

**DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER  
WHEN USED ACCORDING TO DIRECTIONS\***

**2751. Misbranding of Orange Blossom Suppositories. U. S. v. 79 Packages \* \* \***  
(and 2 other seizure actions). (F. D. C. Nos. 26219, 26359, 26375.  
Sample Nos. 27495-K, 45875-K, 45879-K.)

**LIBELS FILED:** December 14, 1948, and January 3, 1949, Eastern District of Missouri and Western District of Tennessee.

**ALLEGED SHIPMENT:** On or about November 8 and 17 and December 6, 1948, by the Dr. J. A. McGill Co., Not Inc., from Chicago, Ill.

**PRODUCT:** *Orange Blossom Suppositories.* 79 packages at St. Louis, Mo., and 242 packages at Memphis, Tenn. Each package contained 6 suppositories. Examination showed that the product was semisolid suppositories consisting essentially of ammonium alum, borax, petrolatum, talc, and powdered cocoa.

**NATURE OF CHARGE:** Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bed time insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days. The use of Orange Blossom Suppositories is not recommended at the menstrual period or during pregnancy."

**DISPOSITION:** January 6 and February 3, 1949. Default decrees of condemnation and destruction.

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

**2752. Misbranding of herb preparations. U. S. v. Arthur Cox. Plea of guilty.**  
Fine, \$100. (F. D. C. No. 23212. Sample Nos 14065-H, 22745-H,  
27167-H.)

**INFORMATION FILED:** August 1, 1947, Southern District of Indiana, against Arthur Cox, Sullivan, Ind.

**ALLEGED SHIPMENT:** Between the approximate dates of February 27 and April 30, 1946, from the State of Indiana into the States of Illinois and Colorado.

**PRODUCT:** Analyses disclosed that there were four different types of *herb preparations*, namely, a light brown colored liquid with an odor of peppermint, containing chiefly water and plant extractives and a small amount of emodin bearing drugs; a black ointment containing chiefly oil of mustard in a grease-type base; plant material consisting chiefly of stems and leaf fragments, with an odor and appearance resembling that of hay; and a black syrupy liquid consisting essentially of water, reducing sugar, and plant extractives, including emodin bearing drugs.

**LABEL, IN PART:** "Arthur Cox Log Saw Herb Preparations."

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (1), the articles failed to bear labels containing the place of business of the manufacturer, packer, and

\*See also No. 2766.

distributor; and, Section 502 (b) (2), the containers of the articles bore no labels containing a statement of the quantity of the contents.

Further misbranding, Section 502 (a), the statement "Recommended for sinus" on the label of the light brown colored liquid was false and misleading since the article would not be efficacious in the cure, mitigation, and treatment of sinus diseases; Section 502 (e) (2), the ointment was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the ointment bore no directions for use, and the labeling of the plant material and syrupy liquid failed to bear adequate directions for use since the labeling failed to reveal the conditions for which the articles were to be used.

DISPOSITION: January 24, 1949. A plea of guilty having been entered, the court imposed a fine of \$100.

**2753. Misbranding of serenium tablets. U. S. v. 7 Bottles \* \* \*. (F. D. C. No. 25870. Sample No. 8347-K.)**

**LIBEL FILED:** October 21, 1948, District of New Jersey.

**ALLEGED SHIPMENT:** On or about May 24, 1948, by E. R. Squibb & Sons, from Brooklyn, N. Y.

**PRODUCT:** 7 bottles of *serenium tablets* at Newark, N. J.

**LABEL, IN PART:** "50 Tablets List 7974 Chocolate Coated Serenium."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for use since the directions for use which appeared on the bottle label "For oral treatment of certain urinary infections. Dose: Adults, 1 tablet by mouth 3 times daily before meals; children over 3 years, ½ tablet twice daily; children under 3 years, ¼ tablet twice daily" were not adequate directions for use in the treatment of urinary infections.

DISPOSITION: May 23, 1949. Default decree of condemnation and destruction.

**2754. Misbranding of succinol tablets. U. S. v. 15 Bottles \* \* \*. (F. D. C. No. 27235. Sample No. 12373-K.)**

**LIBEL FILED:** May 20, 1949, Eastern District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about April 27, 1949, by the Succinol Co., from New York, N. Y.

**PRODUCT:** 15 100-tablet bottles of *succinol tablets* at Philadelphia, Pa.

**LABEL, IN PART:** "Succinol Each tablet contains 0.2 Gm. Phenylsemicarbazide \* \* \* To be used only by or on the prescription of a physician \* \* \* The Succinol Company, New York 7, N. Y."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (2), the labeling of the article 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 the article contained phenylsemicarbazide and its labeling failed to warn that phenylsemicarbazide is capable of producing serious hemolytic anemia.

DISPOSITION: June 21, 1949. The Succinol Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling.