

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 9077

consequently limited to the specific quantity and location of products identified in the seizure complaint.

Recalls of products must be made by the voluntary action of the manufacturer. FDA presently has no recall authority. Because recall actions are voluntary on the part of the manufacturer, FDA cannot control delays in initiating the action.

Both seizures and recalls require time to be initiated. Although section 302 of the FD&C Act provides FDA with authority to seek injunctions to restrain violations of the act, it does not provide FDA with authority to detain products suspected or known to be violative.

FDA also has responsibility for consumer products other than foods, drugs, medical devices, and cosmetics. The Federal Hazardous Substances Act prohibits interstate shipment of household substances and children's articles which do not contain adequate warning labels or which are hazardous regardless of cautionary labeling. The act defines as hazardous such household substances as chemicals or mixtures of chemicals which are toxic, corrosive, irritant, flammable, or which may cause substantial personal injury or illness. FDA's inspection and enforcement authority under this act is similar to that under the FD&C Act. Also techniques used to inspect and remove misbranded products or hazardous substances are similar to those used for foods, drugs, cosmetics, and medical devices. In this report, misbranded products or products which are considered hazardous, regardless of cautionary labeling under the Federal Hazardous Substances Act, are also identified as violative products.

Our review was directed at FDA's ability to remove products suspected or known to be violative from the market. We reviewed applicable legislative history and FDA's regulations, policies, and practices for removing such products. We also examined FDA's records and files pertaining to fiscal year 1970 refusals of access to firms' records and pertaining to fiscal year 1971 seizures and recalls.

We performed our review at FDA district offices in Detroit, Michigan; Philadelphia, Pennsylvania; and San Francisco, California; and at FDA headquarters in Rockville,