APPENDIX I



## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE OFFICE OF THE SECRETARY WASHINGTON, D.C. 20201

JUL 31 1972

Mr. Morton A. Myers Assistant Director General Accounting Office Washington, D. C. 20548

Dear Mr. Myers:

This is in response to your letter of June 6, 1972, requesting the Department's comments on a draft of a proposed report of the General Accounting Office entitled "Lack of Authority Limits Consumer Protection: Problems in Identifying and Removing from the Market Products Which Violate the Law."

The GAO report analyzes the authority of the Food and Drug Administration 1) to examine records needed to identify and remove from the market products known or suspected of violating the statutes administered by the Secretary through FDA, 2) to detain such products; and 3) to remove such products from the market. On the basis of this analysis, the report concludes that legislation should be enacted to provide the Department with certain additional authority.

The GAO conclusions with respect to the limitations of the analyzed statutes are legally correct, and the particular cases and other data cited by the report are confirmed by FDA's records.

We are currently giving the most serious consideration to the inclusion of GAO's legislative proposals in the Department's legislative program for the next Congress. It should be recognized, however, that any such proposals, if adopted by the Department, must be submitted for clearance to the Office of Management and Budget and must be coordinated by that office with other interested agencies within the Executive Branch. It is therefore not possible for us to anticipate the outcome of this process at this time.

Sincerely yours,

James B. Cardwell

Assistant Secretary, Comptroller