

**DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

3361. Misbranding of mineral oil. U. S. v. 20 Cartons * * *. (F. D. C. No. 30503. Sample No. 7051-L.)

LABEL FILED: January 30, 1951, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 13, 1950, by Certified Pharmacal Co., Inc., from New York, N. Y.

PRODUCT: 20 cartons, each containing 12 1-pint bottles, of *mineral oil* at Johnstown, Pa.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Infants * * * May be given ½ to 1 teaspoonful," since mineral oil when given to infants, sometimes is aspirated and causes lipoid pneumonia; and, Section 502 (f) (2), the article failed to bear adequate warnings against unsafe dosage and duration of administration since the labeling failed to warn that the article should not be taken at any time other than bedtime, or administered to infants except on advice of a physician.

DISPOSITION: March 27, 1951. Default decree of condemnation. The court ordered that the product be delivered to a local hospital.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3362. Misbranding of Tibione. U. S. v. 1 Drum * * *. (F. D. C. No. 30412. Sample No. 23054-L.)

LABEL FILED: February 1, 1951, Southern District of New York; amended label filed March 1, 1951.

ALLEGED SHIPMENT: On or about January 16, 1951, by the Berkeley Chemical Corp., from Berkeley Heights, N. J.

PRODUCT: 1 drum, containing 43 pounds, of *Tibione*. Examination disclosed that the product consisted of 4-acetylaminobenzal thiosemicarbazone, otherwise known as TB-1 or *Tibione*.

LABEL, IN PART: "Tibione-Synonym."

NATURE OF CHARGE: Section 505 (a), the label charged as a first cause of action that 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.

The label charged also as a second and alternative cause of action that the article was misbranded under Section 502 (f) (1), in that its labeling failed to bear adequate directions for use, and under Section 502 (f) (2), in that its labeling failed to bear such adequate warnings against unsafe dosage or duration of administration as are necessary for the protection of users.

DISPOSITION: March 26, 1951. Default decree of condemnation and destruction.

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

3363. Misbranding of Benzedrine Sulfate tablets and methyltestosterone tablets. U. S. v. Oliver W. Anderson (Wyre's Pharmacy). Plea of guilty. Fine

*See also Nos. 3361, 3362.