(1) in that statements in the labeling which represented and suggested that it would be efficacious in the treatment of acute and mild chronic infections of the nose, that it would cause a depletion of the swollen mucous membrane, would promote drainage and greatly improve ventilation, would be efficacious to promote healing and would gradually diminish excess discharge, whether due to acute coryza or chronic nasal infection and whether the discharge was purulent or mucopurulent in quality, and would be equally efficient or effective whether dealing with repulsive scab formation or ozena or persistent postnasal drip, were false and misleading since it would not be efficacious for such purposes; (2) in that the following statement in the labeling, "Bacteriological tests have shown that Purpoil No. 22 and Purpoil No. 600 have bacteria destroying properties which are equivalent to phenol in the same strength and in the same type of oil," was false and misleading since it failed to reveal the material fact that phenol in the same strength and in the same type of oil possesses no bacteria-destroying properties. The Purpoil No. 600 was alleged to be misbranded further in that the statement "Used in the treatment of chronic suppurative infections of the nose" was false and misleading since it would not be efficacious in the treatment of suppurative infections of the nose.

The Aurofectol was alleged to be adulterated in that its strength differed from that which it was represented to possess since it was not an antiseptic as represented in its labeling. It was alleged to be misbranded in that certain statements in the labeling which represented that it would be efficacious in the treatment of dermatitis, eczema, and acute catarrhal inflammation of the tympanic membrane; would be efficacious in the treatment of acute and chronic infections of the external auditory canal and acute myringitis and acute catarrhal otitis media; that it was an effective parasiticide and antiseptic in skin diseases; that it would produce desired results in external auditory canal infections; that it would be efficacious in the treatment of infections of the skin of the external auditory canal were false and misleading since it would not be efficacious for such purposes.

On June 11, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

760. Misbranding of Fermlax. U. S. v. 61 Packages of Fermlax. Default decree of condemnation and destruction. (F. D. C. No. 7450. Sample No. 70672–E.)

On May 5, 1942, the United States attorney for the Eastern District of Tennessee filed a libel against 61 packages of Fermlax at Chattanooga, Tenn., alleging that the article had been shipped in interstate commerce on or about March 11, 1942, by Moon-Winn Drug Co., Inc., from Athens, Ga.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of sodium bicarbonate, magnesium carbonate, calcium carbonate, bismuth subnitrate, and rhubarb.

The article was alleged to be misbranded: (1) In that the directions on the label, "Adult dose—Teaspoonful in a full glass of water three times a day after meals. Children in proportion to age," provided for continuous administration, whereas it was a laxative and should not be used continuously, and they also failed to indicate the dosage for children of different ages. (2) In that the labeling failed to warn that a laxative should not be used in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels. (3) In that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

On June 12, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

761. Misbranding of laxative cold tablets and Rx S368230 Pills. Adulteration and misbranding of epinephrine tablets for hypodermic use. U. S. v. 84 Bottles of Laxative Cold Tablets, 14,800 Rx S368230 Pills, and 2,045 Tubes and 6,040 Packages of Hypodermic Tablets. Default decrees ordering destruction of laxative cold tablets, pills, and portion of hypodermic tablets. Consent decree of condemnation ordering portion of hypodermic tablets released under bond to be brought into compliance with the law. (F. D. C. Nos. 7324, 7480, 8271, 8331. Sample Nos. 76829–E, 91224–E, 91225–E, 4959–F, 5078–F.)

The labeling of the laxative cold tablets and of the Rx S368230 Pills (a portion of which had been repackaged and labeled in part, "Gloria Laxative Pills * * * Prepared for John A. Smith Co., Oconomowoc, Wis.") failed to bear adequate directions and warning statements, that of the pills also failed

to bear a satisfactory statement of the active ingredients, and that of the laxative cold tablets and the hypodermic tablets also bore false and misleading statements. The epinephrine hypodermic tablets contained only three-fourths as much epinephrine as the amount declared on the label.

On April 30, May 8, August 29, and September 8, 1942, the United States attorneys for the Northern District of Illinois, Eastern District of Wisconsin, and the Northern and Southern Districts of Ohio filed libels against 49 bottles each containing 100, and 35 bottles each containing 1,000 laxative cold tablets at Chicago, Ill.; 14,800 Rx S368230 Pills at Oconomowoc, Wis.; 6,040 packages each containing 100 epinephrine tablets at Columbus, Ohio; and 2,045 tubes each containing 20 epinephrine tablets at Toledo, Ohio, alleging that the articles had been shipped in interstate commerce within the period from on or about January 13, 1941, to on or about July 14, 1942, by Parke, Davis & Co. from Detroit, Mich.; and charging that the cold tablets and pills were misbranded, and that the epinephrine tablets were adulterated and misbranded.

Analyses of samples showed that the laxative cold tablets each contained approximately 2 grains of acetanilid, plant extractives (including resinous material), a quinine compound, and caffeine; and that the pills contained aloin and an extract of cascara sagrada.

The laxative cold tablets were alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use since it contained no directions as to frequency or duration of administration. (2) In that the labeling failed to bear adequate warnings since (a) they contained acetanilid and it did not warn that frequent or continued use might therefore be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence upon acetanilid, and that they should not be given to children; and (b) they contained laxative ingredients and the label did not warn against their use in case of abdominal pain and nausea, vomiting, or other symptoms of appendicitis; or that frequent or continued use might result in dependence upon laxatives to move the bowels. (3) In that the statement on the label, "Cold * * * (Grip)," was false and misleading since they did not constitute an adequate treatment for cold or grippe.

The pills were alleged to be misbranded: (1) In that the labeling failed to bear any directions for their use. (2) In that the labeling failed to warn that they were not to be used in the presence of abdominal pain, nausea, vomiting, or other symptoms of appendicitis; and that frequent or continued use might result in dependence upon laxatives. (3) In that the label failed to bear the common or usual names of the active ingredients since "Cascarin Bitter" is not the common or usual name of any substance.

The epinephrine tablets were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess, namely, (label) "Tablets Epinephrine 3/200 grain" and "One tablet dissolved in 1cc. of water makes a 0.1% solution," since each tablet contained less than 3/200 grain of epinephrine and 1 tablet dissolved in 1 cc. of water would make a solution of less concentration than 0.1 percent of epinephrine. They were alleged to be misbranded in that the above-quoted statements were false and misleading.

One June 1, August 26, and November 9, 1942, no claimant having appeared for the seizures at Chicago, Oconomowoc, and Columbus, judgments were entered ordering that they be destroyed. On February 6, 1943, Parke, Davis & Co., claimant for the seizure at Toledo, having admitted the material allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration.

762. Adulteration and misbranding of Gloria Tonic tablets. U. S. v. 74 Packages of Gloria Tonic. Default decree of condemnation and destruction. (F. D. C. No. 7338. Sample No. 80185–E.)

On April 16, 1942, the United States attorney for the Northern District of Ohio filed a libel against 74 packages of Gloria Tonic tablets at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about October 20, 1941, by the John A. Smith Co. from Oconomowoc, Wis.; and charging that it was adulterated and misbranded.

Analysis showed that the tablets contained iron (0.77 grain), sodium salicylate (3.64 grains), colchicine (0.003 grain), and extract of cascara sagrada.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, "Each tablet contains reduced Iron 1 gr., * * * Sodium Salicylate 5 gr., Colchicine 1–250 gr."