in the approved New Drug Application labeling, they have not violated Section 502(n) of the Act, nor regulations 21 CFR 1.105(e) and (f), as these sections and regulations only require a brief summary of side effects and contraindications as set forth in the approved New Drug Application labeling, no mention being made of precautions.

We believe that "side effects" and "contraindications" certainly include "precautions" as this word is used in the approved New Drug Application labeling. Congress clearly intended that prescription drug manufacturers should provide physicians with adequate warnings in prescription drug advertisements of those conditions in which use of the drug entailed a high degree of risk. It is pure sophistry to contend that Congress wanted physicians to be warned of side effects and contraindications as set forth in the approved New Drug Application labeling, but not to be warned of the "precautions" as set forth in the approved New Drug Application labeling.

On September 29, 1965, Food and Drug Administration Inspector Paul T. Wiener inspected this firm and learned that it was still manufacturing and shipping in interstate commerce 30 mg. Obetrol tablets without an effective New Drug Application. As a follow-up to this inspection, the Food and Drug Administration collected two samples of Obetrol 30 mg. tablets in interstate commerce because the article was a new drug without an approved New Drug Application (Counts III and IV).

HISTORY OF FIRM AND INDIVIDUALS

This firm first came to the attention of the Food and Drug Administration in early 1953 when the Connecticut State Division of Drugs, Devices, and Cosmetics referred a sample of dextro-amphetamine sulfate to the Food and Drug Administration's office because the label declared a fictitious name and address of a manufacturer. The manufacturer and shipper were believed to have actually been Rexar Pharmacal Corp. As a result of this complaint, an initial inspection of the firm was made on March 11, 1953, which disclosed that the firm was operating with poor manufacturing control conditions. The original sample which bore the fictitious name and address of the manufacturer was assayed and found to contain only 72% of labeled amount of dextro-amphetamine sulfate. However, the sample was placed in permanent abeyance because it could not be definitely ascertained that the subject firm was the manufacturer and distributor of these amphetamine tablets.

The firm was again inspected on December 15, 1953, at which time, according to Mr. Armin Rosner, the firm was doing a minimal business. The firm was not then shipping its drugs in interstate commerce.

The firm was inspected once more on February 15, 1955, at which time it was learned that the firm was manufacturing Obetrol, a new drug, without an effective New Drug Application and shipping the drug while using false and misleading claims. As a follow-up to this inspection, a sample was collected which resulted in a Hearing on September 28, 1956. The sample was placed in permanent abeyance, however, because the firm agreed: (1) to revise its labeling in an effort to bring the drug in compliance with the law, and (2) to submit a New Drug Application for the 10 and 20 mg. Obetrol tablets.

The firm was inspected on July 25, 1955, at which time it was learned that the firm was shipping another new drug, namely, Obertina tablets, a combination of amphetamine and rauwolfia serpentina, without an effective New Drug Application. However, the Food and Drug Administration could not obtain a sample of the product in interstate commerce and no action was brought.

A follow-up inspection, made on July 8, 1958, showed that the firm was marking time while its New Drug Application for Obetrol was under study by the Food and Drug Administration.

The firm was again issued a Notice of Hearing in early 1963 because it had shipped a new drug consisting of thyroid and 30 mg. of amphetamine salts without an effective New Drug Application. At the time of the Hearing, the respondent stated that a New Drug Application was unnecessary as the drug was shipped under, what the firm termed, a physician-pharmacist relationship. The firm had made this drug to order for one physician. The number was placed in permanent abeyance. It was its position that Rexar Pharmacal Corp. was simply asked to fill a prescription for the physician. No further action was taken because the firm agreed to discontinue the interstate distribution of this product.