

tomary conditions of purchase and use. (5) In that the carton containing the set did not bear an accurate statement of the quantity of contents.

On June 24 and September 25, 1941, no claimant having appeared, judgments were entered ordering that the product be destroyed.

434. Misbranding of Happy Day Headache Powders. U. S. v. 21½ Gross Packages of Happy Day Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 4008. Sample No. 50903-E.)

This product would be dangerous to health when used according to directions, its labeling failed to bear adequate directions for use and warning statements, and in addition it bore false and misleading therapeutic claims.

On or about March 21, 1941, the United States attorney for the Western District of Virginia filed a libel against 21½ gross packages of Happy Day Headache Powders at Roanoke, Va., alleging that the article had been shipped from Winston-Salem, N. C., in part in the personally owned automobile of Max Caplan, owner of the Capital Drug Co., Roanoke, Va., on or about September 16, 1940, and in part by the Sessions Specialty Co. on or about November 8, 1940; and charging that it was misbranded. It was labeled in part: "Happy Day Headache Powders * * * Manufactured by Gulf Laboratories Inc. Lafayette Louisiana."

Analyses of samples of the article showed that it consisted essentially of acetanilid (2½ grains per powder), aspirin, caffeine, phenolphthalein, and milk sugar.

The article was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, (envelope containing powder) "Directions Take one powder dry on the tongue followed with water, or mixed with a little water. One powder usually gives the desired results. If necessary, another powder may be taken in 30 minutes. Women will find this especially beneficial during painful menstrual periods"; (circular) "Take one powder dry on the tongue, followed by a swallow of water, or mix well with small quantity of water and take. Repeat in 20 minutes if necessary. One powder usually gives relief. Children over 6 years: ¼ to ½ of one powder. * * * One powder well mixed in a little water at the first sign of cold or fever and one two hours later. One powder at night just before retiring is recommended. Children over six years: ½ powder mixed in water 3 times daily according to age. * * * One powder dissolved in water every 2 or 3 hours as required." (2) In that the labeling failed to bear adequate directions for use. (3) In that the labeling did not bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users. (4) In that statements in the labeling representing that it would be efficacious for the relief of discomfort arising from head colds, hay fever, and nervousness; that it would reduce fever, insuring speedy relief; that it would be efficacious for the relief of pains caused by menstrual disturbances, tonsillitis, headache caused by sinus trouble, rheumatism, influenza, and throat irritations, were false and misleading since it would not be efficacious for such purposes. (5) In that the label did not bear the common or usual names of the active ingredients. (6) In that the label did not bear an accurate statement of the quantity of contents.

On July 15, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

435. Misbranding of Suppletive Formula Number 1, Supportive Formula S. G. M. a, and Formula No. 1. U. S. v. 326 Ampuls of Suppletive Formula Number 1, 88 Ampuls of Supportive Formula S. G. M. a, and 2 Bottles of Formula No. 1. Default decrees of condemnation and destruction. (F. D. C. Nos. 3318, 3548, 3549. Sample Nos. 30843-E, 31909-E, 31912-E.)

Examination of Suppletive Formula Number 1 disclosed that it contained emetine hydrochloride. This product would be dangerous to health when used in the dosage suggested in the labeling. Its label and that of Formula No. 1 failed to bear such warnings as might be necessary for the protection of users. All three products failed to bear adequate directions for use and to name the active ingredients present.

On November 16 and December 20, 1940, the United States attorney for the Northern District of Illinois filed libels against the above-named products at

Chicago, Ill., alleging that the articles had been shipped in interstate commerce on or about May 3 and October 17, 1940, by the E. S. Miller Laboratories, Inc., from Los Angeles, Calif.; and charging that they were misbranded. The articles were labeled in part: "Suppletive Formula Number 1 [or "Supportive Formula S. G. M. a"] Specially prepared for the Samaritan Treatment"; or "Formula No. 1 Manufactured for The Samaritan Treatment."

Analyses showed that the Supportive Formula consisted essentially of glandular material and water; and that Formula No. 1 consisted essentially of compounds of ephedrine, pilocarpine, emetine, and strychnine, sulfates and chlorides, and water.

The Suppletive Formula Number 1 was alleged to be misbranded in that it would be dangerous to health when used in the dosage suggested in its labeling. This product and Formula No. 1 both were alleged to be misbranded in that their labeling failed to bear adequate warnings against use in those pathological conditions (or by children in the case of Formula No. 1) where their use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for protection of users.

All three products were alleged to be misbranded (1) in that their labeling failed to bear adequate directions for use; and (2) in that they were fabricated from two or more ingredients and their labeling failed to bear the common or usual names of their active ingredients.

On January 28 and March 3, 1941, no claimant having appeared, judgments of condemnation were entered and products were ordered destroyed.

436. Adulteration and misbranding of Sterile Uteroids, Prevent-All, Leucorrhea Special No. 9; misbranding of Gleet Specific, Argosine, Picricine, Prostatic Depletent, Prostatic Absorbent, and Aesculus Pile Cerate. U. S. v. 94 Cartons and 125 Tubes of Sterile Uteroids, 10 Cartons of Prevent-All, 94 Cartons of Leucorrhea Special No. 9, 34 Packages of Gleet Specific, 117 Cartons of Argosine, 126 Cartons of Picricine, 23 Cartons of Prostatic Depletent, 21 Cartons of Prostatic Absorbent, and 23 Cartons of Aesculus Pile Cerate. Default decrees ordering destruction. (F. D. C. Nos. 3370 to 3374, incl. 3376, 3378, 3501 to 3503, incl. Sample Nos. 16393-E to 16397-E, incl., 16399-E, 16901-E, 16913-E to 16915-E, incl.)

Adequate directions for use were not borne on the labels of Leucorrhea Special No. 9; the labeling of Picricine and Aesculus Pile Cerate failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; the labeling of all the other products except Prevent-All failed to bear adequate directions for use and adequate warning statements. The Sterile Uteroids, Prevent-All, and Leucorrhea Special No. 9 were adulterated because their strength differed from and their quality fell below that which they purported or were represented to possess. All of the products except Picricine and Argosine bore false and misleading statements regarding their ingredients or their therapeutic properties. The labels on the immediate container (collapsible tube) of the repackaged portion of Leucorrhea Special No. 9, the labeled portion of Argosine (and the cartons of the remainder of these two products), and of all the other products failed to bear the common or usual name of each of their active ingredients.

The packages of all the products (and the cartons in the case of the unlabeled portion of Argosine and the portion of Leucorrhea Special No. 9 that had not been repackaged) failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, since the immediate container (collapsible tube) carried no label; and the name and address Ainsworth Specialty Co., Kansas City, Mo., appearing on the carton were not those of the manufacturer, and were not qualified by a phrase which revealed the connection the firm mentioned had with the drugs. The packages of all the products (the immediate container (collapsible tube) of the labeled portion of Argosine and of the repackaged portion of Leucorrhea Special No. 9, and the cartons containing the unlabeled portion of Argosine and the portion of Leucorrhea Special No. 9 that had not been repackaged) failed to bear the required quantity of contents statement.

On or about November 23 and December 20, 1940, the United States attorney for the Western District of Missouri filed libels against the above-named products at Kansas City, Mo., alleging that the articles had been shipped by C. F. Breitenbach (Mucine Co.) from Chicago, Ill., within the period from on or