guidelines on how soon newly registered producers should be inspected after registration. Since these producers are permitted to produce and distribute drugs for consumer use, we believe FDA should consider making an earlier initial inspection of such producers.

TYPES OF FIRMS NOT INSPECTED AND PRIOR DEVIATIONS

Generally, the drugs produced by most of the 74 producers could be purchased by consumers without a prescription. Many of the producers manufactured or repacked drugs such as vitamins, liniments, salves, bulk drugs, medicinal gases, and reducing tablets. Thirty-nine were small drug producers with annual sales of less than $10,000. Five had annual sales of over $1 million.

Many of the findings during prior inspections related to labeling and misbranding. However, deviations from GMPs included

--failure to prepare control records for each quantity of drugs produced,

--failure to establish production and control procedures to insure the quality of the drug produced,

--failure to code finished products to determine, if necessary, the history of the manufacture and control of the drug, and

--inadequate laboratory controls to insure that components and finished products conform to appropriate standards of identity, strength, quality and purity.

A brief inspection history follows on one of the 74 producers.

Firm E primarily manufactures high-purity laboratory chemicals and solvents. On special order it produces a drug for peptic ulcers which FDA estimated annual sales of $45,000. FDA inspected the producer in March 1969 and found that the producer was using adequate control procedures. However, the drug for peptic ulcers was not being manufactured at the time of inspection. FDA scheduled the producer