

DISPOSITION: 7-17-56. Default—the article was delivered to a charitable institution, and the accompanying labeling was destroyed.

4890. Rectal treatment. (F. D. C. No. 37633. S. No. 3-767 M.)

QUANTITY: 70 labeled boxes and 144 unlabeled boxes, each containing 12 *suppositories* and 1 1-oz. tube of *ointment*, at Rochester, N. Y., in possession of Pharma-Seal, Inc.

SHIPPED: 11-4-54, from Jersey City, N. J.

LABEL IN PART: (Box) "P & S Combination Rectal Treatment Relief Of The Pain And Discomfort Of Internal And External Piles And Rectal Irritations One Dozen Suppositories One Ounce Ointment * * * The active ingredients of the ointment and suppositories are: Istrian Nutgalls, Zinc Oxide, and Ethyl Aminobenzoate."

RESULTS OF INVESTIGATION: The consignee applied the above-described label to the labeled boxes of the article which originally had been shipped unlabeled.

LIBELED: 1-31-55, W. Dist. N. Y.

CHARGE: 502 (b) (1) and (2)—the article, while held for sale, failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the label of the article failed to bear the common or usual name of each active ingredient contained therein; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; and 502 (f) (2)—the labeling of the article failed to bear a warning against the use of the article in case of bleeding piles.

DISPOSITION: 3-4-55. Consent—claimed by Pharma-Seal, Inc., and relabeled.

4891. Hemorrhoidal suppositories and pile and rectal ointment. (F. D. C. No. 37993. S. Nos. 12-690/2 M.)

QUANTITY: 18 boxes of *hemorrhoidal suppositories* and 54 cartoned tubes of *pile and rectal ointment* at Hackensack, N. J.

SHIPPED: Between 12-20-54 and 4-25-55, from New York, N. Y., by Hanex Co.

LABEL IN PART: (Box) "One Dozen * * * Hanex Haemorrhoidal Suppositories * * * Anti-Septic Astringent * * * Components—Zinc Oxide, Balsam Peru, Menthol, Aluminum Acetate, Benzocaine, Camphor, Cocoa Butter"; (carton) "Hanex Pile and Rectal Ointment"; (tube) "Hanex * * * Ointment Contains: Menthol, Camphor, Alumine Acetate, Zinc Oxide, Benzocaine, Balsam Peru in a base of Olive Oil, Lanolin, and Petrolatum."

ACCOMPANYING LABELING: Leaflet entitled "at your druggist Hanex Pile Remedy."

LIBELED: 5-27-55, Dist. N. J.

CHARGE: 502 (a)—the labeling of the articles, when shipped, contained false and misleading representations that the articles were an adequate and effective treatment for itching and bleeding piles and irritated anus; and 502 (f) (2)—the labeling of the articles failed to bear adequate warnings against use in bleeding piles.

DISPOSITION: 6-28-55. Default—destruction.

4892. Devine's Zina-Ray oil and inhalers. (F. D. C. No. 37894. S. Nos. 8-149/51 M.)

QUANTITY: 100 1-oz. btls., 115 3-oz. btls., and 50 8-oz. btls. of *Devine's Zina-Ray oil* and 2,650 *inhalers* at Kansas City, Mo., in possession of Cleo Cissell.

SHIPPED: 12-30-54, from Chicago, Ill.

LABEL IN PART: (Btl.) "Devine's Zina-Ray Oil Aids in the Relief of Coughs and Colds, Stiff Joints and Sore Muscles Due to Overexertion or Fatigue Contains—Eucalyptus Oil, Menthol and Gum Camphor"; (inhaler) "Devine's * * * Inhaler * * * Insert a few drops of Devine's Zina-Ray Oil into the end of inhaler."

ACCOMPANYING LABELING: Circulars designated "Pain Sufferers Don't Take Dope For Muscular Aches and Pains Due To Over Exertion and Fatigue Use Devine's Zina-Ray Oil."

RESULTS OF INVESTIGATION: The *Devine's Zina-Ray oil* consisted of a yellow oil having the odor of eucalyptus, camphor, and menthol. The *inhaler* consisted of glass tubing approximately 70 millimeters long and 12 millimeters in diameter. One end was constricted to an opening of 5 millimeters in diameter, and the other end was closed with a piece of cork containing a small hole. The tube contained a small piece of unmedicated cotton.

LIBELED: On or about 3-18-55, W. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the *Devine's Zina-Ray oil* and the *inhalers*, while held for sale, failed to bear adequate directions for use in the relief, prevention, and treatment of the conditions for which such articles were intended, namely, in the treatment and prevention of sinusitis and colds, in the treatment of bronchitis, hay fever, arthritis, stiff joints, bursitis, earache, and neuralgia, in the prevention of flu and pneumonia, and for the relief of all aches and pains of the body, which were the conditions for which the articles were intended and for which they were offered orally at Kansas City, Mo., by Cleo Cissell, a representative of the shipper, Devine's Remedies, Inc., Chicago, Ill.

DISPOSITION: 4-29-55. Default—destruction.

4893. Atomotrone device (2 seizure actions). (F. D. C. Nos. 37979, 37980. S. Nos. 9-393 M, 9-398 M, 14-914/5 M, 14-960 M, 14-964 M., 15-448/53 M, 15-458 M, 15-561/8 M, 15-576/8 M.)

QUANTITY: 40 *Atomotrone devices* at Hawthorne and elsewhere within the Southern District of California; and, in addition, 40 *Atomotrone devices* at Salinas and elsewhere within the Northern District of California.

SHIPPED: Between 12-1-54 and 5-23-55, from Dallas and McKinney, Tex.

ACCOMPANYING LABELING: Pamphlets entitled "The Atomotrone" and "Testimonials by Users of The Atomotrone," pads of forms entitled "Sale Agreement," and individual testimonial letters.

RESULTS OF INVESTIGATION: The *Atomotrone device* consisted of a metal cabinet containing an electrically operated sunlamp positioned in such a manner that light emanating from the lamp would fall on jugs of water placed in the cabinet. Several sheets of colored glass were interposed between the lamp and the jugs. The device contained also a one-tube radio wave generator.

In operation, jugs of tap water were placed in the device and subjected to the "action" of the rays from the sunlamp and the radio waves generated by the one-tube transmitter. According to the accompanying labeling, ingestion of water treated in the device was effective in the treatment of a number of disease conditions.