706. Misbranding of Greenawalt's Compound Dandelion Liver Disks. U. S. v. 164 Packages of Greenawalt's Compound Dandelion Liver Disks. Default decree of condemnation and destruction. (F. D. C. No. 4937. Sample No. 50252–E.)

The labeling of this product, a laxative, failed to bear adequate directions for use and adequate warnings, and bore false and misleading claims regarding its therapeutic and curative efficacy. The labeling also falsely implied that the physiological activity of the article was derived from dandelion, and failed to bear the ingredients statement, including the quantity or proportion of strychnine and belladonna alkaloids.

On June 14, 1941, the United States attorney for the Middle District of Pennsylvania filed a libel against the above-named product at Chambersburg, Pa., alleging that it had been shipped in interstate commerce on or about March 26, 1941, from Norwich, N. Y., to Chambersburg, Pa., and that it had been removed from the original container and repacked and relabeled—the labeling including a circular by William G. Greenawalt; and charging that as so repacked and relabeled it was misbranded.

Analysis showed that the article consisted essentially of laxative plant drugs, such as podophyllum and aloes, together with small amounts of belladonna and nux vomica (strychnine) alkaloids.

The article was alleged to be misbranded: (1) In that its labeling did not bear adequate directions for use, since the directions, (label) "Dose—1 or 2 at night. When 1 is too active on the bowels, divide a disk and take half," and (circular) "Usual Dose: One or two at bedtime. Should one be too active on the bowels, take half a disk. They can easily be cut in half. For children, usually half a Disk is sufficient," provided for an indefinite and continued use of a laxative which was inappropriate. (2) In that the label 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, since the labeling failed to warn that a laxative should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis; that frequent or continued use might result in dependence upon laxatives; and that the use of an article containing strychnine might be especially dangerous to children and elderly persons and that not more than the recommended dosage should be taken. (3) In that the label did not bear the common or usual names of the active ingredients or a statement of the quantity or proportion of strychnine and belladonna alkaloids contained in the article. (4) In that statements in the labeling which implied that its therapeutic activity was derived from dandelion and which represented that it would relieve biliousness, clear the complexion, clear sallow skin, tone the liver and stomach and clean coated tongue, prevent dizziness and vertigo, stimulate the liver, remove pimples and blotches, improve the condition of the blood, tone up the whole system, relieve liver trouble, and that it was an excellent vegetable remedy for biliousness, dizziness, and stomach trouble caused by inactivity of the liver, were false and misleading since it did not depend upon dandelion for its therapeutic activity and it would not be efficacious for the purposes claimed.

On September 23, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

707. Misbranding of Kalis Capsules. U. S. v. 2¾ Dozen Packages and 9¾ Dozen Packages of Kalis Capsules. Default decree of condemnation and destruction. (F. D. C. No. 7005. Sample No. 71403–E.)

This product consisted essentially of acetanilid, and laxative plant drugs including podophyllin and cascara sagrada, but the labeling failed to bear adequate warning statements required for a drug of this type.

On March 6, 1942, the United States attorney for the Eastern District of Missouri filed a libel against the above-named product at St. Louis, Mo., alleging that it had been shipped on or about November 6 and December 5, 1941, by Kalis Products from Ottumwa, Iowa; and charging that it was misbranded.

The article was alleged to be misbranded in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, since it failed to warn that the drug should not be taken when nausea, vomiting, abdominal pain, or other symptoms of appendicitis are present; and it also failed to bear warnings against unsafe methods or duration of administration, since it failed to warn that frequent

or continued use might be dangerous, causing serious blood diseases, anemia, collapse, or dependence on the drug.

On April 7, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

708. Misbranding of Lanoton for Women. U. S. v. 53 Packages of Lanoton for Women. Default decree of condemnation and destruction. (F. D. C. 6980. Sample No. 83608–E.)

The labeling of this product failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users. The labeling also created the misleading impression that the article was of particular value to women.

On March 7, 1942, the United States attorney for the Eastern District of Texas filed a libel against 53 packages of the above-named product at Marshall, Tex., alleging that it had been shipped in interstate commerce on or about January 10, 1942, by the National Medicine Co. from Nashville, Tenn.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it did not bear adequate directions for use since the labeling provided for frequent and continual administration, whereas the directions for a laxative should provide that it be taken only occasionally and when needed; (2) in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, and failed to bear adequate warnings against unsafe duration of administration; and (3) in that its label was misleading since it represented and suggested that the article was especially adaptable for use by women, whereas its effect would be the same on both men and women.

On May 5, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

709. Misbranding of solution of citrate of magnesia. U. S. v. 1,434 Bottles of Citrate of Magnesia. Default decree of condemnation. Product ordered delivered to a charitable institution. (F. D. C. No. 7421. Sample No. 78814–E.)

The labeling of this product failed to bear adequate warnings; to give the name and place of business of the manufacturer, packer, or distributor; and to bear an accurate statement of the quantity of contents.

On April 30, 1942, the United States attorney for the Western District of Pennsylvania filed a libel against 1,434 bottles of citrate of magnesia at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about March 2, 1942, by S. D. C. Laboratories, Inc., from Buffalo, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that (1) its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since there was no warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, or that frequent or continued use might result in dependence on laxatives to move the bowels; (2) it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and (3) in that it was in package form and its label failed to bear an accurate statement of the quantity of the contents.

On May 19, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a charitable institution.

710. Misbranding of Nurito. U. S. v. 75 Packages of Nurito. Default decree of condemnation and destruction. (F. D. C. No. 6994. Sample No. 83387–E.)

This product contained ⅓ gram of phenolphthalein, a laxative drug, per powder; and its labeling failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of the user.

On March 14, 1942, the United States attorney for the Eastern District of Louisiana filed a libel against 75 packages of Nurito at New Orleans, La., alleging that the article had been shipped in interstate commerce on or about September 27, 1941, and January 23, 1942, by the Nurito Co. from Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded: (1) In that the labeling did not bear adequate directions for use since the directions appearing in the labeling, "Take one powder, followed by full glass of water every three hours in indicated