for another inspection in June 1970. FDA did not perform this inspection or the rescheduled inspection for March 1971.

Because the drug produced by the firm was to be used by the military services, the Defense Supply Agency inspected the producer in June 1971, and identified nine findings which were deviations from GMPs including:

--Inadequate control of raw materials, as written specifications are not established for all raw materials, raw materials are not tested, and approved raw materials are not isolated and distinctly labeled for ready identification as fit for use.

--Possibility of contamination from other products exists in the manufacturing operations.

--All equipment is not routinely inspected and cleaned before each use and promptly cleaned thereafter.

--Positive identification of material is not maintained during processing operation.

--Plant was not clean and orderly. Windows and doors in plant were not screened to prevent entrance of insects and other pests.

The Defense Supply Agency communicated its inspection results to FDA by letter in July 1971. As of April 1972 FDA had not reinspected the producer. The deterioration in the producer's control procedures during the period FDA did not inspect it illustrates the importance of inspecting all producers biennially.

REASONS GIVEN FOR
NOT INSPECTING ALL DRUG PRODUCERS

We noted a lack of controls to insure that producers are rescheduled and inspected biennially. FDA Bureau of Drugs officials told us that no one at headquarters had been assigned responsibility for insuring that all drug producers were inspected every 2 years, although the Bureau has responsibility for this activity. Several officials said that headquarters did not maintain records on statistics identifying drug producers inspected for GMPs. Also, the districts

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