CHAPTER 1

INTRODUCTION

Protecting the consumer from unsafe and ineffective drugs is one of the primary responsibilities of the Food and Drug Administration (FDA). Drugs, one of mankind's most effective means of preventing and treating diseases and other ailments, are produced by about 6,400 drug producers in the United States. Sales of drugs in 1970 amounted to about $12.5 billion. While each producer is responsible for the quality of its products, the Congress gave FDA the responsibility for insuring that only drugs of satisfactory quality are sold to the consumer.

FDA derives its authority to regulate drugs from the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended (21 U.S.C. 301). The FD&C Act defines drugs as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and articles (other than food) intended to affect the structure or any function of the body of man (for example, articles intended for weight reduction). The FD&C Act prohibits the shipment of adulterated drugs in interstate commerce and defines an adulterated drug as, among other things, one which has not been produced in conformity with good manufacturing practices (GMPs).

FDA inspects drug producers to insure that drugs are produced in accordance with GMPs. Because FDA's ability to protect the consumer depends to a large extent on effectiveness of its efforts to inspect drug producers and enforce compliance with GMPs, we examined FDA's inspection and enforcement program in three FDA districts in which nearly 25 percent of the 6,400 drug producers were located.

To keep adulterated drugs from reaching the consumer, the FD&C Act authorizes FDA to inspect drug producers. Each domestic drug producer must register annually with FDA and be inspected at least biennially. FDA's inspections are to determine whether sound methods, facilities, and controls are used in all phases of drug manufacture and distribution; FDA inspections include equipment, finished and unfinished materials, containers, manufacturing records, and laboratory controls.