

was represented to possess in that it was represented to contain in each cubic centimeter not less than 50 rat units of ovarian extract; whereas it contained in each cubic centimeter not more than 4 rat units of ovarian extract. It was alleged to be misbranded in that the statement on the label, "Ovarian Extract * * * 50 Rat Units per cc." was false and misleading.

On April 20, 1942, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$75 on four of the counts, i. e., a total of \$300; and ordered that imposition of sentence on the remaining counts be suspended for 1 year, that the defendant be placed on probation for 1 year, and that if no further violation occurred no further penalties be imposed.

757. Misbranding of Nomo For Piles, Sanafrio, and Asmolac. U. S. v. Albert B. Hirschman (Hirschman Laboratories and Sanafrio Laboratories). Plea of nolo contendere. Fine, \$75 on each of 3 counts; sentence suspended on all but first count. (F. D. C. No. 5491. Sample Nos. 26467-E, 26469-E, 32632-E.)

The labeling of the Asmolac failed to bear adequate directions for use, such adequate warnings as are necessary for the protection of users, and a declaration of the alkaloids of atropine, hyoscyne, and hyoscyamine that were present. The labeling of all three products bore false and misleading curative and therapeutic claims.

On November 3, 1941, the United States attorney for the Southern District of California filed an information against Albert B. Hirschman, trading as Hirschman Laboratories and as Sanafrio Laboratories, San Pedro, Calif., alleging shipment within the period from on or about May 14 to on or about July 1, 1940, from the State of California into the States of Arizona and Oregon of quantities of the above-named drugs which were misbranded.

Analyses of samples showed that the Asmolac consisted essentially of water, alcohol, plant extractives, alkaloids, reducing sugars, potassium iodide, and sodium iodide; that the Sanafrio consisted essentially of fat, zinc oxide, camphor, and menthol; and that the Nomo For Piles consisted essentially of benzoic acid, boric acid, eucalyptus oil, fixed oils, and zinc oxide.

The Asmolac was alleged to be misbranded: (1) In that the directions for use contained no limitation as to duration of administration. (2) In that it contained (a) iodine or iodides and the labeling failed to warn that it should not be used in case of goiter except upon the advice of a physician and should be discontinued if skin rash appears; and (b) the alkaloids of belladonna and hyoscyamus and the labeling failed to warn that frequent or continued use should be avoided, that it should be used cautiously if dryness of the throat occurs, that it should be discontinued if rapid pulse or blurring of the vision occurs, and that it should not be taken by elderly people except upon competent advice. (3) In that the name "Asmolac" and the statements in the accompanying circular, "Where it is not deemed necessary to use Asmolac continuously, you should watch for the approaching of attacks such as nervousness, headache, itching of the nose or skin, severe sneezing, yawning, and other suggestive symptoms. If this is noticeable take half a teaspoon of Asmolac twice a day. In this way the actual spasms are usually to the greatest extent and often completely prevented," were false and misleading since they represented that when used as directed in the above-named conditions, it often would completely prevent the actual spasms of asthma; whereas if used as directed, it would not often, nor at all, completely prevent the actual spasms of asthma. (4) In that it contained the alkaloids of atropine, hyoscyne, and hyoscyamine, but the labeling did not contain the name and quantity or proportion of said alkaloids or, in lieu thereof, the quantity or proportion of total alkaloids of belladonna and hyoscyamus that it contained.

The Nomo For Piles was alleged to be misbranded: (1) In that the name "Nomo For Piles" and the statements in the labeling, (carton only) "Astringent," (carton, tube, and circular) "To Relieve * * * Soreness * * * Associated with Piles," and (circular) "For the relief of pain it is highly recommended," were false and misleading since they represented and suggested that it was a competent treatment for all cases of piles and would be efficacious to relieve the soreness and pain associated with piles; whereas it would not accomplish such results. (2) In that the labeling was misleading since it failed to reveal the fact, material in the light of the representations which it contained, that the preparation did not constitute a treatment for all kinds of piles and that competent advice should be secured in cases of excessive bleeding.

