by the physician."; (2) in that its labeling failed to bear adequate directions for use; and (3) in that its labeling failed to bear adequate warnings against use where such 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.

On September 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

549. Misbranding of Dr. Whitehall's Compound Tablets. U. S. v. 642 Boxes of Dr. Whitehall's Compound Tablets. Default decree of forfeiture and destruction. (F. D. C. No. 3681. Sample No. 38625–E.)

On or about January 17, 1941, the United States attorney for the Western District of Wisconsin filed a libel against 642 boxes of Dr. Whitehall's Compound Tablets at La Crosse, Wis., alleging that the article had been shipped on or about November 27 and December 3, 1940, by the Dr. Whitehall Megrimine Co. from South Bend, Ind; and charging that it was misbranded. It was labeled in part: (Box, carton, and circular) "For Mitigating the Distress and Discomfort of Minor Muscular Aches and Pains," and (circular only) "If you are subject to attacks on change of weather or exposure, one tablet taken in time will often prevent distress and discomfort."

Analysis of a sample of the article showed that it contained acetanilid, sodium salicylate, and plant material.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, since when used in the dosage and with the frequency or duration prescribed, recommended, and suggested, such use might cause serious blood disturbances, anemia, collapse, and a dependence on the drug; (2) in that the labeling failed to bear adequate directions for use since it did not provide for a limit as to the duration or frequency of administration; (3) in that the labeling failed to bear 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; and (4) in that the labeling was false and misleading since it created the impression that the article constituted an appropriate treatment for the conditions described therein; whereas it was not a safe and appropriate remedy but was a dangerous drug, and the label failed to reveal the material fact that its use in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug.

On March 17, 1941, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

550. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 139 Packages of Zerbst's Capsules [25-cent size] and 23 Packages of Zerbst's Capsules [50-cent size]. Default decree of condemnation and destruction. (F. D. C. No. 4970. Sample No. 60418–E.)

These products would be potentially dangerous to health when used according to directions and they failed to bear adequate directions for use and warning statements. The capsules in the 25-cent-sized packages contained more acetanilid than the amount stated on the label, and those in the 50-cent-sized packages bore false and misleading therapeutic claims and failed to bear the required ingredient and quantity of contents statements.

On June 24, 1941, the United States attorney for the District of Oregon filed a libel against the above-named products at Portland, Oreg., alleging that they had been shipped on or about January 20, 1941, by the Zerbst Pharmacal Co. from St. Joseph, Mo.; and charging that a portion were adulterated and misbranded and that the remainder were misbranded.

Analyses of samples of the capsules showed that those in the 25-cent packages contained acetanilid (1¼ grains per capsule), together with caffeine, resinous material, camphor, capsicum, aloin, and asafoetida; and that those in the 50-cent packages contained acetanilid (2⅛ grains per capsule), together with a laxative plant drug.

The capsules in the 25-cent packages were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, namely, "Each Capsule contains as active ingredients, Acetanilid 1 Grain"; whereas they contained materially more than 1 grain of acetanilid.

The capsules in the packages of both sizes were alleged to be misbranded: (1) In that they were dangerous to health when used according to the directions

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.