

**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]

2201-2250

**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.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *January 6, 1948.*

**CONTENTS \***

	Page		Page
Drugs actionable because of failure to bear adequate directions or warning statements.....	403	Drugs and devices actionable because of false and misleading claims.....	410
Drugs actionable because of contamination with filth.....	404	Drugs for human use.....	410
Drugs and devices actionable because of deviation from official or own standards.....	405	Drugs for veterinary use.....	419
		Index.....	425

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

**2201. Misbranding of seconal sodium pulvules. U. S. v. Dayton B. Blaine and Claude C. Schwab. Pleas of guilty. Defendants fined \$500 and \$100, respectively. (F. D. C. No. 21453. Sample Nos. 24032-H, 49052-H, 49162-H.)**

**INFORMATION FILED:** March 11, 1947, Northern District of Texas, against Dayton B. Blaine and Claude C. Schwab, president and manager, respectively, of the Red Cross Pharmacy, Inc., Dallas, Tex.

**INTERSTATE SHIPMENT:** Between the approximate dates of January 14 and 30, 1946, from Indianapolis, Ind.

**LABEL, IN PART (When shipped):** "Pulverized Seconal Sodium 1½ Grs. (0.1 Gm.) (Sodium Propyl-methyl-carbinyl Allyl Barbiturate, Lilly) \* \* \* Caution—to be dispensed only by or on the prescription of a physician."

**NATURE OF CHARGE:** That on or about April 3, 4, and 7, 1946, while a number of capsules of the drug were being held for sale after shipment in interstate commerce, the defendants caused to be removed a number of the capsules from the bottle in which they were shipped, caused to be repacked the aforesaid capsules into envelopes which were unlabeled except for the figure "12" which appeared on several of the envelopes, and caused to be sold these capsules without a prescription.

The information charged further that the acts of the defendants resulted in the misbranding of the drug in the following respects: Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit-forming, and the label

\*For presence of a habit-forming narcotic without warning statement, see No. 2201; omission of, or unsatisfactory, ingredients statements, Nos. 2223, 2234, 2240, 2243; failure to comply with the packaging requirements of an official compendium, No. 2214; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2221, 2232, 2234, 2240, 2243; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2240; cosmetics, subject to the drug provisions of the Act, Nos. 2230-2234.

of the drug in the envelopes failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit-forming"; Section 502 (f) (1), the envelopes containing the drug bore no labeling containing directions for use; and, Section 502 (f) (2), they bore no labeling containing warnings against use of the drug in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage and methods and duration of administration.

**DISPOSITION:** March 11, 1947. Pleas of guilty having been entered, the court imposed fines of \$500 and \$100, respectively, against defendants Blaine and Schwab.

**2202. Misbranding of Nanette Hormone Cream. U. S. v. 274 Jars, etc.** (F. D. C. No. 22989. Sample Nos. 61334-H to 61336-H, incl.)

**LABEL FILED:** April 25, 1947, Western District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about March 8 and 21, 1947, by the Nix Cosmetics Co., Inc., from Memphis, Tenn.

**PRODUCT:** 274 2-ounce jars and 16 6-ounce jars of *Nanette Hormone Cream* at Pittsburgh, Pa. Analysis indicated that the product had essentially the composition stated on its label.

**LABEL, IN PART:** "Nanette Hormone Cream Each 2 Ozs. Contains 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the name "Hormone Cream" and the label statement "Each 2 Ozs. Contain 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)" were false and misleading since they represented and suggested that the article contained a hormone and that it would exert a beneficial hormone-like effect, or beneficial estrogenic effect, upon the body when used as directed, whereas the article did not contain a hormone and would produce no beneficial hormone-like effect, or beneficial estrogenic effect, when used as directed.

Further misbranding, Section 502 (f) (1), the directions for use in the labeling "Apply gently one-half heaping teaspoonful at bedtime. Leave on overnight." were inadequate since they failed to indicate the conditions in which the article was to be used, the body area to which the article was to be applied, and the duration of its use.

**DISPOSITION:** May 20, 1947. Default decree of condemnation and destruction.

**2203. Misbranding of calcium polysulphide solution. U. S. v. 5 Drums \* \* \*** (F. D. C. No. 23499. Sample Nos. 68292-H, 68293-H, 86127-H.)

**LABEL FILED:** July 14, 1947, District of Kansas.

**ALLEGED SHIPMENT:** On or about February 26 and 27, 1947, by the Sulphur Products Co., Inc., from Greensburg, Pa.

**PRODUCT:** 5 drums of *calcium polysulphide solution* at Sabetha, Kans. The shipper supplied the consignee with a suggested form of label containing directions for use, but had not entered into any agreement with the consignee relative to the labeling of the article, as contemplated by Section 503 (a), to the effect that the article would not be adulterated or misbranded when relabeled.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

**DISPOSITION:** September 24, 1947. Default decree of condemnation and destruction.

#### DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

**2204. Adulteration Bethiamin, Livitamin, and calcium gluconate. U. S. v. The S. E. Massengill Company. Plea of guilty. Fine, \$3,000.** (F. D. C. No. 20204. Sample Nos. 7678-H, 20850-H, 21738-H, 21757-H.)

**INFORMATION FILED:** February 3, 1947, Eastern District of Tennessee, against The S. E. Massengill Co., a corporation, Bristol, Tenn.

**ALLEGED SHIPMENT:** On or about December 15, 1944, and November 1 and December 8, 1945, from the State of Tennessee into the States of Missouri and New York.