and 16 small bottles at the Southern Drug Co., and 81 small bottles at National Press Pharmacy; and charging that they were misbranded. The articles were labeled in part: "Capsules Cold Special * * * [or "Cold Special * * * Each Capsule Contains:"] * * * Dose: One capsule every hour as required [or "Directions One Capsule every 2 or 3 hours * * * Notice—Acetanilid is a dangerous drug, over dosage may cause depression of the heart or circulatory system" or "Dosage Adults: 1 capsule every hour until 4 or 5 have been taken, then 1 capsule every three hours as required * * * Acetanilid preparation may depress the heart and should not be taken continuously except under the direction of a physician"]."

Analysis of a sample of the article showed that each capsule contained acetanilid (approximately 2 grains), quinine sulfate (approximately ½ grain), camphor, podophyllin, and aloin.

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 and duration prescribed, recommended, and suggested in the labeling; (2) in that the labeling failed to bear adequate directions for use since the directions appearing thereon were inappropriate for an article of the composition of this one; (3) in that the labeling failed to bear an adequate warning against use in those pathological conditions and by children where its use might be dangerous to health, or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users; and (4) in that the designation "Cold Special," appearing on the labeling, was false and misleading since the article did not constitute a treatment or preventive for the disease condition commonly known as "cold."

On May 20, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

433. Misbranding of Halomist Sets and Refills. U. S. v. 89 Packages of Halomist Sets and 100 Bottles of Halomist (and 1 other seizure of Halomist and Halomist Refills). Default decrees ordering destruction of the products. (F. D. C. Nos. 4347, 4872. Sample Nos. 53047-E, 53048-E, 58037-E, 58038-E.)

This product, in addition to being potentially dangerous when used according to directions, bore false and misleading therapeutic claims in its labeling and also failed to comply with certain other labeling provisions of the law.

On May 27 and June 6, 1941, the United States attorneys for the Southern District of California and the District of Minnesota filed libels against 89 packages (each package containing an applicator, medicine dropper, and a bottle of Halomist) and 100 bottles of Halomist at Los Angeles, Calif., and 11 Halomist Sets, 27 1-ounce and 4 half-ounce Halomist Refills at Minneapolis, Minn., alleging that the article had been shipped by Halomist, Inc., from Seattle, Wash., within the period from on or about March 19 to on or about April 21, 1941; and charging that it was misbranded.

Analyses of samples showed that the Halomist consisted essentially of racemic epinephrine hydrochloride (in one sample, 2.3 grams, in the other, 2.4 grams per 100 cubic centimeters), chlorobutanol, and water.

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, which recommended that it be used at least 3 times daily—with inhalations of 15 to 35 minutes' duration and in extreme cases, of 45 minutes' to 2 hours' duration. (2) In that statements in the labeling that it would be efficacious for the relief of paroxysms of bronchial asthma, for treatment of hay fever or sinusitis; that it would be efficacious to prevent asthma attacks, to build up natural resistance and strength and to build up weight; that the user would be able to eat what he pleased; that it would be soothing to the membranes; that it contained an ideal antiseptic for the sinuses; that it would build up resistance against sinus disorders and catarrhal conditions; and that it would toughen the tissues against infection and irritation, were false and misleading since it was neither a safe nor an appropriate treatment for the conditions named. (3) In that the carton containing the set did not bear the common or usual names of the active ingredients nor a statement of the quantity or proportion of chlorobutanol present. (4) In that the name and address of the manufacturer was not prominently placed on the carton with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read by the ordinary individual under cus-

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