*SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6781–6820*

*Adulteration*, 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), 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 the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; 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 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.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**6781. Entoquel syrup and Entoquel with Neomycin syrup (2 seizure actions).** (F.D.C. Nos. 46217, 46220. S. Nos. 88–031/2 R, 91–339/40 R.)

QUANTITY: 20 6-oz. btls. of *Entoquel syrup* and 21 6-oz. btls. of *Entoquel with Neomycin syrup* at Baltimore, Md.; 44 6-oz. btls. of *Entoquel syrup* and 59 6-oz. btls. of *Entoquel with Neomycin syrup* at Jamaica, Queens, N.Y.

SHIPPED: Between 2–6–61 and 2–10–61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: "Entoquel Syrup (Thihexinol Methyl Bromide) * * * Each Teaspoon (5 cc) contains * * * Thihexinol Methyl Bromide – 5 mg. Alcohol – 1%" and "Entoquel With Neomycin Syrup * * * Each Teaspoon (5 cc) contains * * * Thihexinol (Entoquel) – 5 mg. Neomycin (from the sulfate) – 50 mg. Alcohol – 0.5%."

ACCOMPANYING LABELING: A promotional form letter mailed on or about 4–10–61, addressed to "Dear Doctor"; a promotional folder mailed on or about 4–27–61, entitled "Are opiates now outmoded in pediatric diarrhea?"; and a promotional folder mailed in June or July 1961, entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover.

LIBELED: 8–1–61, Dist., Md., and E. Dist, N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles was false and misleading:

(1) in that the promotional form letter entitled "Dear Doctor" represented that the drugs would successfully treat diarrhea which threatened pediatric patients, without side effects, which representations were contrary to fact;

(2) in that the promotional folder mailed on or about April 27, 1961, represented that the drugs "acts almost exclusively to inhibit gastro-intestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine-like effects when given in the recommended dosage" and that "the only side effect noted was a mild, more or less transient flushing of the skin," which representations were contrary to fact; and

(3) in that the promotional folder entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover, mailed to physicians in June or July 1961, represented that the articles stopped diarrhea rapidly without side effects; that it did not interfere with gastric secretion, digestive processes, or produce other undesirable atropine-like effects, and that the sole side effect noted in the use of the drugs was a mild flushing of the skin, which representations were contrary to fact; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from the requirement that the articles bear such directions for use since the promotional material for the new drugs was not the same as, or substantially the same as, the labeling authorized by the effective new drug applications; and 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since the effective new drug application filed with respect to the articles did not apply to the conditions for which the articles were promoted to the medical profession, namely,

(a) in a promotional form letter mailed to physicians on or about April 10, 1961, addressed to "Dear Doctor," the drug was offered for the treatment of complications of severe pediatric diarrhea—dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen and constant crying; and

(b) in a promotional folder entitled "Are opiates now outmoded in pediatric diarrhea?" mailed to physicians on or about April 27, 1961, the drug was offered for nonspecific digestive upsets and for nausea and vomiting, which labeling representations differed materially from the labeling claims permitted by the effective new drug application.

DISPOSITION: 8–30–61 and 9–6–61. Default—destruction.

**6782. Entoquel with Neomycin syrup.** (F.D.C. No. 46219. S. No. 76–752 R.)

QUANTITY: 68 6-oz. btls. at San Leandro, Calif.

SHIPPED: 3–1–61, from Kenilworth, N.J., by White Laboratories, Inc.

LABEL IN PART: "Entoquel with Neomycin Syrup Caution: * * * White Laboratories, Inc., Kenilworth, New Jersey Dosage: * * * Each Teaspoon (5 cc) contains * * * Thihexinol (Entoquel)—5 mg. Neomycin (from the sulfate)—50 mg. Alcohol—0.5%."

ACCOMPANYING LABELING: A promotional form letter mailed on or about 4–10–61, addressed to "Dear Doctor"; a promotional folder mailed on or about 4–27–61, entitled "Are opiates now outmoded in pediatric diarrhea?"; and a promotional folder mailed in June or July 1961, entitled "Are opiates now outmoded in pediatric diarrhea?" with a picture of an infant and a bottle of paregoric on the cover.