CHAPTER 4

LIMITED AUTHORITY TO REMOVE PRODUCTS

The methods available to FDA for removing products suspected or known to be violative from the market--seizures and recalls--are often not effective. Seizure actions, besides being slow (see ch. 3), are limited in scope, and recalls--being voluntary--are not enforceable by FDA. As a result, the consumer is frequently exposed to products which should have been removed from the market.

SEIZURES LIMITED IN SCOPE

Seizure actions are limited to the specific quantity and location of a product identified in the complaint filed by the U.S. Attorney. FDA must identify the quantity of a product at each location and recommend a separate seizure action for each location. Removing a product from the market is thus very difficult after it has been distributed nationally, as illustrated by the following example.

> Recently, 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 initially agreed to voluntarily recall the product, and seizure actions were generally not needed. However, the firm was unable to honor its agreement because of financial problems and FDA--despite the intense cooperation from other concerned public and private interests in removing the product from the market--still found it necessary to seize the product at 100 different locations.

Needless to say, such a large number of seizure actions was inefficient but was necessary in the absence of better legal authority to remove products from the market. Because of the difficulties involved in seizure actions, FDA has encouraged voluntary recalls as a means of removing products suspected or known to be violative from the market.