Bureau of Drugs with assistance from a drug quality control expert consultant with extensive industry experience. The Guidelines will be rewritten to more clearly delineate and define actions to be taken. Training programs for field and headquarters officials will be intensified and continuing to assure that everyone making regulatory decisions has written guidelines to the fullest extent possible and the experience to make judgments where guidelines are not possible.

GAO Recommendation

--Consider establishing a time limit for receipt of the written response requested in warning letters.

Department Comment

We concur. Instructions were issued in August 1972 to require a response to all "warning" letters to firms within ten days. These letters include (i) Regulatory Letters, (ii) Reports of Inspectional Findings, and (iii) Section 306 Warning Letters. In addition, FDA's inspectors who issue a report of their GMP findings (FD-2275) to an official other than the firm's principal executive, will also send a copy to the principal executive of the firm.

GAO Recommendation

--Establish an inspection scheduling system monitored by FDA headquarters, to assure that all drug producers are inspected at least every two years.

Department Comment

We concur in that FDA will develop a system (for monitoring at the headquarter's level) for scheduling inspections of all drug producers at least every two years. Its full implementation, however, will depend upon whether the inspection resources presently available to FDA are increased and on other competing priorities for the manpower to perform such inspections.

GAO Recommendation

--Establish guidelines to assure timely initial inspection of newly registered drug producers.

Department Comment

We concur. Instructions will be issued to the field to inspect newly registered drug producers as promptly as possible. The instructions will cover not only newly registered firms but new firms which have failed to register and which come to our attention through other means. These firms will be required to register.