

spastic rectum, rectal fistula, rectal fissure, rectal bleeding, lower colon troubles, swollen rectal protrusions, and rectal soreness; that the articles, when used in combination, would restore normal elimination desire (regularity) and normal conditions, would re-establish rectal health, and would reduce the possibility of rectal cancer; and that the article of device was safe;

502 (f) (1)—the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended;

502 (j)—the device was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in an accompanying circular containing "Instructions for Use."

DISPOSITION: On 1-7-54, a temporary restraining order was entered against the defendants enjoining them against the acts complained of, and on 1-22-54, a preliminary injunction was entered. Thereafter, on 9-3-54, with the consent of the defendants, a decree of permanent injunction was entered enjoining the defendants against introducing into interstate commerce the device and drug involved, or any similar article of device and drug, which were misbranded as alleged in the complaint.

In addition, the decree stated that nothing in the injunction should prevent the defendants from introducing into interstate commerce the ointment designated as "Dr. Reilly's Rectal Remedy and Pile-Aid," under suitable labeling, for use for the temporary relief of itching and irritation associated with hemorrhoids, provided that a new name is adopted for such ointment which does not create the false and misleading impression that the ointment is of value in the treatment or cure of hemorrhoids, and provided further that no labeling statements, collateral literature, or advertising material is used which represents or suggests that the ointment is of value in the treatment or cure of hemorrhoids.

The decree stated also that the defendants could ship the device in interstate commerce to licensed physicians, hospitals, and clinics for professional use and to persons lawfully engaged in the storage or wholesale or retail distribution of medical devices for sale on the prescription of a physician, provided the label on the device stated the method of its application or use and bore the statement "Caution: Federal law restricts this device to sale by or on the order of a physician," and that there was made readily available to physicians licensed by law to use or order the use of the device brochures bearing information concerning the use of the device.

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

4642. Tryptacin tablets (47 seizure actions). (F. D. C. Nos. 35667, 35669, 35670, 35679, 35682/6, 35690, 35693, 35695, 35703, 35709/12, 35715, 35721, 35725, 35726, 35728, 35729, 36022/5, 36030/3, 36035/8, 36041/3, 36045/53, 36055, 36056, 36067, 36068, 36073, 36091/3. S. Nos. 14-743 L, 17-595 L, 19-848 L, 20-097/9 L, 20-104 L, 20-110 L, 35-520/1 L, 35-527/8 L, 39-554 L, 39-562 L, 42-630 L, 42-891/3 L, 43-163 L, 43-165/6 L, 43-169/70 L, 43-313/4 L, 47-921 L, 48-106/7 L, 58-253/5 L, 58-257 L, 58-260/2 L, 59-184/5 L, 59-392/6 L, 64-364 L, 65-375/6 L, 70-052 L, 72-361 L, 73-888/90 L, 75-976 L, 83-473/4 L, 83-477 L, 83-481 L, 83-855 L.)

*See also No. 4641.

QUANTITY: 12,028 100-tablet btl. at Atlanta, Ga.; Minneapolis and St. Paul, Minn.; Los Angeles, Oakland, San Francisco, Sacramento, and Vernon, Calif.; Chicago, Ill.; Philadelphia, Pa.; Tampa, Fla.; Charleston, W. Va.; New Orleans, La.; Denver, Colo.; Burlington, Des Moines, Cedar Rapids, Ottumwa, and Waterloo, Iowa; Everett and Seattle, Wash.; and Houston, Tex.

SHIPPED: Between 1-13-53 and 10-9-53, from Cleveland, Ohio, by Rhodes Pharmacal Co., Inc.

LABEL IN PART: (Btl.) "Tryptacin Rhodes * * * Tablets."

RESULTS OF INVESTIGATION: Advertisements concerning the use of the article in the treatment of stomach ulcers appeared in various newspapers circulated in the areas where the product was located, but the labeling of the article bore no reference to stomach ulcers.

LIBELED: Between 9-24-53 and 11-10-53, N. Dist. Ga., Dist. Minn., N. Dist. Calif., S. Dist. Calif., N. Dist. Ill., E. Dist. Pa., S. Dist. Fla., S. Dist. W. Va., E. Dist. La., Dist. Colo., N. Dist. Iowa, S. Dist. Iowa, W. Dist. Wash., and S. Dist. Tex.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to state all the conditions or diseases for which the article was intended to be taken, and its labeling failed also to bear adequate directions for use in the treatment of such conditions and diseases.

DISPOSITION: Between 11-6-53 and 8-16-54. 4 seizure actions: Default—destruction. 43 seizure actions: Consent—Claimed by Rhodes Pharmacal Co., Inc., and relabeled.

4643. C-Tone. (F. D. C. No. 36104. S. No. 45-595 L.)

QUANTITY: 27 cases, 12 8-oz. btl. each, at Cambridge, Mass.

SHIPPED: 10-9-53, from New York, N. Y., by Balanced Foods, Inc.

LABEL IN PART: (Btl.) "C-Tone The *Natural* Vitamin C Tonic."

RESULTS OF INVESTIGATION: Prior to the receipt of this shipment, the consignee had distributed to prospective customers a number of circulars entitled "Which of These Dread Killers Threaten Your Advancing Years?" These circulars were identical in text (except for the imprint of consignee) to other circulars concerning this product distributed to various dealers by the shipper of the article.

LIBELED: 11-3-53, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use in the treatment of high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, dizzy spells, and for providing energy and improving digestion, which were the conditions and purposes for which the article was intended.

DISPOSITION: 2-21-55. Default—destruction.

4644. Anterior pituitary whole ovarian solution. (F. D. C. No. 37035. S. No. 78-918 L.)

QUANTITY: 14 vials at Dayton, Ohio.

SHIPPED: 1-15-54 and 6-21-54, from Los Angeles, Calif., by American Bio-Chemical Corp.