The Sanafrio was alleged to be misbranded in that the following statements in the labeling, (carton) "For * * * Chest Colds * * * Relieves Headache, Neuralgia, Inflammation in Head Colds, and similar conditions. * * * Directions Apply externally to the chest. Acts much like a plaster and helps to relieve local congestion," and (jar) "Relieves Headache, Neuralgia, Congestion, and Inflammation in * * * Chest Colds and similar conditions * * * Chest Colds, Cough, Sore Throat," were false and misleading since it would not be efficacious as a treatment or relief for such conditions.

On May 19, 1942, the defendant having entered a plea of nolo contendere, the court imposed a fine of \$75 on each of the 3 counts and suspended the sentence on counts 2 and 3 on condition that the defendant comply with instructions of the Government.

758. Misbranding of agar and oil with phenolphthalein. U. S. v. 28 Dozen Bottles of Royale Agar and Oil (and 1 other seizure action against Agar and Oil with Phenolphthalein). Default decrees of condemnation and destruction. (F. D. C. Nos. 7052, 7647. Sample Nos. 40894-E, 77140-E.)

The bottles containing this product were unlabeled when shipped in interstate commerce.

On March 18, and June 15, 1942, the United States attorney for the Eastern District of Pennsylvania filed libels against 61 dozen bottles of Agar and Oil with Phenolphthalein at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about January 7 and March 21, 1942, by the Vital Laboratories from Union City, N. J.; and charging that it was misbranded. After shipment a portion of the article was labeled in part, (bottle) "Royale Agar and Oil with Phenolphthalein"; and the cartons containing the remainder were labeled in part, "I. S. 137 1 Doz 16 Oz."

Analysis showed that the article was an emulsion containing mineral oil and phenolphthalein.

It was alleged to be misbranded in that it bore no labeling containing (1) adequate directions for use; (2) adequate warnings, since the label failed to warn that it should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon laxatives; (3) the name and place of business of the manufacturer, packer, or distributor; (4) an accurate statement of the quantity of the contents; and (5) the common or usual name of each active ingredient.

On May 1 and July 6, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

759. Adulteration and misbranding of Aurofectol; misbranding of Purpoil No. 22 and Purpoil No. 600. U. S. v. 6 $\frac{3}{4}$ Dozen Packages of Purpoil No. 22, 3 $\frac{1}{2}$ Dozen Packages of Purpoil No. 600, and 2 $\frac{1}{2}$ Dozen Packages of Aurofectol. Default decree of condemnation and destruction. (F. D. C. No. 7474. Sample Nos. 87163-E, to 87165-E., incl.)

The labeling of the Purpoil Nos. 22 and 600 failed to bear such warnings as are necessary for the protection of users and also contained false and misleading curative and therapeutic claims. The labeling of the Aurofectol contained false and misleading claims regarding its curative, therapeutic, and antiseptic properties.

On May 6, 1942, the United States attorney for the District of Columbia filed a libel against the above-named products at Washington, D. C., alleging that they had been shipped in interstate commerce on or about March 9 and 25, 1942, by Purpoil Laboratories, Inc., from Baltimore, Md.; and charging that they were misbranded and that the Aurofectol was also adulterated.

Analyses of samples of the Purpoil Nos. 22 and 600 showed that both consisted essentially of mineral oil containing small quantities of iodine, chlorobutanol, and menthol. Analysis of a sample of the Aurofectol showed that it consisted essentially of a mixture of oils and phenols. Bacteriological tests of the Aurofectol showed that it was not antiseptic.

The Purpoil Nos. 22 and 600 were alleged to be misbranded in that their labels failed to bear adequate warnings against use by children where their use might be dangerous to health and failed to bear adequate warnings against unsafe duration of administration or application in such manner and form as are necessary for the protection of users, since they failed to warn that use by children might be dangerous and that frequent or excessive use might cause injury to the lungs. The Purpoil No. 22 was alleged to be misbranded further