Access to records

To carry out what the laws intend--provide consumer protection--FDA must be able to identify and remove products suspected or known to be defective from the market. The first step is for FDA to obtain, from manufacturers' records, information that will assist in identifying and locating such products.

However, with the exception of prescription drugs, present law does not require firms to provide FDA access to this information. Most firms cooperate with FDA in making necessary records available, but many have been unwilling to do so. Consequently FDA sometimes is unable to obtain information essential to identifying and removing defective products from the market. (See p. 9.)

During fiscal years 1969 through 1971, 3,300 firms refused to cooperate with requests by FDA inspectors on over 10,000 occasions, including about 7,900 denials of recorded information.

A company which processed walnuts refused to provide FDA with access to its shipping records, even though FDA had found that some of that company's walnuts were contaminated and had told its officials so. Their refusal to grant FDA access to shipping records delayed removal of the contaminated product at one location, prevented removal of the walnuts from other locations, and exposed consumers to needless risk. (See p. 11.)

GAO believes that FDA should have sufficient authority to review records for all products where there are questions of defectiveness. (See p. 16.)

Detention of products

FDA's lack of authority to detain suspected defective products from reaching the market also seriously hampers FDA's efforts to protect the consumer.

FDA has authority under existing law to seek court injunctions prohibiting some act by a firm or individual; however, FDA has no authority to temporarily detain products suspected or known to be defective.

FDA has the authority to undertake seizure actions to prevent suspected products from reaching the market. The seizure process is a civil court action involving review by several authorities. A number of days are usually required before a product legally can be seized and taken off the shelf. As a result, FDA has been unable to prevent substantial quantities of products suspected or known to be defective from reaching the public. (See p. 18.)

GAO's review of 91 seizures--for which the percent of the total amount of a product actually seized could be determined--showed that, on an average, 69 percent of the total amount identified for seizure actually was removed from the market. The remaining 31 percent apparently was sold.

A firm stored fifty-one 100-pound bags of flour under insanitary conditions. An FDA inspection showed that rodents had gnawed into the bags, that rodent urine and excreta were on the bags, and that the flour had been contaminated.