Memorandum

Date FEB 13 2002

From Deputy Inspector General
for Audit Services

Subject Review of the Accuracy of the Food and Drug Administration's Official Establishment Inventory (CIN: A-15-01-20001)

To Jeffrey M. Weber
Acting Senior Associate Commissioner
for Management and Systems
Food and Drug Administration

The attached final report provides the results of our self-initiated review of the accuracy of the Food and Drug Administration's (FDA) Official Establishment Inventory (CIN: A-15-01-20001).

In written comments to the draft report, FDA agreed with our recommendations and provided a plan for implementation. The FDA comments are summarized in the Agency Comments and OIG Response Section of this report. The complete text of FDA's comments is included in the Appendix.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act (see 45 C.F.R. Part 5). As such, within 10 business days after this report is issued, it will be posted on the World Wide Web at http://www.hhs.gov/progorg/oig.

We would appreciate being advised on the status of corrective actions within 60 days of this memorandum. Should you wish to discuss the issues raised in our report, please call me or have your staff contact Joseph J. Green at (301) 443-3582 or through e-mail at jgreen3@os.dhhs.gov. To facilitate identification, please refer to Common Identification Number A-15-01-20001.

Thomas D. Roslewicz

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE ACCURACY OF THE FOOD AND DRUG ADMINISTRATION'S OFFICIAL ESTABLLLISHMENT INVENTORY

JANET REHNQUIST
INSPECTOR GENERAL
FEBRUARY 2002
A-15-01-20001

Memorandum

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From Deputy Inspector General
for Audit Services

Subject Review of the Accuracy of the Food and Drug Administration's Official Establishment Inventory (CIN: A-15-01-20001)

To Jeffrey M. Weber
Acting Senior Associate Commissioner
for Management and Systems
Food and Drug Administration

This final report provides the results of our self-initiated review of the accuracy of the Food and Drug Administration's (FDA) official establishment inventory (OEI)—a computerized data base of establishments under the regulatory purview of FDA. Section 510(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires FDA to inspect, at least once every 2 years, establishments registered with FDA that are engaged in the manufacture, preparation, propagation, compounding, or processing of drugs and devices. Other establishments such as food manufacturers and processors are not subject to this statutory requirement and may be inspected less frequently. The FDA inspections identify objectionable conditions and practices and may form the basis for administrative or regulatory action against the establishments such as warning letters, license suspension, product seizure, injunction, or prosecution. Inspections are primarily carried out by FDA's field force located in 19 district offices, under the direction of the Office of Regulatory Affairs (ORA). Some states also conduct inspections for FDA under contracts or partnership agreements.

OBJECTIVE

The objective of our review was to test the accuracy of FDA's OEI.

SUMMARY OF FINDINGS

The FDA's OEI, which listed 135,885 establishments at the time of our review, is not accurate and could be reduced by 21,742 establishments,[1] or 16 percent. This error rate is higher than the goal FDA set for itself, which is accuracy within 5 percent. These inaccuracies were due to the district offices suspending their quality assurance reviews of their respective portions of the OEI during the transition to an updated management

[1] Based on the results of our random sample, we estimate 21,742 establishments listed in the OEI cannot be contacted for inspection by telephone. The 95 percent confidence interval of our sample results has a lower limit of 12,818 establishments and an upper limit of 33,531 establishments that could not be contacted by telephone.

information system. With an inaccurate OEI, FDA does not have the best information available on which it can base its inspection plans. Accordingly, we recommend that FDA's Associate Commissioner for Regulatory Affairs ensure that: (1) the importance of an accurate OEI and the need for its continuous review is communicated to all cognizant officials and staff; and (2) the FDA district offices, under the direction of ORA headquarters, implement the periodic random sampling review procedures described in an existing FDA field directive to improve the accuracy of the OEI, and specifically to ensure that: (a) establishments that are out of business and no longer subject to inspection are promptly removed from the OEI; and (b) all names, addresses, telephone numbers, and other information for establishments remaining in the OEI are correct.

In written comments on the draft report, FDA agreed with our recommendations and provided a plan for implementation. The FDA comments are summarized in the "Agency Comments and OIG Response" section of this report. The complete text of FDA's comments is included in the Appendix.

