Date inspected	Number of deviations	Date of letter	Calendar days
11-27-68	5	2-24-69	89
6-12-69	6	7-24-69	42
11-06-69	4	12-05-69	29
1-08-70	9	3-13-70	64
3-13-70	9	none issued	-
11-17-70	1	none issued	-

Action taken on the fourth inspection indicates what can happen when post inspection letters are not issued timely. Upon completing the inspection on January 8, 1970, the inspector discussed his findings with plant personnel and issued a list of inspectional observations, indicating that the deviations identified could lead to product contamination. Nevertheless, the producer continued to manufacture the product and release it for distribution. Later FDA analysis of the product showed it had been contaminated with particulate matter.

On March 13, 64 days after completing the inspection, FDA issued a post inspection letter reemphasizing that any one of the deviations could lead to product contamination. The producer was also reinspected on the same day. The inspection report stated that the management was apathetic to the indicated deviations and would not agree to any corrective action. Two weeks later, after receiving the post inspection letter, the producer stated in a written reply to FDA that it discontinued manufacturing this product and was in the process of correcting the deviations; and that the product produced in 1969 and 1970 had been recalled.

Delays in informing top management of drug producers of deviations are not conducive to prompt correction and may result in prolonging the exposure of consumers to adulterated drug products. According to FDA, optimum consumer protection requires that FDA report to the producer, in a timely manner, all significant inspection findings, and schedule an inspection to insure compliance.

FOLLOWUP INSPECTIONS

FDA's followup inspections to insure that producers have corrected deviations from GMPs have generally been