--Injunction action may be considered when a producer has generally ignored the principles of GMPs in the past and sufficient evidence is available to establish that continued violations are likely to occur.

--Prosecution may also be considered when a producer has generally ignored the principles of GMPs. A record of faulty past performance may be necessary to warrant prosecution when inspectional evidence is not accompanied by sample analysis showing adulterated drugs.

To evaluate FDA's effort to enforce compliance with GMPs, we reviewed the inspection records of 73 drug producers. Sixty-eight of these were randomly selected from 857 drug producers that had been inspected during the 2-year period ended March 1971 in the 3 FDA districts included in our review. We also reviewed the inspection records of 5 major prescription drug producers that received a more intensified FDA inspection of GMPs as part of a special program. According to FDA, this indepth inspection program of the major prescription drug manufacturers resulted in massive improvements in manufacturing practices but was discontinued because it consumed tremendous resources.

LIMITED USE OF LEGAL SANCTIONS TO ENFORCE GMP COMPLIANCE

FDA has not always aggressively used its legal sanctions to enforce compliance with GMPs. Our examination of the inspection records for the 73 drug producers showed that

--58 of the 73 producers had a total of 1,015 GMP deviations of which 382 according to FDA administrative guidelines were critical and

--35, including the 5 major prescription drug producers, or 60 percent, of the 58 firms had critical deviations from GMPs on successive inspections.

FDA identifies critical deviations from GMPs as those deviations having the greatest probability of creating adulterated products. The 382 critical deviations included: