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]

1601-1650

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.

MAURICE COLLINS, Acting Administrator, Federal Security Agency.

WASHINGTON, D. C., June 4, 1946.

CONTENTS*

| | Page | | Page |
|--|------|---|------|
| Drugs actionable because of failure to bear ade- | _ | Drugs actionable because of false and mis- | _ |
| quate directions or warning statements | 61 | leading claims | 72 |
| Drugs actionable because of contamination | | Drugs for human use | 72 |
| with filth | 63 | Drugs for veterinary use | 77 |
| Drugs and devices actionable because of devia | | Drugs actionable because of omission of, or un- | |
| tion from official or own standards | 64 | satisfactory, ingredients statements | 81 |
| | | | |

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

- 1601. Misbranding of Munyon's Remedy for Round Worms and Munyon's Improved Paw-Paw Pills (also known as Munyon's Laxative Pills). U. S. v. Penn Drug & Supply Co. Plea of guilty. Fine, \$400. (F. D. C. No. 15530. Sample Nos. 42281-F, 77721-F.)
- INFORMATION FILED: June 5, 1945, Middle District of Pennsylvania, against the Penn Drug & Supply Co., a corporation, Scranton, Pa.
- ALLEGED SHIPMENT: On or about November 12, 1943, and January 3, 1944, from the State of Pennsylvania into the States of Delaware and Indiana.
- PRODUCT: Analyses disclosed that the *Munyon's Remedy for Round Worms* consisted essentially of sugar, with a small proportion of mineral matter; and that the *Munyon's Paw-Paw Pills* consisted essentially of aloin and laxative drugs.
- LABEL, IN PART: "Munyon's Remedy for Round Worms [or "Munyon's Improved Paw-Paw Pills—Cathartic"] * * * Munyon Remedy Corp. [or "Co."] Scranton, Pa."
- NATURE OF CHARGE: Munyon's Remedy for Round Worms, misbranding, Section 502 (a), the label statement, "Munyon's Remedy for Round Worms Prepared for expelling worms and as a tonic for weak children," was false and misleading since the article would not be efficacious in the cure, mitigation, treatment, and prevention of roundworms; it would not be efficacious for expelling roundworms; and it would not be an effective tonic for weak children; Section 502 (b) (2), the labels on the vials containing the article bore no statement of the quantity of the contents of the vials; and, Section 502 (e) (2), the labels

^{*}For failure to comply with the labeling requirements of an official compendium, see No. 1624; presence of a noncertified coal-tar color, No. 1633; deceptive packaging, No. 1648.

failed to bear the common or usual name of each active ingredient of the article.

Munyon's Improved Paw-Paw Pills, misbranding, Section 502 (a), the label statements, "For * * * Indigestion, Headaches and Similar Disorders" and "for * * * Indigestion, Liver Ailments, Headaches and Similar Disorders," were false and misleading, since the article would not be efficacious in the cure, mitigation, treatment, and prevention of indigestion, liver ailments, headaches, and similar disorders; Section 502 (b) (2), the labels on the vials containing the article bore no statement of the quantity of the contents; Section 502 (e) (2), the labels failed to bear the common or usual name of each active ingredient of the article; and, Section 502 (f) (2), the article was a laxative and its labeling failed to bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that continued and habitual use of the article might result in dependence on laxatives to move the bowels.

DISPOSITION: June 12, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$200 on each count, a total fine of \$400.

1602. Misbranding of George's Rx 205 Tablets and Pepotabs Tablets. U. S. v. George F. Hauptman (Market Drug Co.). Plea of nolo contendere. Fine, 250. (F. D. C. No. 15505. Sample Nos. 50684-F, 50857-F.)

Information Filed: April 26, 1945, Eastern District of Pennsylvania, against George F. Hauptman, trading as the Market Drug Company, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about January 8 and June 10, 1944, from the State of Pennsylvania into the State of New Jersey.

PRODUCT: Analyses disclosed that the *George's Rx 205 Tablets* consisted of red tablets containing plant material and small proportions of strychnine and phosphorus compounds and white tablets containing thiamine chloride; and that the *Pepotabs Tablets* consisted of brown tablets and white tablets, the brown tablets containing a bitter resin, such as damiana, and small proportions of strychnine and phosphorus compounds, and the white tablets containing thiamine chloride.

NATURE OF CHARGE: George's Rx 205 Tablets, misbranding, Section 502 (a), the label statement, "Recommended * * * for persons over 35 years of Age," created the misleading impression that the red and white tablets, when used in conjunction with each other, would be of especial value to persons over 35 years of age, i. e., that they would rejuvenate persons over 35 years of age. Further misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the fact that orchic substance is therapeutically inert when taken orally, as directed in the labeling of the article, which fact was material in the light of the label representation, "Red Tablets Contain: * * * Avenin Orchic Substance * * * Directions: One Red Tablet and one White Tablet, with half glass of water, twice a day."

Pepotabs Tablets, misbranding, Section 502 (a), the name "Pepotabs" created the misleading impression that the article possessed the health-giving and rejuvenating properties implied in the expression "Pep"; and the label statement, "Recommended * * * for persons over 35 years of Age," created the misleading impression that the brown and white tablets, when used in conjunction with each other, would be of special value to persons over 35 years of age, i. e., that they would rejuvenate persons over 35 years of age. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings since the brown tablets contained strychnine and the labeling failed to warn that frequent or continued use of the article was to be avoided and that use of the article by children and elderly persons might be especially dangerous.

Disposition: June 20, 1945. A plea of nolo contendere having been entered, the court imposed a fine of \$250.

1603. Misbranding of Prentils. U. S. v. 705,792 Tablets, 13,680 Tablets, and 36 Cartons of Prentils. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14605. Sample Nos. 76092-F, 76093-F, 76099-F, 76100-F.)

LIBEL FILED: December 4, 1944, Northern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of October 22, 1943, and September 12, 1944, by the Ivers-Lee Co., from Newark, N. J.