

VOLUNTARY RECALLS NOT ENFORCEABLE

A voluntary recall is an action taken by a firm, at the request of FDA or on its own initiative, to remove a product suspected or known to be violative from the market. When recalling a product, the firm involved assumes full responsibility for removing the product. As a result, manufacturers often decide whether or not to initiate a recall and often initiate a recall without notifying FDA. In contrast to seizures, neither FDA nor U.S. Attorneys and Marshals are directly involved. To the extent possible, however, FDA monitors the firm's effectiveness in removing the product from the market. In fiscal year 1971 FDA monitored over 1,900 recalls.

We were advised by FDA that, to make certain that violative products are removed from the market, manufacturers should be required to notify FDA when they discover such products so that FDA would be in a position to determine the nature and extent of any hazard and to monitor all recalls.

When quickly and effectively implemented, voluntary recalls usually remove greater quantities of the violative products in less time than seizure actions. The firm involved can readily identify the location of the product and advise its customers and consignees that the product should be returned at the firm's expense. Most important, however, is that the recall can be nationwide in scope rather than limited to a specific quantity at a specific location, as is the case with a seizure.

Voluntary recalls do have a significant disadvantage in that there is no statutory authority for such removal actions. Because FDA cannot enforce recalls, they have become a matter of negotiation between industry and FDA and thus can be delayed or ineffectively performed by the firm involved. If FDA is not satisfied with the progress of a recall, seizure action is the only alternative provided under existing law to remove a product from the market. FDA officials told us that seizures were often necessary because firms did not voluntarily remove products suspected or known to be violative from the market.