or about 42 percent of the amount distributed, were not recovered. FDA officials advised us that seizure of the drug was not practical because of its national distribution.

Example I--A firm produced a prescription drug that did not meet Federal standards for dissolution. FDA tests of the drug showed that the dissolution range was only between 5 and 39 percent compared with the 60-percent minimum dissolution rate required by the Federal standard. FDA considered this defect to be a moderate-to-serious health hazard. FDA notified the firm of the problem on March 19, 1971. The firm initiated the recall 55 days later. According to the firm's estimated consumption rates, this delay permitted about 75,000 of the tablets to be sold to the public.

INDUSTRY AND MANUFACTURING ASSOCIATION COMMENTS

During the course of our review we discussed the need for recall authority with officials of 20 firms. We also discussed our review and tentative conclusions with officials from five manufacturing associations. Most officials agreed that the quick and complete removal of hazardous products is important to protect the consumer. However, several officials were concerned about how FDA would implement recall authority. Generally the same questions discussed on page 23 on detention authority also applied to recalls. They stated that recalls should be limited to products that present a significant health hazard. We believe that these concerns have merit and should be considered before taking action to establish recall authority.

We noted that such legislative proposals as the proposed Pure Food Act of 1972 include provisions which would authorize recall. The proposal states that, when the Secretary of HEW determines that a food product posses a significant potential health hazard, he may order the recall of the food product. Similarly the proposed Federal Environmental Pesticides Control Act of 1972 includes provisions for recall by EPA when the registration of a pesticide is suspended.