on the label. (2) In that the directions for use, namely, "Adults—To allay the discomfort in breaking up a common head cold, simple headache, or neuralgia, take one capsule every half hour until three are taken [25-cent size] then one capsule in two or three hours until three more capsules are taken. Children—12 years old, one capsule repeated in three hours [50-cent size] then one every 2 or 3 hours as may be desired. Children—5 to 10 years old, one-half to one capsule, repeated in three hours if necessary," were inappropriate for articles of such composition because of their indefiniteness and because they provided amounts of acetanilid which might prove harmful to the user and were therefore inadequate. (3) In that the labels failed to bear adequate warnings against their use by children or in those pathological conditions where their use might be dangerous to health and against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since there was no warning against their use by children nor against use in the presence of symptoms of appendicitis, nor with reference to the deleterious effects of acetanilid in causing serious blood disturbances, nor against frequent or continued use which might result in dependence upon the drug.

The capsules in the 50-cent-sized packages were alleged to be misbranded further (1) in that the statements (box label) "Should give a free evacuation which is very important in breaking up a cold" and (circular) "For relieving common head colds" were false and misleading since they would not break up a cold nor otherwise favorably influence the course of a head cold; (2) in that the label failed to bear the common or usual name of each active ingredient since, of the several active ingredients present, only acetanilid was mentioned on the label; and (3) in that the label did not bear a statement of the quantity of contents of the retail package.

On August 27, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR DIRECTIONS FOR USE OR ADEQUATE WARNING STATEMENTS[1]

551. Adulteration and misbranding of Sunshine Brand Powders. U. S. v. Frank W. Lavoine (Lavoine Drug Co.). Plea of guilty. Fine, $25. (F. D. C. No. 4113. Sample No. 36160-E.)

These powders contained acetanilid in excess of the amount declared on the label. The labeling failed to bear such warnings as are necessary for the protection of users and it also failed to bear a statement of the quantity of contents.

On July 29, 1941, the United States attorney for the District of Massachusetts filed an information against Frank W. Lavoine, trading as the Lavoine Drug Co., Worcester, Mass., alleging shipment on or about October 5, 1940, from the State of Massachusetts into the State of Maine of a quantity of Sunshine Brand Powders which were adulterated and misbranded.

Adulteration was alleged in that the strength of the article differed from that which it purported and was represented to possess since each powder purported and was represented to contain 2 grains of acetanilid; whereas each powder contained approximately 3.158 grains of acetanilid.

Misbranding was alleged (1) in that the labeling did not bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since frequent or continued use might cause serious blood disturbances, anemia, or collapse; (2) in that it might be dangerous if administered to children, and its labeling did not bear a warning that it should not be given to children; (3) in that the statement "Each powder contains 2 grains Acetanilid," borne on each of the boxes and envelopes, was false and misleading; and (4) in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents in terms of weight or numerical count.

On December 15, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $25.

552. Misbranding of Floracubes. U. S. v. Eugene H. Hunter (Floracube Co.). Plea of nolo contendere. Imposition of sentence suspended and defendant placed on probation for 5 years. (F. D. C. No. 2899. Sample No. 7356-E.)

This product was labeled to indicate that it derived its physiological activity in important respects by means of its lubrication, bulk, alkaline, and germicidal

[1] See also Nos. 547-550.

qualities; whereas it derived its physiological activity principally from the ingredient phenolphthalein.

On March 28, 1941, the United States attorney for the Southern District of California filed an information against Eugene H. Hunter, trading as Floracube Co., Los Angeles, Calif., alleging shipment on or about March 9, 1940, from the State of California into the State of Arizona of quantities of Floracubes that were misbranded.

The article was alleged to be misbranded in that the statements "Floracubes * * * contain certain lubrication, bulk, alkaline, and germicidal qualities, and are non-irritating in action. May be used over a long period of time. * * * Floracubes * * * contain per average dose (1-6 box) less than 2 grains each of calcium carbonate, sodium bicarbonate, chlorides, podophyllum, magnesium, phenolphthalein, oil of juniper, boron, buchu, sodium benzoate, cascara, iron and dextrin. Also mineral oil and jelly, agar and celluloses, sugar, artificial color and flavor, combined with free oxygen, hydrogen and Ultra Violet. The above ingredients are combined with water under a special process to change their form and action to meet the requirements of Floracubes. * * * (Additional ingredients present, less 1 Gr.) Manganese, Aloin, nitrates, florides, sassafras, sulphates, calcium and silica," borne on the carton, were false and misleading since they represented that the article derived its physiological activity in important respects by reason of its lubrication, bulk, alkaline, and germicidal qualities; that it was nonirritating in action and might safely be used over a long period of time; and that it contained the ingredients listed in significant amounts and that these ingredients were combined with water under a special process which changed their form and action; whereas it derived its physiological activity practically, if not entirely, from the ingredient phenolphthalein, which is irritating; it was not germicidal, and could not be used over a long period of time without risk of injury; and it did not contain the ingredients listed in significant amounts, since it contained no appreciable amount, if any, of the ingredients iron, boron, manganese, fluorine, sodium bicarbonate, calcium as calcium carbonate, or sodium benzoate, and the ingredients were not combined with water under a special process which changed their form and action. It was alleged to be misbranded further in that it did not bear a label containing the name and place of business of the manufacturer, packer, or distributor, nor an accurate statement of the quantity of the contents prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, since the ingredients listed in the labeling were in large part inert and the list did not indicate that phenolphthalein was the only important active ingredient. It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use, and 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, in such manner and form as are necessary for the protection of users, since the labeling did not inform purchasers that the use of the article in cases of abdominal pain, nausea, vomiting, or other symptoms of appendicitis might result in serious injury, and that frequent or continuous use might result in dependence upon laxatives.

On August 25, 1941, the defendant entered a plea of nolo contendere, and the court ordered that imposition of sentence be suspended and that the defendant be placed on probation for a period of 5 years.

553. Misbranding of Mackenzie Cold and Grippe Tablets. U. S. v. 100 Packages of Mackenzie Cold and Grippe Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4876. Sample No. 60255–E.)

These tablets had been repackaged after shipment and after such repackaging, in addition to failure to bear adequate warning statements, the labeling bore false and misleading statements regarding their therapeutic efficacy and the amount of acetanilid that they contained. The tablets also were deceptively packaged since approximately 30 percent of the upper space in the carton was empty.

On June 10, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Seattle, Wash., alleging that it had been shipped on or about March 19, 1941, by C. E. Jamieson & Co. from Detroit, Mich., and that subsequently it had been repackaged by Guy, Inc., at Seattle, Wash.; and charging that it was misbranded.