--Enjoin a producer or individual from violating the FD&C Act and FDA regulations.

--Seize any drug product that is adulterated or misbranded when introduced into, or while in, interstate commerce.

Although recall is not provided for under the FD&C Act, FDA permits producers to voluntarily recall drugs that are alleged to violate the FD&C Act. During fiscal years 1970 and 1971, respectively, 889 and 1,421 voluntary recalls of drugs were instituted. FDA officials stated in an August 1968 inspection instruction that most recalls stem from deviations from GMPs. Appendix III contains comments on FDA's enforcement alternatives.

A Commissioner, under the direction of the Assistant Secretary for Health, HEW, administers FDA. The drug firm inspection program, under the overall administration of FDA headquarters in Rockville, Maryland, is carried out by 19 district offices located throughout the United States and in Puerto Rico. FDA's appropriation for fiscal year 1972 was about $110 million.

For fiscal year 1972 FDA devoted about $5 million, including 275 man-years, to the inspection of drug producers.

We directed our review primarily at FDA's inspection program for drug producers to insure that quality drugs are produced and that actions are taken to have producers correct deviations from current GMPs. We also tested the accuracy and reliability of data generated by FDA's management information system.

We reviewed inspection records for 171 drug producers, of which all except 5 were randomly selected.

We interviewed FDA officials and reviewed applicable legislative history and FDA's regulations, policies, and practices for inspecting drug producers and initiating corrective actions. We also reviewed FDA records and files for fiscal years 1969-71 pertaining to the inspection of firms and the sampling of drug products.