BACKGROUND

The FDA's Mission

A vital part of FDA's mission is to protect the public health by ensuring that food is safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; and public health and safety are protected from electronic product radiation. A primary way that FDA carries out its mandate of consumer protection is by inspecting establishments engaged in the production and distribution of these products.

Inspection Requirements

The FDA is responsible for protecting the public health, including ensuring that manufacturing establishments and the products being produced by these establishments, both domestic and foreign, are meeting acceptable United States safety and quality standards. Under the provisions of the FD&C Act, FDA is required to conduct biennial inspections of registered establishments, which are those engaged in the manufacture, preparation, propagation, compounding, or processing of drugs or devices. The FDA OEI includes approximately 16,000 "registered" firms. Establishments not engaged in these activities, such as food manufacturers and processors or entities who manufacture or process drugs not for sale but solely for use in research, teaching, or chemical analysis, are not required to register with FDA and are not subject to the biennial inspection requirement. For the non-registered firms, FDA sets goals within establishment categories to achieve an average inspection cycle of once every 4 years, with appropriate risk-based variations in this cycle where warranted. The FDA is aware that it is falling

short of meeting the statutory requirement of inspecting all registered establishments at least once every 2 years, and attributes this shortcoming to limited resources.

The FDA Field Organization for Inspections

The FDA ORA is responsible for the activities, operations, and resources of the agency's field staff. The FDA's field responsibilities focus on inspections, investigations, and enforcement of regulated industries and products. The ORA field organization is geographically divided into 5 regions: Northeast, Southeast, Central, Southwest, and Pacific. Each regional office, which controls from 2 to 7 district offices, is headed by a director who reports to the Associate Commissioner for Regulatory Affairs. The FDA's 19 district offices are located in cities throughout the United States and in Puerto Rico.

A typical district office comprises four branches: (1) Administrative; (2) Compliance; (3) Investigations; and (4) Laboratory. According to ORA, in Fiscal Year (FY) 2000, the field was authorized 2,635 positions. This represents 29 percent of FDA's total staff of approximately 9,000.

The OEI Information Systems Changes

The FDA's OEI was formerly maintained in an information system called the Field Information System (FIS). The agency is replacing the FIS with a new information system called the Field Accomplishments and Compliance Tracking System (FACTS). Under FIS, OEI data were stored in multi-district office computer systems with monthly updates to an FDA headquarters file. The FACTS is a comprehensive online information system which can be accessed by district office and headquarters staff. In addition to providing OEI data, FACTS will be FDA's automated system for field assignments, work results, compliance actions, and time reporting. One significant difference between FIS and FACTS is that FACTS permits more sources, including individuals from outside FDA, such as import brokers, to enter establishment information into the OEI data base. Data about firms can be entered directly on data entry canvas screens or indirectly through the Operational and Administrative System for Import Support. According to some district offices, allowing firm data to be added or modified by many individuals increases the potential for erroneous or duplicate data to be entered into the OEI and may make their job of maintaining the accuracy of OEI more difficult.

SCOPE AND METHODOLOGY

The scope of our review was FDA's OEI as of November 2000, which was provided to us on November 13, 2000. However, FDA officials advised us in June 2001 that the OEI was current only as of September 1999 because the district offices ceased updating the OEI during the conversion to FACTS and only maintained the FACTS firms file. The OEI that was provided to us contained information on 135,885 establishments sorted by

program as follows: foods and cosmetics - 64,756; devices and radiological health - 37,839; human drugs - 17,625; animal drugs and feeds - 7,702; biologics - 4,223; multi-product storage warehouses - 2,320; and miscellaneous food-related items - 1,420.

