

CHAPTER 3

NEED FOR AUTHORITY TO DETAIN PRODUCTS

FDA's lack of detention authority--coupled with the slowness of seizure actions--seriously hampers FDA's efforts to protect the consumer from products suspected or known to be violative.

FDA has authority under existing law to seek court injunctions prohibiting an act by a firm or individual; however, FDA has no authority to temporarily detain products suspected or known to be violative. Further, because the seizure process is a civil court action involving several levels of review, the seizure process always takes a number of days before a product legally can be seized and taken off the shelf. As a result of these limitations, FDA has been unable to prevent substantial quantities of products suspected or known to be violative from reaching the public.

SLOWNESS OF SEIZURE ACTIONS

Seizure actions are initiated by FDA after analysis of a product or examination of the conditions under which the product was manufactured, packed, or repacked indicates that the product violates the FD&C Act or the Federal Hazardous Substances Act. Usually an FDA district office collects and analyzes a sample of the product to confirm that the product is violative and then recommends seizure action to FDA headquarters. If headquarters approves the recommendation, it requests a U.S. Attorney to initiate seizure action in the appropriate Federal District Court.

After a seizure warrant is issued, a U.S. Marshal presents it to the firm and has the product removed from the market. This procedure takes time, and considerable delay often results between the date the FDA inspector identifies the problem and the date the U.S. Marshal executes the seizure.

Our review of 88 seizures--for which we could determine the time required to seize the product--showed that the average time required to remove a product from the market