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]

2001–2050

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.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *June 5, 1947.*

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DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2001. Misbranding of Anademin Tablets. U. S. v. 52 Packages and 5 Packages of Anademin Tablets. Default decree of condemnation and destruction. (F. D. C. No. 20102. Sample No. 14079–H.)

LIBEL FILED: June 26, 1946, Southern District of Ohio.

ALLEGED SHIPMENT: On or about October 30, 1945, and April 8 and May 29, 1946, by the Anademin Chemical Co., from Chattanooga, Tenn.

PRODUCT: 52 100-tablet packages and 5 500-tablet packages of *Anademin Tablets* at Cincinnati, Ohio. Assay by the method described in the Twelfth Revision of the United States Pharmacopoeia showed that each tablet of the product had a potency of 3.17 U. S. P. Digitalis Units.

LABEL, IN PART: "100 [or "500"] 5 grain Tablets Anademin * * * Caution: To be used only by or on the prescription of a physician. Assay: As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units."

*For omission of, or unsatisfactory, ingredients statements, see Nos. 2003, 2005, 2008, 2031, 2034, 2035, 2046; failure to comply with the packaging requirements of an official compendium, No. 2028; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2003, 2028.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units," was false and misleading since the potency of the article as indicated by the method described in the Twelfth Revision of the United States Pharmacopoeia was materially in excess of 1.25 U. S. P. Digitalis Units; and, Section 502 (j), the article was dangerous to health when used in the dosage suggested by the statement quoted above, since, if prescribed by a physician in reliance upon such statement of potency, the patient would receive an excessive amount of a potent drug.

DISPOSITION: August 9, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2002. Misbranding of penicillin sodium. U. S. v. 102 Vials of Penicillin Sodium. Default decree of condemnation. Product ordered delivered to public welfare institution. (F. D. C. No. 20248. Sample Nos. 14070–H, 14072–H, 14073–H.)

LIBEL FILED: June 12, 1946, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about February 8, 1946, by the Hale-Justis Drug Co., from Cincinnati, Ohio.

PRODUCT: 102 vials of *penicillin sodium* at Lexington, Ky. The product had not been certified in accordance with the requirements of the law.

LABEL, IN PART: "No. 732 Penicillin Sodium 100,000 Oxford Units (Mfd. by Heyden Chemical Corporation) * * * Supplied by Lakeside Laboratories Milwaukee, Wisconsin."

NATURE OF CHARGE: Section 502 (l), the article was a drug composed in whole or in part of a derivative of penicillin, and it was not from a batch with respect to which a certificate of release, issued pursuant to the regulations, was in effect.

DISPOSITION: August 9, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to public welfare institutions, since the Food and Drug Administration had certified that the product was fit for use.

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

2003. Misbranding of sulfathiazole tablets, sulfadiazine tablets, and nembutal capsules. U. S. v. I. James Hendelberg (Southeast Pharmacy). Plea of nolo contendere. Fine, $400. (F. D. C. No. 19538. Sample Nos. 2966–H to 2968–H, incl., 2971–H.)

INFORMATION FILED: April 19, 1946, District of Columbia, against I. James Hendelberg, trading as Southeast Pharmacy, Washington, D. C.

PRODUCT: *Sulfathiazole tablets* and *sulfadiazine tablets*, sulfa drugs; and *nembutal capsules* which contained pentobarbital, a derivative of barbituric acid, which has been designated as habit forming.

NATURE OF CHARGE: That between the approximate dates of December 27, 1945, and January 17, 1946, while the articles were in interstate commerce, the defendant repacked a quantity of the various articles in unlabeled envelopes and boxes.

The information further charged that the acts of the defendant resulted in the misbranding of the articles in the following respects: Section 502 (b) (1) and (2), the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e), they were not designated solely by names recognized in an official compendium, and they failed to bear labels declaring the common or usual names of the articles; Section 502 (f) (1), they were without labels bearing adequate directions for use; and, Section 502 (f) (2), they were without labels bearing such adequate warnings against use in those pathological conditions or by children where their use may be