

SHIPPED: Between 7-21-60 and 4-12-61, from Chicago, Ill., and Brooklyn, N.Y.

LABEL IN PART: (Btl. and ctn.) "Barry-Martin Menstrual Pain Relief \* \* \* Tablets Distributors Barry-Martin & Co., Miami 46, Fla. \* \* \* Each tablet contains: Salicylamide, Phenacetin, Phenylpropanolamine HCl Hyoscyamine HBr, Atropine Sul., Hyoscine HBr, Mag. Glycinate."; (repack btl.) "Barosil \* \* \* One teaspoonful contains Magnesium Trisilicate 0.5 Gm. (7.5 Grains) Aluminum Hydroxide 0.25 Gm. (4.0 grains) \* \* \* Distributors Barry-Martin & Co., Miami, Florida"; (repack btl.) "B-M \* \* \* Barogel Amphoteric Aluminum Hydroxide Gel."

RESULTS OF INVESTIGATION: The bulk lots of articles described above were repacked by the dealer into the bottles described above.

LIBELED: 9-1-61, S. Dist. Fla.

CHARGE: (*Barosil* and *Barogel*), 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that they were adequate and effective for the management of peptic ulcers; (*menstrual pain relief tablets*), 502(e)(2)—the article was a drug fabricated from two or more ingredients, and its label failed to bear the quantity or proportion of phenacetin (acetophenetidin), hyoscyamine, atropine, and hyoscine contained therein; and 502(f)(2)—the labeling failed to bear the warning statements for preparations containing belladonna alkaloids: "Not to be used by elderly persons or by children under 6 years of age unless directed by physician" and "Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs" and the warning statement for preparations containing phenylpropanolamine hydrochloride: "Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician."

DISPOSITION: 2-26-62. Consent—claimed by Barry-Martin & Co. and released under bond for relabeling.

6927. Paregoric. (F.D.C. No. 46925. S. No. 54-621 T.)

QUANTITY: 41 cases, 12 2-oz. btls. each, 98 cases, 12 1-oz. btls. each, and 66 cases, 12 ½-oz. btls. each, at Atlanta, Ga., in possession of Southern Drug-gists, Inc.

SHIPPED: 1-15-62, from Memphis, Tenn.

LABEL IN PART: (Btl.) "Ev-R Pure Brand Paregoric U.S.P. Anhydrous Mor-phine 0.35 to .045 Gm in 100 cc. \* \* \* Directions: 3 days old, 1 drop; 1 week old, 2 drops; 1 month old, 3 drops; 1 year old, 8 drops; 5 years old, 20 drops. Adults a teaspoonful. \* \* \* Packed by Tolleson Laboratories, Atlanta, Georgia."

RESULTS OF INVESTIGATION: The article was shipped in gallon bottles and repacked by the dealer into the bottles described above.

LIBELED: 1-17-62, N. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in that it did not state the conditions and purposes for which the article was intended to be used, and in that the directions for use for infants were improper.

DISPOSITION: 2-26-62. Default—destruction.