--Raw materials not assayed.

--Incomplete or no master formula or batch production record.

--Incomplete or no production and control procedures.

--No laboratory controls

--No distribution records.

In most instances FDA relied on communication with the producers and reinspection to encourage voluntary corrective action. Although these steps may have resulted in some improvements, FDA inspection reports revealed that in most instances the action taken had not achieved compliance with GMPs.

The following three examples illustrate FDA's enforcement of GMPs, as noted during our review.

Firm A is a drug producer with estimated annual drug sales of $200,000. FDA made four inspections of this firm during the 50-month period ended December 1971. In each instance FDA concluded that the firm was not in compliance with GMPs. The inspection reports revealed, as summarized below, a total of 34 deviations of which 15 were critical according to FDA guidelines.