COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

LACK OF AUTHORITY LIMITS CONSUMER PROTECTION: PROBLEMS IN IDENTIFYING AND REMOVING FROM THE MARKET PRODUCTS WHICH VIOLATE THE LAW
Food and Drug Administration
Department of Health, Education, and Welfare B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

The Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Act were enacted to protect American consumers from harmful and potentially harmful commercial products. They were intended specifically to protect consumers from products moved in interstate commerce to market, which are:

Adulterated--defective either in their ingredients or as a result of processing and packing;

Misbranded--having false or misleading labels or packaging; or

Illegally marketed--not federally approved for safety and efficacy, such as new drugs, as required by law.

Congress placed responsibility for enforcing these laws on the Food and Drug Administration (FDA), an agency in the Department of Health, Education, and Welfare (HEW).

The General Accounting Office (GAO) examined and evaluated FDA's actions in fulfilling the intent of the legislation. GAO also evaluated the authority provided FDA under these laws to protect consumers.

Background

By inspecting manufacturing practices and by testing finished products, FDA becomes aware of those that are adulterated, misbranded, illegally marketed, potentially harmful, or suspected of being so. These products are referred to in this digest as "defective" but in the report as "violative," the technical term. Once it is determined that any of these conditions exists, FDA takes steps to remove the product or products from the market. However, the effectiveness of FDA depends largely on its ability to act promptly if consumers are to be protected. It is here that GAO found problems.

FINDINGS AND CONCLUSIONS

FDA has had difficulties in removing defective products from markets because it lacks the authority to

--obtain access to records needed to identify, examine, and remove products suspected or known to be defective (as defined above);

--detain products from interstate shipment until determination can be made whether they should be removed from the market; and

--take steps required to withdraw them.