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."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs repacked from physicians' samples into containers which had labels bearing the brand names of the drugs, the words "Physician's Sample," "Physician's Trial Package," or similar wording, and the names of manufacturers, packers, or distributors located outside the State of Florida. Some of the articles were prescription drugs which had not, at the time the articles were libeled, been repacked by the dealer and which bore labels similar to the other articles.

LIBELED: 10–19–61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Physician's Sample," "Physician's Trial Package," and similar wording on the labels of the articles, were false and misleading as applied to the articles then in the possession of a repacker and intended for sale, and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(2)—the labels of a number of the articles failed to bear the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug, as required by regulations; and 503(b)(4)—a number of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–24–61. Default—destruction.

6784. Various prescription drugs. (F.D.C. No. 46279. S. Nos. 97–376 R, 98–403/6 R.)

QUANTITY: Various quantities of tablets, capsules, and liquid, at Grand Island, N.Y., in possession of Grandyle Pharmacy, Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some drugs) "Physician's Sample Not for Sale," "Special Package for the Medical Profession Only," or "Professional Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of New York, and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of New York.

LIBELED: 8–22–61, W. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the statements "Physician's Sample Not for Sale," "Special Package for the Medical Profession Only," "Professional Sample," and similar wording on the labels of a number of the articles of drug were false and misleading as applied to these articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary – not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the repacked articles of drug failed to bear a label containing the name and place of business of the