

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

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

4724. Vaginal suppositories. (F. D. C. No. 37501. S. No. 15-081 M.)

QUANTITY: 14 boxes, 6 suppositories each, at Sacramento, Calif.

SHIPPED: 10-14-54, from Cleveland, Ohio, by Williams Mfg. Co.

LABEL IN PART: (Box) "Orange Blossom Suppositories * * * Alum - Borax - Petrolatum * * * Prepared by Dr. J. A. McGill Co., Not Inc., 2001-3 Indiana Ave., Chicago 16, Ill."

ACCOMPANYING LABELING: Leaflets entitled "Dr. J. A. McGill Co.'s Suppositories."

LIBELED: 12-13-54, N. Dist. Calif.

CHARGE: 502 (a)—the label statements "For Simple Irritations of The Vaginal Tract" were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: 3-3-55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4725. Terramycin capsules. (F. D. C. No. 37604. S. No. 11-380 M.)

QUANTITY: 538 16-capsule btl. at Houston, Tex.

SHIPPED: Prior to 1-23-53, from New York, N. Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Btl.) "Pfizer Terramicina Clorhidrato Cristalina Frasco De 16 Capsulas * * * Formula: Cada capsula contiene Clorhidrato de Terramicina Cristalina Equivalente a: 0.250 g. de Terramicina Cristalina Anfoterica Pura Fabricado por Chas. Pfizer & Co., Inc. Nueva York * * * Control No. WLP 527747."

LIBELED: 2-23-55, S. Dist. Tex.

CHARGE: 502 (c)—the information required by 502 (b) and 502 (e) to appear on the label of the article was not placed thereon, when shipped, in such terms

as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since the label was printed entirely in the Spanish language; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement; and 503 (b) (4)—the article was subject to 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6-16-55. Default—destruction.

4726. Ovary powder. (F. D. C. No. 37634. S. No. 12-290 M.)

QUANTITY: 1 drum containing 1 lb., 6 4-oz. jars, and 2 1-lb. jars at Jersey City, N. J.

SHIPPED: 12-22-54, from New York, N. Y., by Desmo Chemical Corp.

LABEL IN PART: (Drum) "Net: 5 lbs. * * * Ovarian Substance Powder N. F."; (jar) "Ovary Powder N. F. * * * Scientific investigation has not demonstrated the presence of therapeutically useful constituents in this product * * * Caution: Federal law prohibits dispensing without prescription."

RESULTS OF INVESTIGATION: The article in the jars was repacked by the consignee from the bulk drum.

LIBELED: 2-1-55, Dist. N. J.

CHARGE: 502 (a)—the labeling of the article (in bulk and as repacked), when shipped and while held for sale, contained false and misleading representations that the article was recognized in the National Formulary, an official compendium; 502 (f) (1)—the labeling of the article (in bulk and as repacked), when shipped and while held for sale, failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement; and 503 (b) (4)—the label of the article (as repacked), while held for sale, bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not one to which 503 (b) (1) applies.

DISPOSITION: 6-30-55. Default—destruction.

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

4727. Liquid herbal drugs. (F. D. C. No. 35576. S. Nos. 53-354/5 L, 53-460 L, 53-870 L, 63-141 L, 63-150 L, 63-314/5 L, 63-711/3 L.)

INDICTMENT RETURNED: 10-25-54, W. Dist. Ky., against Ples Griffin, La Center, Ky.

SHIPPED: Between 11-18-53 and 12-20-53, from Kentucky to Illinois, Missouri, and Tennessee.

CHARGE: 502 (b)—when shipped, the drugs failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502 (e) (2)—the labels of the drugs failed to bear the common or usual name of each active ingredient; and 502 (f) (1)—the labeling of the drugs failed to bear adequate directions for use in the treatment of the diseases, symptoms, conditions, and purposes for which the drugs were prescribed, recommended, and suggested orally by the defendant, and in the cases of some drugs, the labeling failed also to reveal the conditions for which such drugs were to be used.

*See also Nos. 4725, 4726.