CHAPTER 5

NEED FOR IMPROVEMENT IN FDA'S REGISTRATION LISTING AND OFFICIAL ESTABLISHMENT INVENTORY

Our review showed that two master listings--the registration listing and the official establishment inventory (OEI)--maintained by FDA for management and control purposes, were inaccurate and incomplete, and that FDA had neither monitored nor enforced annual registration of drug producers. The purpose of the registration listing is to identify all drug producers subject to biennial inspection. The OEI is FDA's official record of all firms that fall into FDA's regulatory purview. The OEI is one tool headquarters uses in deciding on the annual allocation of inspection manpower resources within each district. We were told that data in the OEI is assumed to be correct.

In our opinion, the usefulness of the listings has been significantly reduced as a basis for management decisionmaking and control. Both listings for calendar year 1971 contained inaccurate and incomplete information. The registration listing included firms that were not subject to registration and inspection. The OEI listed some firms, which were not included on the registration listing, as drug producers subject to registration and inspection. Conversely, drug producers shown on the registration listing were not included on the OEI. Also, some firms on the OEI list had gone out of business. In addition, we found little use made of the registration listing as a means of control.

REGISTRATION LISTING

Annual registration is to identify firms that produce drugs and are subject to FDA biennial inspections. Each November, FDA mails registration forms to all producers that registered during the prior year. Other drug establishments, including new drug producers, may request registration forms. Completed forms are returned to FDA headquarters for review and distribution, with copies going to the responsible district offices.