FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

951–1000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *August 21, 1944.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

951. Misbranding of Improved Cold Tablets. U. S. v. 126 Packages of Improved Cold Tablets. Default decree of condemnation and destruction. (F. D. C. No. 8936. Sample No. 26201–F.)

On December 2, 1942, the United States attorney for the Northern District of Indiana filed a libel against 126 packages of Improved Cold Tablets at Fort Wayne, Ind., alleging that the article had been shipped in interstate commerce on or about September 14, 1942, by the Hygenol Co. from Minneapolis, Minn.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of acetanilid 1½ grains per tablet, camphor monobromated, cinchonidine sulfate, capsicum, caffeine, and extracts of plant drugs, including a laxative drug.

The article was alleged to be misbranded (1) in that the statements appearing upon its label, "Cold Tablets * * * For the Relief from Common Head Colds, * * * For the relief of distress and discomfort due to Common Head Colds, etc.," were false and misleading since such statements represented and suggested that the article was effective in the treatment of head colds, whereas it was not so effective; (2) in that its labeling failed to bear ade-

*For omission of, or unsatisfactory, ingredients statements, see Nos. 954, 956, 961, 991, 994; inconspicuousness of required label information, No. 958; cosmetic, subject to the drug provisions of the Act, No. 992.

quate directions for use since the directions appearing on the label provided for an excessive amount of acetanilid and were therefore not adequate for an article of such composition; (3) in that its labeling failed to bear such adequate warnings against use by children, and in those pathological conditions wherein its use might be dangerous to health, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and since the article contained acetanilid and its labeling failed to warn against use by children; (4) in that its labeling failed to bear such adequate warnings against unsafe dosage and methods and duration of administration in such manner and form as are necessary for the protection of users, since its labeling failed to warn that frequent or continued use of a preparation containing acetanilid might cause serious blood disturbances, anemia, collapse, or a dependence on the drug, and since its labeling also failed to warn that frequent or continued use of a laxative might result in dependence upon laxatives; and (5) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof, since the article, when taken in accordance with the directions appearing on the labeling, "Directions Adults: Take 2 tablets every 2 or 3 hours until bowels move freely, then take 1 or 2 tablets 3 or 4 times a day until relieved. Warning! Do Not Take More Than Six Tablets In Any Twenty-Four Hour Period," would provide, even with the limitation of 6 tablets a day, a maximum of 9 grains of acetanilid a day for an indefinite period of time, and was dangerous to health.

On April 5, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

952. Misbranding of triple bromide tablets. U. S. v. 11⅔ Dozen Packages of Triple Bromide Tablets. Decree of condemnation and destruction. (F. D. C. No. 8967. Sample No. 17109–F.)

On December 5, 1942, the United States attorney for the Northern District of New York filed a libel against 11⅔ dozen packages of triple bromide tablets at Albany, N. Y., alleging that the article had been shipped in interstate commerce on or about September 21, 1942, from Chicago, Ill., by the Savoy Drug & Chemical Co.; and charging that it was misbranded. The article was labeled in part: "Wards 50 Triple Bromide Tablets * * * Distributed by Montgomery Ward & Co."

Examination showed that the article contained a total of 15 grains per tablet of the combined sodium, potassium, and ammonium bromides.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling thereof, "Adult Dose: One tablet three times daily."

On January 23, 1943, 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*

953. Adulteration and misbranding of solution of magnesium citrate. U. S. v. 222 Bottles of Effervescing Solution Citrated Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 8388. Sample No. 19441–F.)

This product was sold under a name recognized in the United States Pharmacopoeia and its strength, quality, and purity differed from the standard prescribed in such authority. It was a laxative and its labeling failed to warn that it should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, or that frequent or continued use might result in dependence upon a laxative to move the bowels.

On September 22, 1942, the United States attorney for the District of Rhode Island filed a libel against 222 bottles of the above-named product at Providence, R. I., alleging that the article had been shipped on or about August 5, 1942, by the White-Stone Laboratories from Boston, Mass.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from and its

*See also No. 951.