D. D. N. J., F. D. C. 656–700 Issued February 1943

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]

656–700

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. December 21, 1942.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

656. Adulteration and misbranding of sulfathiazole. U. S. v. Winthrop Chemical Co., Inc. Plea of guilty. Fine, $15,800. (F. D. C. No. 5502. Sample Nos. 5579–E, 14283–E, 14292–E, 29186–E, 29394–E, 36299–E, 38674–E, 39717–E, 39718–E, 39753–E, 40580–E, 40581–E, 40619–E, 40620–E, 49234–E, 50523–E, 50527–E, 50949–E, 51120–E, 51122–E, 51124–E, 51501–E, 51508–E, 57062–E to 57065–E, incl., 57581–E, 57644–E, 57727–E, 57728–E, 58427–E, 69305–E.)

This product was represented to consist of 0.5 gram, or 7.72 grain, sulfathiazole tablets, but in 12 of the 14 shipments there were tablets which contained little or no sulfathiazole but which did contain phenobarbital in amounts varying from approximately 4¼ grains to 6 grains. Two of the shipments contained tablets containing approximately the declared amount of sulfathiazole and small amounts of phenobarbital.

On December 17, 1941, the United States attorney for the Southern District of New York filed an information against Winthrop Chemical Co., Inc., a corporation having its principal place of business at New York, N. Y., alleging shipment within the period from on or about August 3, 1940, to on or about January 2, 1941, from the State of New York into the District of Columbia and into the States of Florida, Iowa, Kentucky, Massachusetts, Minnesota, Missouri, Pennsylvania, and Virginia of quantities of sulfathiazole tablets that were adulterated and misbranded.

Portions of the drug when examined by this agency were in their original labeled bottles. The remaining lots had been removed from their original bottles and, at the time of such examination, bore no labeling.

The article in all shipments was alleged to be adulterated: (1) In that its strength differed from and its purity and quality fell below that which it pur-

ported and was represented to possess since it purported to be and was represented as tablets each of which contained 0.5 gram, or 7.72 grains, of sulfathiazole and no other physiologically active ingredient; whereas in 12 of the 14 shipments there were tablets which contained inconsequential amounts of, or no, sulfathiazole but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet, and in the remaining 2 shipments there were tablets containing phenobarbital in amounts varying from 0.03 grain to 0.24 grain. (2) (12 of the 14 shipments.) In that tablets which contained inconsequential amounts of, or no, sulfathiazole but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet, or (remaining 2 shipments) tablets which contained phenobarbital in amounts varying from 0.03 grain to 0.24 grain, had been substituted in part for tablets containing ½ gram (7.72 grain) of sulfathiazole and no other physiologically active ingredient.

Misbranding was alleged with respect to all or part of the tablets (in 6 shipments), which were in their original labeled containers, in that they would be dangerous to health when used in the dosage or with the frequency or duration suggested in the labeling, i. e., "0.5 Gm. (7.72 grains) Sulfathiazole Winthrop (2-sulfanilamido thiazole) * * * Caution: To be used only by or under the direct supervision of a physician," since the statement suggested administration of the drug in dosages appropriate for the administration of 0.5 gram (7.72 grain) tablets of sulfathiazole, whereas if administered in dosages appropriate for the administration of sulfathiazole tablets of such strength, they would be dangerous to health because of admixture therewith of tablets containing phenobarbital in amounts varying from 0.274 gram (4.23 grains) to 0.391 gram (6.03 grains) per tablet.

All shipments of the article were alleged to be misbranded in that a number of tablets containing phenobarbital, a physiologically active ingredient, in amounts hereinbefore stated, had been offered for sale under the name of another drug, namely, "Tablets 0.5 Gm. (7.72 grains) Sulfathiazole," or "Sulfathiazole Tabs [or "Tablets"] 0.5 Gm."

Portions of the article, i. e., those which were in their original labeled containers were alleged to be misbranded further: (1) In that the statement on the label, "Tablets 0.5 Gm. (7.72 grains) Sulfathiazole," was false and misleading since it represented and suggested that the drug consisted of tablets each containing 0.5 gram (7.72 grains) of sulfathiazole and no other physiologically active ingredient; whereas it consisted of tablets some of which contained an inconsequential amount of, or no, sulfathiazole, but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet. (2) In that the labeling was misleading since it failed to reveal the fact material with respect to the consequences which might result from its use under conditions prescribed in the labeling or under such conditions of use as are customary or usual, i. e., the fact that there was present in said drug a number of tablets that contained phenobarbital, a physiologically active ingredient, in amounts varying from 0.274 gram (4.23 grains) to 0.391 gram (6.03 grains) per tablet, and that when administered in dosages in which sulfathiazole is customarily administered it would produce phenobarbital poisoning.

On January 28, 1942, the defendant entered a plea of guilty and the court imposed a fine of $1,000 on each of the counts charging that the product was dangerous to health, and a fine of $350 on each of the additional 28 counts, totaling $15,800.

657. Adulteration and misbranding of Interferin. U. S. v. 3 Tubes and 3 Boxes each containing 1 Tube of Interferin. Default decrees of condemnation and destruction. (F. D. C. Nos. 6320, 6741. Sample Nos. 14766–E, 54630–E.)

This product would be dangerous to health when use as recommended or suggested in its labeling.

On December 1, 1941, and January 20, 1942, the United States attorney for the Eastern District of Pennsylvania filed libels against the above-named drug product at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about November 3 and 27, 1941, by the Keefer Laboratories from Chicago, Ill.: and charging that it was misbranded and that a portion was also adulterated.

Analysis showed that the article consisted essentially of potassium soap (approximately 11.3 percent), sodium soap (approximately 12.5 percent), potassium iodide (approximately 6 percent), benzoic acid (0.4 percent), fats and/or oils (0.4 percent), alcohol, and water.