FDA has not provided the districts with guidelines to assist in developing a sound case. In addition, the Director of the Division of Case Guidance, Bureau of Drugs, said that some district personnel did not know what was needed for compiling a sound case for legal action against violations of GMPs. He said that as a result district recommendations were frequently disapproved because the cases lacked documentation and completeness rather than significance.

Also, the Director of the Division of Case Guidance, who is responsible for approving the district recommendations, said that his staff did not have guidelines for making case decisions. Rather, they rely on their expertise and judgment developed over a period of many years of experience. The benefit of this experience, however, has not been passed on to the district offices in the form of written guidance for their consideration when developing recommendations. The following case illustrates the resultant confusion.

FDA officials in one district, which initiated 18 of the 51 seizure actions approved in the 2-year period ended June 1971, stated that it had become increasingly difficult to obtain headquarters approval of seizure recommendations. The officials said five seizure recommendations were disapproved during the 2-year period and showed us seven similar examples from fiscal year 1972. One of these examples follows.

Firm D produces drugs with estimated annual sales of $2 million. In December 1971 the district office completed an inspection during which it observed 26 deviations from GMPs. Production of two separate quantities of a drug were considered adulterated based on inspectional evidence showing they were not manufactured in conformity with current GMPs. Accordingly the district recommended seizure of both quantities of production. Consistent with provisions of the law and implementing regulations, no laboratory analysis was considered necessary to support the recommendation.

In disapproving the seizure action, FDA headquarters stated that the identified deviations were not significant without FDA analysis of the product or other evidence of widespread defects. Officials in the Bureau of Drugs stated: