FDA EFFORTS TO PROTECT CONSUMER HAMPERED

In a 1968 report to the Office of the Secretary of the Department of Health, Education, and Welfare, FDA officials stated that:

> "Often an FDA inspector, during the course of an inspection, observes something that indicates that a violation of law is occurring or that violative goods are being held in the plant. But unless he is voluntarily shown control records or other relevant data, he can neither confirm nor disprove his suspicion. And he is usually not shown these records. Before samples can be taken and analyzed and a seizure complaint prepared if needed, the suspected goods are often already on their way to retailers or even in the hands of consumers."

In fiscal year 1970 FDA inspectors in the three district offices which we visited reported that they were refused access to records during 398 inspections of 319 firms. We reviewed case files of 290 inspections made at 235 firms.[1] We found that refusals of access to firms' records prevented FDA from (1) removing products suspected or known to be violative from the market and (2) evaluating firms' production and quality control procedures affecting the quality of their products. Such information is needed by FDA to determine whether to initiate court action for seizure or whether to ask for voluntary recall.

Refusals delay or prevent actions

For 45, or 16 percent, of the 290 cases reviewed, FDA had indications from other sources that the products involved may have been violative.

--In 34 of the cases, FDA did not or could not pursue the matter further because of insufficient information,

[1]The cases selected for review represent the first inspection at each of the 235 firms during which FDA encountered refusals and subsequent followup inspections at certain of the firms.