In the three FDA districts reviewed, at least 213 drug producers, or about 16 percent, had not been inspected during the 2-year period April 1969 through March 1971. Another 123 firms were listed as not inspected but records were not available to substantiate that the firms were in fact subject to inspection. (See p. 30.)

Records of 98 of the 213 firms not inspected showed that an average of 36 months had elapsed (as of March 31, 1971) since 74 of these firms were last inspected. The remaining 24 firms had registered for the first time during the 2-year period and were not required to have been inspected by March 31, 1971. The 24 firms had been registered an average of 9 months--7 for over 12 months. (See pp. 31 and 32.)

FDA had not established guidelines on how soon firms should be inspected after registration. Since newly registered firms are permitted to produce and distribute drug products for consumer use, FDA should consider making an earlier initial inspection of such firms.

The failure to inspect some producers when required can be attributed to weaknesses in the inspection scheduling process, the priority given to reinspecting other producers with a history of deviating from good management practices, diversion of manpower to crisis situations, and the lack of manpower.

Although GAO 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. (See p. 32.)

Inaccurate drug firm listings

FDA maintains two master firm listings for management and control purposes: the drug firm registration listing and the official establishment inventory.

The purpose of the registration listing is to identify all drug producers subject to the 2-year inspection requirement. The official establishment inventory is FDA's official record of all firms producing products which fall into FDA's regulatory purview. The official establishment inventory is one tool headquarters uses to decide the annual allocation of each district's inspection manpower resources among various types of inspections.

GAO found that these two listings for calendar year 1971 were inaccurate and FDA had neither monitored nor enforced annual registration of drug producers as required by law. In GAO's opinion, the usefulness of the listings has been significantly reduced as a basis for management decisionmaking and control. (See p. 37.)

RECOMMENDATIONS

The Secretary of Health, Education, and Welfare (HEW) should direct the Commissioner, FDA, to:

--Establish more definitive guidelines to be followed by FDA headquarters and district offices, specifying (1) when products should be seized--especially those posing a questionable health