As of December 1971, FDA had not reinspected the firm to determine whether corrective action had been taken.

Firm C is a drug producer with an estimated annual sales of $80,000, consisting primarily of dental drugs. FDA inspected the producer's manufacturing practices three times during the 32-month period ended December 15, 1971--each time concluding that the producer was not complying with GMP requirements such as formula and production control records not being maintained. The number of deviations increased from 6 in the first inspection, to 23 in the second, to 49 in the third--including critical deviations of 5, 9, and 25, respectively. Although a total of 78 deviations were found, of which 39 were critical, FDA did not recommend that legal action be taken to correct them; it relied on communication with the producer and followup inspections to promote voluntary corrective action.

Although the producer corrected some of the deviations, the last inspection showed the producer had continued to manufacture drugs under conditions that did not conform to GMPs. An FDA supervisory inspector in this district advised us that they usually wait at least two inspections before recommending legal action to allow the firm to correct its deviations.