

10568 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

APPENDIX I

GAO Recommendation

--Properly enforce the annual drug producers registration requirement and effectively monitor the accuracy and completeness of the registration listing to permit its use as a cross-check on the OEI listing.

Department Comment

We concur. Each quarter (headquarters') staff will match the Official Establishment Inventory (OEI) file with the drug registration file and provide the district offices a list of "non-matches." The two sources of information will be used to increase the accuracy of both OEI and registration files. When the Drug Listing Act and voluntary inventory data become available these data will automatically update the list of drug manufacturers.

GAO Recommendation

--Correct the inventory of drug producers subject to the 2-year inspection requirement so that FDA will have complete and accurate knowledge of the scope of its inspection responsibilities.

Department Comment

We concur. As part of the first major Official Establishment Inventory validation since 1963, we have contracted with a major private concern to compare FDA's establishment inventory with their inventory of firms dealing in commodities subject to the FD&C Act. Discrepancies between these two lists will be resolved by FDA's District Offices by June 1973. Other sources of commercial information will also be used by the Districts to correct the inventory. Updates will be received from the contractors at regular intervals, and will become part of prescribed OEI updatings.