APPENDIX I

Comments of the Department of Health, Education, and Welfare on the GAO Draft Report entitled, "Problems in Obtaining and Enforcing Compliance With Good Manufacturing Practices for Drugs"

General

We concur in the recommendations offered by GAO. FDA with its limited resources has, and will continue to seek ways to best protect the consumer. Manufacturers and processors, however, must strictly comply with the provisions of the Food, Drug and Cosmetics Act if the consumer is to be assured of quality, safety and wholesomeness in their products.

With respect to this report, GAO faults FDA for the limited number of inspections made of firms manufacturing non-prescription drugs. Elsewhere in the report, however, it is brought out that such drugs usually do not pose a significant threat to the public health. We concede that these firms should have been inspected in a more timely manner -- but want to point out that FDA's limited manpower precluded our reaching this goal. Instead, decision was made to use this manpower in inspecting those plants and those operations that do or could pose a significant health hazard to the consumer.

We believe it is unfortunate the scope of the audit was not such that a number of approaches taken by FDA to protect the consumer were not commented on in this report. For example, the agency's new Quality Assurance Program which calls for large numbers or samples to be analyzed prior to inspection to detect specific flaws. Under this approach, inspectors can focus on the conditions in a firm that led to these flaws.

Finally, we believe that the use of the term "critical deviations" throughout the report in referring to inspections of drug firms is unfortunate and possibly misleading. In the Administrative Guidelines for Good Manufacturing Practices (GMPs), there is a list of "Critical Areas" with instructions on when to recommend regulatory actions where critical deviations are found. These guidelines stress the importance of judgement in determining whether a situation exists that requires regulatory action. Wherever truly critical deviations from GMPs are found we always act to correct the situation.

GAO Recommendation

--Establish more definitive guidelines to be followed by FDA headquarters and district office personnel, specifying (i) when products should be seized -- especiallly those posing a questionable health hazard, (ii) the amount and type of documentation needed to adequately support the seizure action, and (iii) when firms should be cited for prosecution.

Department Comment

We concur. The Administrative Guidelines for GMPs as well as the current good manufacturing practice regulations themselves, are under study by the