

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]

1701-1750

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., September 6, 1946.

CONTENTS*

	Page		Page
Drugs actionable because of potential danger when used according to directions.....	117	Drugs actionable because of deviation from official or own standards.....	120
New drug shipped without effective application.....	118	Drugs and devices actionable because of false * and misleading claims.....	127
Drugs actionable because of contamination with filth.....	119	Drugs for human use.....	127
Drugs actionable because of the presence of non-certified coal-tar colors.....	120	Drugs for veterinary use.....	137
		Drug actionable because of deceptive packaging.....	14

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

1701. Misbranding of sulfathiazole tablets. U. S. v. Abraham H. Kaitz (American Proprietaries). Plea of guilty. Fine, \$500. Sentence of 3 months in jail suspended and defendant placed on probation for 6 months. (F. D. C. No. 16571. Sample No. 4701-H.)

INFORMATION FILED: November 8, 1945, Eastern District of Pennsylvania, against Abraham H. Kaitz, trading as American Proprietaries, at Philadelphia, Pa.

INTERSTATE SHIPMENT: On or about June 17, 1944, from New York, N. Y., to Philadelphia, Pa., of a quantity of *sulfathiazole tablets*.

LABEL, WHEN SHIPPED: "1000 Tablets Sulfathiazole U. S. P. XII 0.5 Gram (7.7 grains) Ommis Orbis Warner * * * Caution: To be used only by or on the prescription of a physician * * * William R. Warner & Co., Inc. New York St. Louis."

NATURE OF CHARGE: That on or about January 12, 1945, the defendant removed a number of tablets from a bottle bearing the label described above, repacked the tablets into a box bearing the label, "Sal-T Directions one 4 times a day No. 2 TR-TAB TTK," and sold those tablets without a prescription.

The information charged further that the act of the defendant resulted in the misbranding of the article in the following respects: Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since

*For failure to bear adequate directions or warning statements, see No. 1701; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 1719, 1746, 1747; omission of, or unsatisfactory, ingredients statements, Nos. 1720, 1736, 1746; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 1742, 1743; cosmetics, subject to the drug provisions of the Act, Nos. 1741, 1742.

the directions, "one 4 times a day," borne on the labeling, were not adequate directions for use; and, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: December 4, 1945. A plea of guilty having been entered, the court imposed a fine of \$500 and sentenced the defendant to serve 3 months in jail. The jail sentence was suspended and the defendant was placed on probation for 6 months.

1702. Adulteration and misbranding of boric acid ointment. U. S. v. S. Pfeiffer Manufacturing Co. and John A. Mueller. Pleas of nolo contendere. Corporate defendant fined \$200; individual defendant fined \$20. (F. D. C. No. 16593. Sample Nos. 5625-H, 5626-H.)

INFORMATION FILED: November 13, 1945, Eastern District of Missouri, against the S. Pfeiffer Manufacturing Co., a corporation, St. Louis, Mo., and John A. Mueller, plant manager for the corporation.

ALLEGED SHIPMENT: On or about October 7, 1944, from the State of Missouri into the State of Connecticut.

PRODUCT: Examination of samples disclosed that the product did not contain any boric acid, but that it contained, in the two samples examined, 0.3 percent and 0.58 percent, respectively, of oil of mustard.

LABEL, IN PART: "Gold Medal * * * Boric Acid Ointment U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (d), a substance containing oil of mustard had been substituted in whole or in part for "Boric Acid Ointment U. S. P."

Misbranding, Section 502 (a), the label statements, "Boric Acid Ointment U. S. P." and "A soothing emollient ointment for Chafing, Bruises, Sunburn, Minor Burns and Scalds, and Minor Skin Irritations * * * Cleanse affected area well and apply ointment once or twice daily. Cover with clean gauze or bandage if possible," were false and misleading since the article was not "Boric Acid Ointment U. S. P.," and it was not a soothing emollient ointment for the conditions stated.

Further misbranding, Section 502 (j), the article, because of the presence of oil of mustard, was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, "cleanse affected area well and apply ointment once or twice daily. Cover with clean gauze or bandage if possible."

DISPOSITION: January 15, 1946. Pleas of nolo contendere having been entered on behalf of the defendants, the court imposed upon the corporate defendant a fine of \$100 on each of 2 counts; and the court also imposed upon the individual defendant a fine of \$10 on each of 2 counts.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

1703. Misbranding of Hyatrone Androgenic Hormone Preparation. U. S. v. 20 Jars of Hyatrone Androgenic Hormone Preparation, and an accompanying booklet. Default decree of condemnation and destruction. (F. D. C. No. 19013. Sample No. 7323-H.)

LABEL FILED: January 28, 1946, District of New Jersey.

ALLEGED SHIPMENT: From New York, N. Y., by the Johay Corporation. The product was shipped on or about August 4, 1945, and the booklet was shipped subsequent to that date.

PRODUCT: 20 jars of *Hyatrone Androgenic Hormone Preparation* at Hohokus, N. J., together with a booklet entitled "Hyatrone * * * Hormone Preparations for Men and Women."

LABEL, IN PART: "Hyatrone Androgenic Hormone Preparation Contains 36,100 MG Pure Crystalline Testosterone."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article, in the booklet, and in a letter addressed to the consignee by the Johay Corporation, were false and misleading since they represented and suggested that the article would combat old age, compensate hormone deficiency, prolong the prime of life, restore the vigor of youth, build new tissues, promote endurance, improve mental capacity, stimulate new strength, correct impotency, and renew confidence. The labeling represented further that the article would