

10560 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

If a firm has not registered previously, the district office prepares a master card on the firm, recording the information submitted in the registration form and sometimes classifying the firm as to the type of establishment, e.g., drug producer, distributor, or warehouser. If the firm has previously registered, the master card is updated. The updated master card forms the basis for OEI changes. Firms are recorded on the registration listing when the district office returns the registration form to FDA headquarters.

We identified 161 firms shown as drug producers on the registration listing for the three districts included in our review that were not on the OEI. Our review of district records for 65 of the firms showed that 15 were not drug producers and therefore not required to register or be inspected. FDA headquarters officials told us that registration forms were issued on request without determining that the firms were subject to registration and inspection.

Our review showed that the districts prepare master cards without screening the firms. We were told by a district supervisor that only limited information is requested of the drug firm on the registration form. The supervisor said that this lack of information sometimes makes it necessary to guess at what the firm's classification should be, e.g., a drug producer and subject to the biennial inspection or a distributor or warehouser not subject to the inspection. Rather than guessing, we believe the information should be verified and, if needed, enlarged upon via a telephone call or visit before the firm is classified in FDA's information systems. We were told visits or telephone calls for such purpose were made infrequently.

We were told that, if an inspection later shows that the firm was improperly classified, the inspector would have to prepare a change slip to correct the master card and the OEI. Since the registration listing is a separately maintained system, the change would also have to be furnished to FDA headquarters. Such changes were not always made.

We reviewed the inspection records at one FDA district office for 31 of the 124 firms that distribute drugs in the district. Twelve of 13 firms that were registered were misclassified and did not have to register. FDA did not correct the misclassification until we brought it to their attention.