

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN
VIOLATIONS REPORTED IN D. D. N. J. NOS. 4721-4740**

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality and purity fell below the standard set forth in such compendium; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its 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), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (c), certain information required by the Act to appear on the label of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; 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 (g), the article purported to be a drug the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not packaged as prescribed therein; Section 502 (j), the article was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, or suggested in its labeling; and, Section 503 (b) (4), the article in one case was subject to Section 503 (b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," and in another case the label of the article bore the caution statement as quoted above, but the article was not one to which Section 503 (b) (1) applies.

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

4721. Vaginal suppositories (3 seizure actions). (F. D. C. Nos. 37610, 37617, 37675. S. Nos. 1-234/5 M, 6-931 M, 14-246 M.)

QUANTITY: 187 boxes at Denver, Colo., St. Louis, Mo., and Miami, Fla.

SHIPPED: Between 8-3-54 and 11-26-54, 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 article contained between 44 percent and 50 percent ammonium alum.

LIBELED: Between 1-21-55 and 2-21-55, Dist. Colo., E. Dist. Mo., and S. Dist. Fla.

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: 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.