

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: Between 2-21-55 and 3-25-55. Default—destruction.

4722. Vaginal suppositories. (F. D. C. No. 37643. S. No. 6-180 M.)

QUANTITY: 35 boxes at Terre Haute, Ind.

SHIPPED: 10-8-54, from Cleveland, Ohio, by Williams Mfg. Co.

LABEL IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum - Borax - Petrolatum Prepared by Dr. J. A. McGill Co., Not Inc. 2001-3 Indiana Ave., Chicago 16, Ill."

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

RESULTS OF INVESTIGATION: Examination showed that the suppositories each weighed approximately 5.3 grams and contained approximately 47 percent ammonium alum.

LIBELED: On or about 2-15-55, S. Dist. Ind.

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 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: 3-18-55. Default—destruction.

4723. Vaginal suppositories. (F. D. C. No. 37916. S. Nos. 14-958 M, 15-240 M.)

QUANTITY: 17 boxes at Fresno, Calif.

SHIPPED: Between 8-24-54 and 12-19-54, from Chicago, Ill., by Dr. J. A. McGill Co.

LABEL IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum - Borax - Petrolatum Prepared by Dr. J. A. McGill Co. * * * Chicago 40, Ill."

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

RESULTS OF INVESTIGATION: Examination showed that the suppositories each weighed approximately 5.2 grams and contained approximately 50 percent ammonium alum.

LIBELED: 4-1-55, S. Dist. Calif.

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