

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1051-1100

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *January 24, 1945.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1051. Misbranding of sterile solution of sodium citrate. U. S. v. The National Drug Co. Plea of nolo contendere. Fine, \$4,000. (F. D. C. No. 9670. Sample Nos. 3633-F, 5762-F, 11611-F, 29380-F, 29472-F, 34613-F, 37501-F, 41782-F.)

On July 15, 1943, the United States attorney for the Eastern District of Pennsylvania filed an information against the National Drug Co., a corporation, Philadelphia, Pa., alleging shipment from on or about November 11 to December 31, 1942, from the State of Pennsylvania into the States of Kansas, Missouri, Colorado, Georgia, Virginia, and Ohio of quantities of the above-named product, which was misbranded.

Examination of samples disclosed that the article contained pyrogens.

The article was alleged to be misbranded in that, by reason of the presence of pyrogens, it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, "The contents of a 50 cc. ampul containing the 2½% solution, mixed with 450 cc. of blood produces a transfusion mixture." It was alleged to be misbranded further in that the statement in its labeling, "For use in transfusions to prevent the clotting of blood," was misleading, since the

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1053, 1075, 1087, 1088, 1093, 1097, 1100; failure to bear adequate statements of quantity of contents, Nos. 1055, 1062, 1075, 1099; cosmetic, subject to the drug provisions of the Act, Nos. 1073, 1090.

article would not be safe or appropriate for use in transfusions to prevent the clotting of blood.

On September 22, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of \$500 on each of 8 counts, a total of \$4,000.

1052. Misbranding of Re-Sude-Oids. U. S. v. 20 Packages of Re-Sude-Oids. Default decree of condemnation and destruction. (F. D. C. No. 10033. Sample No. 42658-F.)

On or about June 18, 1943, the United States attorney for the District of Oregon filed a libel against 20 packages of Re-Sude-Oids at Portland, Oreg., alleging that the article had been shipped on or about May 11, 1943, by the American Medicinal Products, Inc., from Los Angeles, Calif.; and charging that it was misbranded.

Examination showed that the article consisted of capsules containing, in each, approximately 0.68 grain thyroid, 0.41 grain potassium iodide, 0.02 grain phenolphthalein and dried glandular tissue.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency or duration prescribed, recommended, and suggested in the labeling thereof: (On bottle label, carton, and circular enclosed in the package) "Take one capsule daily for six days, then one capsule twice a day for six days, then one capsule three times a day with all following bottles." The article was alleged to be misbranded further in that the statements appearing in its labeling which created the impression in the minds of readers that the article was a safe, appropriate, and effective treatment for obesity were false and misleading, since the article was not a safe, appropriate, or effective treatment for such conditions, but was a potentially harmful drug.

On August 10, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1053. Misbranding of Chynos. U. S. v. Watchung Laboratories and Emil J. Widmer. Pleas of guilty. Fines, \$50 on count 1 and \$500 on count 2 as to each defendant. Payment of fines on count 2 suspended and defendants placed on probation. (F. D. C. No. 9642. Sample No. 18924-F.)

On June 3, 1943, the United States attorney for the District of New Jersey filed an information against the Watchung Laboratories, a corporation, Bound Brook, N. J., and Emil J. Widmer, president and treasurer of the corporation, alleging shipment on or about October 26 and December 12, 1942, from the State of New Jersey into the State of New York of quantities of the above-named product.

Analyses of samples of the article showed that it was in the form of tablets which consisted essentially of aminopyrine (approximately 2 grains per tablet) and by hydroxyquinoline sulfonic acid.

The article was alleged to be misbranded in that it was not designated solely by a name recognized in an official compendium; it was fabricated from two or more ingredients, one of which was aminopyrine (amidopyrine); and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of aminopyrine named therein. It was alleged to be misbranded further in that it contained aminopyrine, which might cause the serious blood disturbance known as agranulocytosis, and might therefore produce serious or fatal injury unless used under adequate and continuous medical supervision; and its label failed to bear such adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users.

On June 21, 1943, the defendants having entered pleas of guilty, the court imposed upon each defendant a fine of \$50 on count 1 and a fine of \$500 on count 2. Payment of the fines on count 2 were suspended, and the defendants were placed on probation for a period of 1 year.

1054. Adulteration and misbranding of effervescing solution citrated magnesia. U. S. v. Henry Perlmuter (Crystal Drug and Magnesia Co., and White-Stone Laboratories). Plea of guilty. Fine, \$50. (F. D. C. No. 9655. Sample No. 19441-F.)

On June 22, 1943, the United States attorney for the District of Massachusetts filed an information against Henry Perlmuter, trading as the Crystal Drug and Magnesia Co. and as the White-Stone Laboratories, Dorchester,