16. Misbranding of Elixir Pheno Barbidon. U. S. v. 23 Bottles and 3 Bottles of Elixir Pheno Barbidon. Default decrees of condemnation and destruction. (F. D. C. Nos. 123, 124. Sample Nos. 36763–D, 36764–D.)

This drug consisted essentially of aminopyrine and phenobarbital. It was recommended in the labeling that it be administered in the dosage as directed by the physician. Its labeling, however, created the impression that its physiological effects were those of barbituric acid derivatives and failed to inform the physician that it contained aminopyrine. It would be dangerous to health when used as suggested in the labeling, particularly in view of the failure of the labeling to reveal the fact that it contained aminopyrine, which fact is material in the light of the representation in the labeling that it contained dimethylamino-antipyrine and phenylethylmalonylurea (barbituric acid derivative), and since it was capable of producing agranulocytosis; and because of the failure of the labeling to bear such adequate warnings against use in that pathological condition or where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration as are necessary for the protection of users.

On January 19, 1939, the United States attorney for the Northern District of California filed a libel against 26 bottles of Elixir Pheno Barbidon at San Francisco, Calif.; alleging that the article had been shipped in interstate commerce on or about October 19, 1938, by Premo Pharmaceutical Laboratories from New York, N. Y.; and charging that it was misbranded for the reasons appearing hereinbefore.

On May 9, 1939, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

17. Misbranding of Tablets Sedormid "Roche." U. S. v. 138 Packages and 154 Packages of Tablets Sedormid "Roche." Default decrees of condemnation and destruction. (F. D. C. Nos. 220, 224. Sample Nos. 47321–D, 47430–D.)

This drug consisted of tablets containing allyl-isopropylacetyl-carbamide. It would be dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, which contained directions that in the daytime one-half tablet be taken two or three times daily and that at night one or two tablets be taken shortly before bedtime. Its labeling failed to reveal facts material in the light of the recommended dosage or material with respect to consequences which might result from its use under the conditions of use prescribed therein, and failed to bear such adequate warnings against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users.

On April 10 and 26, 1939, the United States attorney for the District of Maryland filed libels against 292 packages of Tablets Sedormid "Roche" at Baltimore, Md.; alleging that the article had been shipped in interstate commerce within the period from on or about January 20 to on or about March 17, 1939, by Hoffmann-La Roche, Inc., Nutley, N. J.; and charging that it was misbranded for the reasons appearing hereinbefore.

On May 8 and 17, 1939, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

18. Misbranding of Sodasal. U. S. v. 15 Bottles and 21 Bottles of Sodasal. Default decree of condemnation and destruction. (F. D. C. Nos. 194, 210. Sample Nos. 42971–D, 52224–D.)

This product contained aminopyrine, sodium salicylate, compounds of magnesium and calcium, citrates and carbonates, sugar, and water. It would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, which directed that 1 tablespoonful or 4 teaspoonfuls be taken in water, milk, or orange juice, followed by a full glass of water or milk, 3 times a day before or after meals or on retiring, and that the dose be cut down "if the ears ring or if allergic."

On March 9 and March 25, 1939, the United States attorney for the Western District of Pennsylvania filed libels against 36 bottles of Sodasal at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about February 18 and 21, 1939, by the Sodasal Laboratories from Detroit, Mich.; and charging that it was misbranded for the reasons stated above.

The libels charged that the article was also misbranded in violation of the Food and Drugs Act of 1906, reported in notice of judgment No. 30895 published under that act.

On April 17, 1939, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.