(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.

LIBELED: 8-1-61, N. Dist. Calif.

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 drug 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 drug "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 in June or July 1961, represented that the article 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 drug was a mild flushing of the skin, which representations were contrary to fact;

502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from the requirement that the article bear such directions for use since the promotional material for the new drug was not the same as, or substantially the same as, the labeling authorized by the effective new drug application; and 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since the effective new drug application filed with respect to the article did not apply to the conditions for which the article was 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: 9-21-61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6783. Various prescription drugs. (F.D.C. No. 46582. S. Nos. 63/69 T, 71/73 T.)

QUANTITY: 4,988 tablets and capsules and 42 btls. of liquid at Jacksonville, Fla., in possession of Griffin Pharmacy, Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Sample" and "Physician's Trial Package."