

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

3501. TB-1-PSL tablets. U. S. v. 97 Bottles, etc. (F. D. C. No. 30310. Sample No. 35715-K.)

LIBEL FILED: December 8, 1950, Northern District of California.

ALLEGED SHIPMENT: On or about November 8, 1950, U. S. Factors, San Francisco, Calif., acting for Pacific States Laboratories, Inc., San Francisco, Calif., delivered the product for shipment to Bangkok, Thailand.

PRODUCT: 97 100-tablet bottles and 497 12-tablet bottles of *TB-1-PSL* at San Francisco, Calif., together with a number of leaflets entitled "Reference Manual 601 TB1-PSL The New Antituberculous Drug."

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 such drug.

DISPOSITION: July 31, 1951. Default decree of condemnation and destruction.

3502. Tetraethylthiuram disulfide. U. S. v. 1 Drum * * *. (F. D. C. No. 30915. Sample No. 22825-L.)

LIBEL FILED: April 13, 1951, Eastern District of New York.

ALLEGED SHIPMENT: Prior to April 13, 1951, the Red Star Chemical Co., Inc., introduced the drug into interstate commerce at Long Island City, N. Y., for shipment to Santiago, Chile, in response to an order dated February 26, 1951.

PRODUCT: 1 drum containing 10 kilograms of *tetraethylthiuram disulfide* at Long Island City, N. Y.

LABEL, IN PART: "Tetraethylthiuram Disulfide New Drug—For Experimental Purposes Only."

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 such drug.

DISPOSITION: June 22, 1951. Default decree of condemnation and destruction.

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

DRUGS FOR HUMAN USE

3503. Adulteration and misbranding of amphetamine sulfate dextrorotatory tablets, amphetamine phosphate dextrorotatory tablets, rutin and ascorbic acid tablets, ascorbic acid tablets, and sulfamerazine tablets, and misbranding of stilbestrol tablets and elixir of phenobarbital. U. S. v. Hopkins & Hopkins Pharmaceutical Co. and Michael P. Hopkins. Pleas of guilty. Fine of \$1,200 against company. Sentence of 1 day in jail against individual suspended; individual placed on probation for 1 day. (F. D. C. No. 30590. Sample Nos. 34820-K to 34822-K, incl., 63510-K to 63512-K, incl., 76150-K.)

INFORMATION FILED: June 6, 1951, Eastern District of Pennsylvania, against the Hopkins & Hopkins Pharmaceutical Co., a corporation, Philadelphia, Pa., and Michael P. Hopkins, president of the corporation.

ALLEGED SHIPMENT: On or about May 15 and 23 and June 22, 1950, from the State of Pennsylvania into the States of California, Maine, and Iowa.

NATURE OF CHARGE: *Amphetamine sulfate dextrorotatory tablets* and *ampheta-*

mine phosphate dextrorotatory tablets. Adulteration, Section 501 (d) (2), amphetamine racemic or a salt of amphetamine racemic had been substituted for amphetamine sulfate dextrorotatory and amphetamine phosphate dextrorotatory, which the respective drugs were represented to be. Misbranding, Section 502 (a), the label designations "Amphetamine Sulphate Dextro Rotatory" and "Amphetamine Phosphate Dextro Rotatory" were false and misleading since the drugs were amphetamine racemic or a salt of amphetamine racemic.

Rutin and ascorbic acid tablets. Adulteration, Section 501 (c), the strength of the tablets differed from that which they were represented to possess since they were represented to contain 100 milligrams of ascorbic acid in each tablet, whereas the tablets contained less than 100 milligrams of ascorbic acid in each tablet. Misbranding, Section 502 (a), the label statement "Ascorbic Acid 100 mg." was false and misleading.

Sulfamerazine tablets. Adulteration, Section 501 (b), the article was represented to be a drug the name of which, "Sulfamerazine Tablets," is recognized in the United States Pharmacopeia, an official compendium; and its strength differed from the official standard since the article contained less than 95 percent of the labeled amount of sulfamerazine, the minimum permitted by the standard, and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Sulfamerazine Tablets 7.7 gr." was false and misleading since the article contained less than 7.7 gr. of sulfamerazine.

Ascorbic acid tablets. Adulteration, Section 501 (b), the article was represented to be a drug the name of which, "Tablets Ascorbic Acid," is recognized in the United States Pharmacopeia, an official compendium; and its strength differed from the official standard since the article contained less than 95 percent of the labeled amount of ascorbic acid, the minimum permitted by the standard, and the difference in the strength of the article from the standard was not stated on its label. Misbranding, Section 502 (a), the label statement "Tablets Ascorbic Acid 100 mg." was false and misleading since each tablet of the article contained less than 100 milligrams of ascorbic acid.

Stilbestrol tablets. Misbranding, Section 502 (f) (1), the labeling of the article bore no directions for use; and, Section 502 (f) (2), the labeling of the article bore no warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Elixir of phenobarbital. Misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, namely, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the proportion of such derivative contained in the article and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the article bore no directions for use.

DISPOSITION: June 21, 1951. Pleas of guilty having been entered, the court imposed a fine of \$1,200 against the company and a sentence of 1 day in jail against the individual defendant. The jail sentence against the individual was suspended, and he was placed on probation for 1 day.

3504. Misbranding of Donnatal tablets, Benzedrine Sulfate tablets, Tuinal capsules, and Dexedrine Sulfate tablets. U. S. v. Wiles Drug Store, a partnership, and Clyde B. Wiles and W. Paul Wiles. Pleas of nolo con-