To determine the accuracy of the OEI, we performed the following steps:

- Reviewed those sections of the FD&C Act applicable to inspection requirements;

- Reviewed FDA's Field Management Directive (FMD) No. 130, *Official Establishment Inventory Development and Maintenance Procedures,* dated May 16, 1997;

- Reviewed district office policies and procedures related to maintaining the accuracy and quality of the OEI;

- Held discussions with cognizant FDA officials concerning guidelines and responsibilities for maintaining the accuracy and quality of the OEI;

- Using a random numbers generator, drew a random sample of 100 establishments listed in the November 2000 OEI;

- Attempted to contact a random sample of the 100 establishments listed in the OEI by placing telephone calls to these establishments using the telephone numbers provided in the OEI;

- If we could not contact the establishments by calling the telephone numbers provided in the OEI because they were not in service or disconnected, we attempted to obtain the correct telephone numbers for the establishments by first calling directory assistance and then using the Internet yellow pages and called those numbers, if provided, to attempt to contact the establishments; and

- Provided FDA with the names of the establishments we could not contact using these methods and requested the agency to attempt to contact the establishments.

We placed our telephone calls to the 100 establishments during the week of April 9-13, 2001. We provided the names of the establishments we could not contact to FDA on April 30 and received the agency's response on May 18. We limited our review to identifying an overstatement of the number of establishments listed in the OEI; however, we recognize the possibility that the OEI may also be understated. An understatement may occur when new firms and establishments start operations, but have not notified or

otherwise come to the attention of FDA. Our sampling methodology did not include steps to attempt to identify firms that should have been listed in the OEI, but were not. We conducted our review in accordance with generally accepted governmental auditing standards from October 2000 through June 2001 at FDA offices in Rockville, Maryland.

RESULTS OF REVIEW

The FDA's OEI, which listed 135,885 establishments at the time of our review, is not accurate and could be reduced by 21,742 establishments, or 16 percent. This error rate is higher than the goal FDA set for itself, which is accuracy within 5 percent. These inaccuracies were due to the district offices suspending their quality assurance reviews of their respective portions of the OEI during the transition to an updated management information system. With an inaccurate OEI, FDA does not have the best information available on which it can base its inspection plans. Accordingly, we recommend that the Associate Commissioner for Regulatory Affairs ensure that: (1) the importance of an accurate OEI and the need for its continuous review is communicated to all cognizant officials and staff; and (2) FDA district offices, under the direction of ORA headquarters, implement the periodic random sampling review procedures existing in FMD No. 130 to improve the accuracy of the OEI, and specifically to ensure that: (a) establishments that are out of business and no longer subject to inspection are promptly removed from OEI; and (b) all names, addresses, telephone numbers, and other information for establishments remaining in OEI is accurate.

The FDA Requires an Accurate OEI for Managing its Inspection Process and Justifying Resources

The FDA FMD No.130 states that "the need for accurate, complete, and uniform information in OEI has become more crucial each year as the data are used by the agency to provide information about the type and number of establishments we regulate to Congress, other governmental organizations, and the public. This information is also used in budget presentations to justify resources received and to request additional resources to accomplish our obligations under the FD&C and other Acts." In addition, FDA uses the OEI to allocate resources to the district offices for the various compliance programs and assignments identified in the annual field work plan.

The ORA headquarters staff share responsibility for the OEI's accuracy with the district offices. The FMD No. 130 states that, among other things, ORA headquarters officials are responsible for conducting reviews of each district office's OEI, with a focus on discovering obvious discrepancies.

The directive states that if the OEI random sample exceeds 15 percent, the district office director should take steps to assure that an accurate and up-to-date OEI receives a high priority until the error rate falls to 5 percent or below.

The ORA FMD No. 130 states that the district offices will, through written procedures, assure the overall quality of their OEI files through periodic reviews. The directive specifically requires each district office to:

- Conduct a random sample review of the OEI to ensure its accuracy;
- Identify establishments that are out of business and remove them from the OEI;
- Identify prospective new establishments for inclusion in the OEI by telephone calls, visits, information obtained from other local State agencies, or any other appropriate means;
- Take steps necessary to achieve an overall 95 percent accuracy rate based on sample reviews;
- Ensure that an "accurate and up-to-date" OEI receives high priority until the error rate drops to 5 percent or below; and
- Name an OEI coordinator who will be responsible for the overall quality of the OEI, and identify the names and titles of persons authorized to add, delete, or otherwise manipulate OEI records.

The FDA OEI is not Accurate

Our analysis of the random sample of 100 establishments selected from the November 2000 OEI revealed that FDA's OEI is not accurate. Specifically, we determined that 16 of the 100 establishments (16 percent) could not be contacted and may be out of business.

