CONCLUSION

FDA's efforts to obtain drug producers' voluntary compliance with GMPs in many instances were not effective because proper and timely written notification of needed corrections was not provided to producers' top management. Followup inspections were usually untimely, if made at all, and were often ineffective when firms were found to have taken no action.

Proper implementation of the August 1972 policy statement regarding post inspection and regulatory letters should assist FDA in insuring that (1) district offices properly monitor drug producers' replies and (2) producers take needed corrective actions. However, we believe that FDA should also consider establishing a time limit for receipt of written responses requested in warning letters.

RECOMMENDATION TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to consider establishing a time limit for receipt of the written response requested in warning letters.

HEW concurred in our recommendation and advised us that instructions were issued in August 1972 to require a response to all warning letters to firms within 10 days.

Our review of the August 1972 instructions showed, however, that the 10-day response was required only for post inspection and regulatory letters, and was not required for warning letters. We believe FDA should clarify its instructions to also establish a specific time limit for receipt of the written responses requested in warning letters.