COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

9089

was 54 days. The following table shows the average time required at each major action level.

Action level	Average number of days
FDA district office	22
FDA headquarters	14
Department of Justice (note a)	<u>18</u>
Total	54

^aIncludes the Federal District Court's time and the U.S. Marshal's time to seize the product.

An FDA official advised us that delays at the district level were generally due to the lack of resources and equipment to complete the analyses of samples. He told us that, when large numbers of samples were collected, a backlog could develop. Our review of five seizure actions confirmed that delays resulted because of the limited manpower and laboratory facilities needed to make the analyses.

Delays are also encountered at FDA headquarters in using the mail and in the handling of correspondence by the mailroom and clerical staffs. For the five seizure actions reviewed, we found that there was an average delay of 10 days between the time the correspondence was mailed from the district office and the time it was received by the proper officials at FDA headquarters.

FDA has recognized the need for additional resources to improve the processing of seizure actions. FDA's proposed budget for fiscal year 1973 includes a request for major increases in dollars and manpower resources, which should assist in expediting FDA laboratory analyses and processing of seizures. Some minimum amount of laboratory time will always be needed to perform an analysis of a product. For example, the laboratory time required to test foods for salmonella is 7 to 10 days, whereas testing the sterility of drugs requires a minimum of 14 days.