United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

28301–28375

[Approved by the Acting Secretary of Agriculture, Washington, D. C., June 7, 1938]

28301. Adulteration of cathartic compound tablets and phenobarbital sodium tablets. U. S. v. Direct Sales Co. Plea of guilty. Fine, $300. (F. & D. No. 39475. Sample Nos. 27734–C, 27736–C.)

These cathartic compound tablets were sold under a name recognized in the National Formulary, but they contained more mild mercurous chloride than prescribed by that authority. The phenobarbital sodium tablets contained less sodium phenobarbital than declared on the label.

On December 16, 1937, the United States attorney for the Western District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Direct Sales Co., a corporation, Buffalo, N. Y., alleging shipment by the said defendant in violation of the Food and Drugs Act on or about September 25, 1936, from the State of New York into the State of Pennsylvania of quantities of the drugs hereinafter described, which were adulterated. The articles were labeled in part: "Tablets Cathartic Compound U. S. P. [or "Phenobarbital Sodium ½ Grain"] * * * Manufactured By Direct Sales Co. Inc., Buffalo, N. Y."

The cathartic compound tablets were alleged to be adulterated in that they were sold under a name recognized in the National Formulary but differed from the standard of strength, quality, and purity prescribed therein in that 100 tablets contained more than 6 grams, namely, not less than 7.35 grams of mild mercurous chloride, equivalent to 1.13 grains of mild mercurous chloride per tablet, whereas the National Formulary provides that 100 pills of compound cathartic, i. e., compound pills of mild mercurous chloride shall contain not more than 6 grams of mild mercurous chloride, and the standard of strength, quality, and purity of the article was not declared on the container.

The phenobarbital sodium tablets were alleged to be adulterated in that their strength and purity fell below the professed standard and quality under which they were sold in that each tablet was represented to contain one-half grain of sodium phenobarbital; whereas they contained not more than 0.436 grain of sodium phenobarbital per tablet.

On December 16, 1937, a plea of guilty having been entered, the defendant was sentenced to pay a fine of $300.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

28302. Adulteration and misbranding of solution of citrate of magnesia. U. S. v. Roma Extract Co. and Joseph Graceffa. Plea of nolo contendere. Fine, $10 each. (F. & D. No. 39455. Sample Nos. 12131–C, 12132–C.)

This product differed from the standard laid down in the United States Pharmacopoeia since it contained materially less magnesium citrate than prescribed therein and contained magnesium sulphate (Epson salt), an ingredient not specified therein.

On May 17, 1937, the United States attorney for the District of Massachusetts, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Roma Extract Co., Boston, Mass., and Joseph Graceffa, an officer of the corporation, alleging shipment by the said defendants in violation of the Food and Drugs Act on or about August 13 and October 17, 1936, from the State of Massachusetts into the State of Rhode Island of quantities of

solution of citrate of magnesia which was adulterated and misbranded. The article was labeled in part: "Roma Brand * * * Roma Extract Co. Inc. Boston, Mass."

It was alleged to be adulterated in that it was sold under a name recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the test laid down therein since 100 cubic centimeters of the article contained magnesium citrate corresponding to less than 1.6 grams, namely, 0.14 gram of magnesium oxide, and 10 cubic centimeters of the solution after precipitation and conversion of the citric acid into ash, required less than 26 cubic centimeters, namely, not more than 3.3 cubic centimeters, of half-normal hydrochloric acid to neutralize the alkalinity of the ash, and 100 cubic centimeters of the articles contained 5.0 grams in the case of one lot, and 5.2 grams in the case of the other, of magnesium sulphate; whereas the pharmacopoeia provides that solution of magnesium citrate shall contain in each 100 cubic centimeters an amount of magnesium citrate corresponding to not less than 1.6 grams of magnesium oxide, that 10 cubic centimeters of the solution after precipitation and conversion of the citric acid into ash, shall require not less than 26 cubic centimeters of half-normal hydrochloric acid to neutralize the alkalinity of the ash, and magnesium sulphate is not mentioned in the pharmacopoeia in the formula for the product, and the standard of strength, quality, and purity of the article was not declared on the container.

It was alleged to be misbranded in that the statements, "Solution of Citrate of Magnesia with Magnesia Sulphate," borne on the wrappers, "Solution Citrate Magnesia," blown in the bottles, and "Citrate of Magnesia Solution," borne on the bottle caps, were false and misleading. The article was alleged to be misbranded further in that it was a product composed in large part of magnesium sulphate prepared in imitation of and offered for sale under the name of another article, solution citrate magnesia and citrate of magnesia solution.

On October 13, 1937, pleas of nolo contendere were entered by the defendants, and they were sentenced to pay fines in the total amount of $20.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

28303. Adulteration of tincture of nux vomica, camphorated tincture of opium, elixir terpin hydrate and codeine, elixir triple bromides, and Fowler's solution. U. S. v. Goodrich-Gamble Co., Inc. Plea of guilty. Fine, $25. (F. & D. No. 38598. Sample Nos. 63326–B to 63330–B, incl.)

These products were sold under names recognized in the United States Pharmacopoeia or the National Formulary but differed from the standard established by those authorities, and with the exception of the Fowler's solution, they differed from their own declared standard, since they were found to contain certain drugs either in greater or smaller amounts than those declared

On April 6, 1937, the United States attorney for the District of Minnesota, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Goodrich-Gamble Co., a corporation, St. Paul, Minn., alleging shipment by said company in violation of the Food and Drugs Act on or about May 4, 1936, from the State of Minnesota into the State of Wisconsin, of quantities of the above-described drugs, which were adulterated. They were labeled in part: "Goodrich-Gamble Company, St. Paul, Minn."

The articles were alleged to be adulterated in that they were sold under names recognized in the United States Pharmacopoeia or in the National Formulary and to differ from the standard of strength, quality, and purity as determined by the tests laid down in those authorities in the following respects: The tincture of nux vomica yielded not less than 0.303 gram of the alkaloids of nux vomica per 100 cubic centimeters, whereas the pharmacopoeia provides that tincture of nux vomica shall yield not more than 0.263 gram of the alkaloids of nux vomica per 100 cubic centimeters; the camphorated tincture of opium contained not more than 3.42 grams of powdered opium per 1,000 cubic centimeters, whereas the pharmacopoeia provides that camphorated tincture of opium shall contain not less than 4 grams of opium per 1,000 cubic centimeters; the elixir terpin hydrate and codeine contained no codeine, whereas the National Formulary provides that the product shall contain codeine; the elixir triple bromides contained not more than 45.6 grams of ammonium bromide, not more than 44 grams of potassium bromide and not more than 51.9 grams of sodium bromide per 1,000 cubic centimeters; whereas the National Formulary provides that elixir of three bromides shall contain in 1,000 cubic centimeters not less than 80 grams each of ammonium bromide, potassium bromide, and sodium bromide; the Fowler's solution contained not more than