*SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6701–6740*

*Adulteration*, 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 fell below the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) 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(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; 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 the labeling thereof; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

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

**6701. Doxifer tablets and syrup.** (F.D.C. No. 45806. S. Nos. 32–278/9 R.)

QUANTITY: 647 100-tablet btls. of *Doxifer Hematinico* and 215 8-oz. btls. of *Jarabe Doxifer-Hematinico*, at Santurce, P.R.

SHIPPED: 10–26–60 and 1–4–61, from Forest Hills, N.Y., by American Medicinal Corp.

LABEL IN PART: (Btl.) "Doxifer-Hematinico Formula – Cuatro Tabletas Contiene—Acido Folico 1.5 MG.—Dosis Sugerida: Adultos, 1 tableta cuatro veces al dia—American Medicinal Corporation, Forest Hills, New York – 49959" and (btl.) "Jarabe Doxifer-Hematinico De cuatro cucharaditas /20 cc./ Contiene – acido folico 1.5 mg.—Dosis sugerida: Adultos, 1 cucharadita cuatro veces al dia – American Medicinal Corporation Forest Hills, New York – 01049."

LIBELED: 5–18–61, Dist. P.R.

CHARGE: 502(j)—when shipped, the articles were dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, since the articles under the directions for use, would supply 1.5 mg. of folic acid daily.

DISPOSITION: 8–8–61. Consent—destruction.