untimely, especially for small drug producers, which comprise the vast majority of the 6,400 producers.

We reviewed 83 inspection cases involving deviations from GMPs for which followup inspections were scheduled and were to be made during a specific month before December 31, 1971. Twenty-five reinspections were made on time; i.e., when scheduled, 32 were made late and 26 were not made as of December 31, 1971. For example:

--An inspection of a drug manufacturer with annual sales of $115,000 was completed in December 1967. FDA found five deviations from GMPs and scheduled a followup inspection for April 1968, 4 months later. However, the firm was not reinspected until May 1969--17 months later--and four deviations were noted. Three were among the deviations identified during the December inspection. A routine followup inspection was scheduled for May 1971 but had not been made as of December 1971.

Other than the requirement of the FD&C Act for biennial inspection, FDA has no definitive guidelines for scheduling followup inspections of producers that deviate from GMPs. Instead, followup inspection depends on each district office's interpretation of the significance of its findings, the availability of resources, and the likelihood of the producer's voluntary corrective action.

FDA routinely schedules followup inspections at varying time intervals in those instances where inspectors note deviations. As the table shows, the scheduled time interval in one district varied from 1 to 24 months for 48 followup inspections scheduled to be made before December 31, 1971.