hazard, (2) the amount and type of documentation needed to adequately support the seizure action, and (3) when firms should be cited for prosecution.

--Consider establishing a time limit for receipt of the written response requested in warning letters.

--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.

--Establish an inspection scheduling system monitored by FDA headquarters to insure that all drug producers are inspected at least every 2 years.

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

--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 official establishment inventory listing.

AGENCY ACTIONS AND UNRESOLVED ISSUES

HEW concurred in GAO's recommendations and advised that a number of corrective actions had been or would be taken. (See pp. 22, 29, 35, 36, and 41.)

MATTERS FOR CONSIDERATION BY THE CONGRESS

This report provides the Congress with information on FDA's drug firm inspection coverage and enforcement of good manufacturing practices.