COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

PROBLEMS IN OBTAINING AND ENFORCING COMPLIANCE WITH GOOD MANUFACTURING PRACTICES FOR DRUGS Food and Drug Administration Department of Health, Education, and Welfare B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

Drugs sold in the United States during recent years have been produced by about 6,400 firms. Although each is accountable for the quality of its products, the Congress placed upon the Food and Drug Administration (FDA) the responsibility that drugs, shipped across State borders, be of satisfactory quality when sold to consumers.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) makes FDA responsible for insuring that adulterated drugs are prevented from reaching the market. This law

--defines an adulterated drug as one, among other things, which has not been produced in conformity with good manufacturing practices and

--requires FDA to inspect drug manufacturers and repackers (referred to hereinafter as drug producers) at least once every 2 years.

Good manufacturing practices include (1) maintaining formula and batch-production control records and procedures, (2) establishing test procedures to insure that drug components or the finished product conform to appropriate standards of identity, strength, quality, and purity, and (3) keeping distribution records of each batch of a drug to facilitate its recall from distribution, if necessary.

In this review the General Accounting Office (GAO) has evaluated FDA's program for inspecting drug producers and enforcing compliance with good manufacturing practices. GAO reviewed the inspection records of 73 drug producers inspected during the 2-year period ended March 31, 1971, and the inspection records of 98 drug producers which were not inspected during this period.

Except for five large drug producers, firms were randomly selected for review. The drug producers were in three FDA districts in which nearly 25 percent of the Nation's 6,400 drug producers were located.

FINDINGS AND CONCLUSIONS

Overall findings

Several factors have hindered FDA's obtaining and insuring compliance with good manufacturing practices by drug producers.

--FDA has not always enforced aggressively compliance with good manufacturing practices by many