

That the *Nose Spraying Solution* would be efficacious in the cure, mitigation, treatment, and prevention of head colds, hay fever, sinus, and catarrhal trouble.

That the *Eye Bath* possessed healing properties, and was an antiseptic; and that it would be efficacious in the cure, mitigation, treatment, and prevention of eye strain, blue, granulated lids, and sore eyes.

Further misbranding, Section 502 (a), the labeling of the *Pronto-Lax* was false and misleading since it represented and suggested that the article contained healing minerals, and that it was recommended by the Food and Drug Administration as the greatest mineral water in the world. The article did not contain healing minerals, and was not recommended by the Food and Drug Administration.

Misbranding Section 502 (f) (2), the *Pronto-Lax* and *Mineral Crystals* were laxatives; and their labeling failed to warn that they should not be used in the presence of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, and that frequent or continued use of the articles might result in dependence upon laxatives to move the bowels.

DISPOSITION: November 12, 1946. Pleas of guilty having been entered, the court imposed a fine of \$100 against each individual on count 1 of the information, which related to the *Pronto-Lax*. The court imposed also a fine of \$500, generally, upon the defendants on the other counts, but suspended the latter fine for 3 years.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2103. Adulteration of amphetamine sulfate tablets. U. S. v. 576 Bottles and 1 Drum * * *. (F. D. C. No. 22375. Sample No. 52302-H.)

LIBEL FILED: January 17, 1947, District of Minnesota.

ALLEGED SHIPMENT: On or about August 31, 1946, by the Penn Lee Products, from St. Paul, Minn.

PRODUCT: 576 1,000-tablet bottles of *amphetamine sulfate tablets* and 1 unlabeled drum containing broken tablets of the same article removed from the labeled bottles, at St. Paul, Minn.

LABEL, IN PART: (Bottles) "Amphetamine Sulfate Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), desoxyephedrine hydrochloride had been substituted for amphetamine sulfate in the article.

DISPOSITION: March 27, 1947. No claimant having appeared, judgment was entered ordering the product destroyed.

2104. Adulteration of poke root and skullcap herb. U. S. v. 21 Bags, etc. (F. D. C. No. 19422. Sample Nos. 8617-H, 8618-H.)

LIBEL FILED: March 14, 1946, District of New Jersey.

ALLEGED SHIPMENT: On or about January 30, 1946, by the St. Louis Commission Co., from St. Louis, Mo.

PRODUCT: 21 bags containing approximately 1,535 pounds of *poke root* and 3 bales containing approximately 746 pounds of *skullcap herb* at Jersey City, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of rodent hair fragments, insects, and insect fragments.

DISPOSITION: April 29, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2105. Alleged adulteration and misbranding of Hormo-Fen Capsules and alleged misbranding of Hormo-Gen Capsules. U. S. v. Harlow B. Boyle and Charles E. Boyle (Boyle & Co.). Pleas of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 20190. Sample Nos. 28653-H, 32251-H.)

INFORMATION FILED: October 15, 1946, Southern District of California, against Harlow B. Boyle and Charles E. Boyle, partners, trading as Boyle & Co., Los Angeles, Calif.

*See also No. 2101.

ALLEGED SHIPMENT: On or about April 28 and August 9, 1945, from the State of California into the States of Washington and Arizona.

LABEL, IN PART: "Hormo-Fen (Female Hormone) 2,000 International Units Per Capsule," or "Hormo-Gen (Male Hormone) 10 Capon Units Per Capsule."

NATURE OF CHARGE: *Hormo-Fen.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, since each capsule of the article was represented to contain 2,000 International Units of estrogenic substance, whereas each capsule contained less than 2,000 International Units of estrogenic substance. Misbranding, Section 502 (a), the label statement, "Each capsule contains 2,000 International Units of Estrogenic Substance," was false and misleading. Further misbranding, Section 502 (e), the article was not designated solely by a name recognized in an official compendium, it was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient. The label designation "Estrogenic Substance" is not the common or usual name of any particular active ingredient, but is a generic name for a class of substances.

Hormo-Gen. Misbranding, Section 502 (a), the label statement, "Hormo-Gen (Male Hormone) * * * To support androgenic parenteral or inunction therapy in hypogonadism in the male and the male climacteric," was false and misleading in that the article would not be efficacious for such purposes.

The information contained also charges of adulteration and misbranding of Nova-Tron Capsules, Mina-Vita Tablets, and Vita-Health Tablets under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 18, 1947, the defendants having entered pleas of not guilty, the case came on for trial before the court. After consideration of the evidence and arguments of counsel, the court returned a verdict of not guilty, and the information was ordered dismissed.

2106. Adulteration and misbranding of vitamin B complex and misbranding of Ov hormone. U. S. v. The Alpinol Corporation, Louis Rubella, and Ugo Quarantelli. Pleas of guilty. Fine of \$2,000 against the defendants, jointly. (F. D. C. No. 17827. Sample Nos. 4457-H, 4460-H, 16551-H.)

INFORMATION FILED: July 22, 1946, Southern District of New York, against the Alpinol Corporation, New York, N. Y., and Louis Rubella, president, and Ugo Quarantelli, secretary-treasurer, of the corporation.

ALLEGED SHIPMENT: On or about March 27 and April 17 and 30, 1945, from the State of New York into the States of Pennsylvania and Illinois.

PRODUCT: The product labeled "Vitamin B Complex" was devoid of thiamine and riboflavin, two of the vitamin constituents declared on the label. It had the characteristics of an oil, being immiscible with water. Substances immiscible with water may cause serious consequences if injected intravenously. The product was apparently a hormone in oil solution, to which had been applied the label of a different product.

LABEL, IN PART: "Vitamin B Complex No. 2 * * * Intramuscular Intravenous * * * Distributed by D. F. Strohm Upper Darby, Pa.;" "Ov hormone 10,000 I. U. * * * Distributed by Edgar Metz Lansdowne, Pa.," or "Ov hormone 30,000 I. U. * * * Distributed By The National Colloid Co. Chicago, Ill."

NATURE OF CHARGE: *Vitamin B Complex.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. It was represented to contain in each cubic centimeter 20 milligrams of thiamine hydrochloride and 1 milligram of riboflavin, whereas it contained no thiamine hydrochloride or riboflavin. Misbranding, Section 502 (a), the labeling of the article was misleading in that the label statement "Intravenous" represented and suggested that the article was for intravenous use, and the labeling failed to reveal the material fact with respect to the consequences which may result from the use of the article under the conditions of use prescribed in its labeling, i. e., intravenously.

Ov hormone. Misbranding, Section 502 (a), the label statement, "Contains * * * Estrogenic Hormone derived from gravid mare's urine," was false and misleading since it represented and suggested that the estrogenic substance present in the article was estrogenic substance as it occurs in and is extracted from gravid mare's urine, whereas the estrogenic substance present