The seizure action took 47 days. Because FDA could not detain shipment of the flour during this period, 59 percent of it reached the market. Only 21 bags, or 41 percent, were seized. (See p. 21.)

FDA should have authority to temporarily detain products believed to be defective. (See p. 24.)

Removal actions and voluntary recall

Methods available to FDA for removing from the market products suspected or known to be defective--called seizures and recalls--often are not effective. As shown, seizure actions, besides being slow, are limited to a specific quantity and location of the product. After it has been distributed nationally, the product is difficult to find and remove from the market. (See p. 26.)

A food firm found that some of its canned products contained botulism, a deadly poison. Had FDA been required to seize the product at each location, over 25,000 separate seizure actions would have been needed. The firm agreed to recall the product, and there was responsive cooperation from other concerned public and private interests in removing the product from the market. However, because of financial problems, the firm believed it could not honor the agreement. FDA found it necessary to seize the product at 100 different places. (See p. 26.)

"Voluntary recall" is an action taken by a firm, at the request of FDA or at its own initiative, to remove from the market a product suspected or known to be defective. Voluntary recalls, however, have a disadvantage in that there is no law requiring such removal actions. Because FDA cannot enforce recalls, they are a matter of negotiation between industry and FDA and can be delayed or ineffectively carried out by the companies involved.

GAO's review of 106 recalls requested by three FDA district offices during fiscal year 1971 showed that an average of 15 days passed before the firm acted on FDA's request.

Of the recalls, 23 percent required more than 25 days to initiate. In these cases GAO found that an average of 38 percent of the product was sold during the delay. (See p. 28.)

A firm produced a prescription drug that did not meet Federal standards for dissolution. After FDA notified the company of the defective product, the firm took 55 days to initiate the recall. During this period, about 75,000 of the defective tablets were sold. (See p. 29.)

FDA should have authority to order recalls when products are found to be defective. (See p. 30.)

Comments by industry and manufacturing associations

GAO discussed FDA's need for additional authority with officials of 20 firms and five manufacturing associations. Many responses showed recognition of the need for quicker, more complete removal of defective products from the market. Reservations most often expressed were whether (1) trade secrets and formulas would be protected and (2) FDA would use its authority to detain any product suspected of violating the law or order a recall of the product, regardless of the health hazard involved.