CONCLUSIONS

FDA lacks an effective means to insure biennial inspection of all drug producers. Although we found that noninspected firms generally were small producers of nonprescription drugs, the FD&C Act clearly requires that FDA inspect all drug producers regardless of size or product type.

We believe that FDA should develop an effective means for insuring biennial inspection of all drug producers and headquarters should monitor the district offices more closely to insure that the 2-year requirement is met. FDA may want to consider the procedure discussed on page 34 for wider implementation. An up-to-date listing of producers not inspected would aid in providing needed control.

Also, FDA should make a more timely initial inspection of newly registered producers since these producers are permitted to market drugs.

RECOMMENDATIONS TO THE SECRETARY, HEALTH, EDUCATION, AND WELFARE

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to:

--Establish an inspection scheduling system monitored by FDA headquarters to insure that all drug producers are inspected biennially.

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

HEW concurred in our recommendations and advised us that FDA will develop a system (to be monitored at the headquarters level) for scheduling biennial inspections of all drug producers. HEW stated that full implementation of the system, however, will depend on an increase in inspection resources presently available to FDA and on other competing priorities for the manpower to perform such inspections.

HEW pointed out that most of the firms not inspected biennially were manufacturing nonprescription drugs which