

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10561

It appears that little emphasis has been placed on the importance of insuring the accuracy of the registration listing and little use has been made of it. The Director, Division of Case Guidance, stated that the annual registration requirement is not strictly enforced by FDA because once the firm registers, it is maintained on the OEI listing. Further, we were told by FDA headquarters officials that they rely on district office personnel to monitor the listing. However, guidelines have not been provided to the district offices instructing them how to perform the monitoring.

OFFICIAL ESTABLISHMENT INVENTORY

FDA officials told us that the OEI is a useful, essential management tool, and that it is used in resource allocation and inspection planning. A district official said, however, that the OEI contains firms erroneously classified as drug producers, and thus portrays a false image of firms requiring biennial inspections.

A total of 1,396 firms were classified as drug producers on the 1971 OEI listing for the 3 districts included in our review.¹ However, 368 of these firms did not appear on FDA's registration listing. District records of 204 of the 368 firms showed 67 had not registered, 25 had registered but were not on the list, and 105 were misclassified on the OEI and not required to be registered or inspected biennially. Information was inadequate to determine the classification of 6 of the remaining 7 firms and 1 firm was listed twice.

A data processing supervisor in one FDA district attributed the inaccurate and incomplete information to

¹The difference between the total number of firms identified by the OEI and the narrative inspection history as discussed previously on p.30 had not been reconciled by FDS at the time of our review. FDA has contracted with a private credit organization to obtain data on establishments whose products may be subject to FDA regulatory authority. The contract required the data to be reconciled with current FDA inventory records.