CHAPTER 2

LIMITED ENFORCEMENT OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICES

Although deviations from GMPs can lead to adulterated drugs, FDA has not enforced compliance with GMPs by many of the drug producers it has inspected. Of the 7,124 inspections during fiscal year 1971, nearly 4,000 were followup inspections where deviations from GMPs had been previously encountered. Over half--2,174--of the followup inspections showed that producers were still not complying with the FD&C Act.

The FD&C Act provides FDA with legal sanctions to enforce drug producer compliance with GMPs:

--Authority under section 301 to prohibit the introduction or delivery for introduction into interstate commerce of any drug that is adulterated.

--Authority under section 302 to initiate injunction proceedings--civil court actions--to restrain violations of section 301.

--Authority under section 303 to impose penalties for conviction of any person who violates a provision of section 301.

--Authority under section 304 to seize any drug that is adulterated or misbranded when introduced into or while in interstate commerce.

FDA's guidelines for using this authority provide that prosecution, injunction, or seizure may be considered on the basis of inspectional evidence only; i.e., a product need not be sampled and analyzed to show that it is adulterated. The guidelines also provide that:

--Support for seizure actions should include documentation of the deviations from GMPs that demonstrate inadequate assurance of identity, strength, quality, or purity of the drug.