions or diseases for which the article was intended to be taken, and its label failed also to bear adequate directions for use in the treatment of such conditions and diseases.

DISPOSITION: Rhodes Pharmacal Co., Inc., appeared as claimant and filed an answer on October 30, 1952, denying that the product was misbranded. Thereafter, the Government filed a motion for summary judgment on the grounds that since the newspaper advertisement on its face recommended and sug-