

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 4581-4600**

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling; and, Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of penicillin or aureomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507.

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN
USED ACCORDING TO DIRECTIONS**

4581. Vaginal suppositories. (Inj. No. 279.)

COMPLAINT FOR INJUNCTION FILED: 5-20-54, N. Dist. Ill., against Harriet McGill Fickinger, t/a Dr. J. A. McGill Co., Not Inc., and Clara H. Nielsen, general manager of the business, to enjoin the interstate shipment of the above-mentioned article.

LABEL IN PART: (Box) "Contents 6 Suppositories Orange Blossom Suppositories Active Ingredients of Each Suppository: Alum—Borax—Petrolatum Prepared by DR. J. A. MCGILL CO., Not Inc. 2001-3 Indiana Ave., Chicago 16, Ill. For Simple Irritations Of The Vaginal Tract Directions—Remove tinfoil and at bed time 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. The use of Orange Blossom Suppositories is not recommended at the menstrual period or during pregnancy."

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

CHARGE: The complaint alleged that the article, when used as a suppository in the vagina in the manner recommended in its labeling, or in any other dosage, was unsafe and dangerous to health and that the article, because of its alum content, may cause serious injury by destroying normal, healthy tissue in the vaginal tract and that the defendants had been and still were engaged in preparing, selling, and introducing into interstate commerce such article which was misbranded under 502 (a), and that its labeling, when con-

sidered in its entirety and in the setting in which it was used, created the false and misleading impression that the article was a safe, adequate, and effective treatment for simple irritations of the vaginal tract; and under 502 (j), in that the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling.

The complaint further alleged that if the defendants were forced by an injunction to refrain from using the existing labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article in interstate commerce without labeling stating the dosage for the article and without labeling stating the conditions and purposes for which the article was intended; and that, in such case, the article would be misbranded under 502 (f) (1), in that its labeling would fail to bear adequate directions for use because of the omission from its labeling of the dosage for the article and because of the omission from its labeling of statements of the conditions and purposes for which the article was intended.

DISPOSITION: 12-23-54. The defendants having consented, the court entered a decree of injunction perpetually enjoining the defendants from introducing into interstate commerce the article, or any other article of similar composition, which was misbranded under 502 (a), 502 (f) (1), and 502 (j).

4582. Vaginal suppositories (11 seizure actions). (F. D. C. Nos. 36339, 36340, 37064, 37083, 37084, 37092, 37119, 37274, 37368, 37563, 37611. S. Nos. 43-171 L, 43-173 L, 47-896 L, 67-955 L, 74-102/3 L, 79-885 L, 79-888 L, 80-067 L, 81-080 L, 86-437 L, 6-261/2 M, 14-247 M.)

QUANTITY: 11,048 boxes at Los Angeles, Oakland, Sacramento, and San Francisco, Calif., New Orleans, La., Indianapolis, Ind., Houston, Tex., St. Louis, Mo., and Cleveland, Ohio.

SHIPPED: Between 3-19-54 and 12-13-54, from Chicago, Ill., by Dr. J. A. McGill Co.

LABEL IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum—Borax—Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

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

LIBELED: Between 6-16-54 and 1-17-55, N. Dist. Calif., S. Dist. Calif., E. Dist. La., S. Dist. Ind., S. Dist. Tex, E. Dist. Mo., N. Dist. Ohio.

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment of 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 bed time 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 6-29-54 and 3-3-55. Default—destruction.