

10562 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

- misclassification of firms by inspection personnel,
- failure of inspectors to submit data needed to change the OEI when reclassification or other changes are made to the firm's central records, and
- clerical errors in processing and maintaining data.

We also noted that FDA instructions for classifying firms on the OEI requires that firms be classified in a manner which will best indicate the overall type of establishment. Thus, firms have been classified, for example, as a food establishment even though they may also manufacture or repack drugs. Of the 65 firms whose district file records were reviewed, 30 were properly listed as drug producers on the registration listing but were classified on the OEI as other types of producers, such as foods, cosmetics, etc.

The OEI is one source of information used by headquarters in preparing district offices' annual work plans. The work plans include an allocation of each district's manpower resources to the basic problem areas, i.e., foods, drugs, cosmetics, etc., based on the number of firms in the district and priorities which the FDA Commissioner establishes. Actual selection of drug producers to be inspected is left to the district offices. We believe the usefulness of the OEI in making such resource allocations is reduced by listing drug producers as other types of producers and by the various other misclassification errors we found.

CONCLUSIONS

The usefulness of the registration listing and the OEI as tools for management decisionmaking and control has been reduced because the lists have not been complete or accurate. Firms incorrectly listed on the OEI as drug producers inflate the number of firms subject to biennial inspection. Conversely, firms which produce or repackage drugs but whose primary business is other than drugs, may not be subject to biennial inspection.

FDA has not adequately monitored or enforced the annual registration of drug producers required by the FD&C Act. As a result some firms have registered unnecessarily and some have not registered although required to do so.