Projecting the results of the random sample to the 135,885 establishments listed in the OEI, we estimate that 21,742 establishments may no longer be in business and could be removed from the OEI. This is an average of about 1,144 establishments for each district office. Our sample results provide that at the 95 percent confidence level, the range of establishments that could be removed from the OEI is a lower limit of 12,818 establishments to an upper limit of 33,531 establishments.

In discussing our results with cognizant FDA officials, they noted the errors appear to be more heavily concentrated in product areas that are not currently required to register with FDA, such as food establishments. Indeed, of the 16 establishments that could not be contacted, there were 8 foods, 4 devices, and 1 each of human drugs, biologics, cosmetics, and multi-product storage warehouses. The Director of ORA's Division of

Planning, Evaluation, and Management indicated that our results provide support for the agency's intention to expand the registration requirement to all firms under its regulatory purview.

In our tests of the raw accuracy of the establishment information listed in the OEI (i.e., before obtaining updated contact information through directory assistance, the Internet yellow pages, or from FDA), we noted that 54 percent of the 100 establishments in our sample had incorrect names, addresses, or telephone numbers, or had no telephone numbers listed in the OEI. In some cases, the firm listed in the OEI was bought out by another firm, or the nature of the business changed (e.g., from a wholesale grocery establishment to a warehouse).

District Offices have not Conducted Random Sample Reviews of the OEI to Maintain Accuracy

In order to determine whether FDA's district offices were conducting random sample reviews of their OEIs during the transition to FACTS, we requested ORA to obtain for us from five district offices (1) the district offices' OEI quality assurance policies and procedures; (2) the dates of their most recent OEI random sample reviews; and (3) the results of the random sample reviews.

The responses received varied widely from one district office that had conducted no random sampling in the past several years, to another that had at least completed an audit of the OEI in January 2000, which revealed an error rate of 9 percent. The ORA headquarters officials told us that they had not conducted reviews of each district office's OEI because of the significant systems changes that occurred during the transition to FACTS.

The FDA does not have Accurate Information for Planning Inspections and Requesting Resources

The FDA uses the OEI for a number of important reasons such as planning inspections, justifying existing resources, and requesting additional resources based on its workload obligations. The OEI data base contains a field for entering the date an establishment was last inspected. The date of the last inspection and an accurate list of establishments are essential elements for planning inspections of those registered drug and device manufacturing establishments which, under statute, must be inspected at least once every 2 years. Also, FDA is moving toward a goal of inspecting high-risk food establishments every 1 to 2 years, and moderate-to-low risk establishments every 4 years. In order to efficiently plan these inspections, the agency should be working with an up-to-date OEI to have a more accurate number of the firms requiring inspection.

Because the number of establishments that must be inspected has a direct relationship to FDA's resource requirements, the possibility that the OEI includes more than 21,742 establishments that may no longer be in business and do not have to be inspected can have a significant effect on the distribution and deployment of the agency's scarce resources. We believe that having an accurate OEI is the first step in correctly determining inspection resource needs: first for FDA's major programs, such as drug and device regulation; and then for the district offices to carry out the required number of inspections for these programs within their geographical areas.

RECOMMENDATIONS

We recommend that the Associate Commissioner for Regulatory Affairs ensure that:

(1) The importance of an accurate OEI and the need for its continuous review is communicated to all cognizant officials and staff; and

(2) The FDA district offices, under the direction of ORA headquarters, implement the periodic random sampling review procedures existing in FMD No. 130 to improve the accuracy of the OEI, and specifically to ensure that:

   (a) establishments that are out of business and no longer subject to inspection are promptly removed from the OEI; and

   (b) names, addresses, telephone numbers, and other information for establishments remaining in the OEI is correct.

AGENCY COMMENTS AND OIG RESPONSE

In its December 31, 2001 memorandum commenting on our draft report dated October 26, 2001, FDA agreed with our recommendations and submitted a plan for implementation.

Throughout its response, FDA referred to statutory firms (i.e., firms that by law must be inspected by FDA at least once every 2 years) and non-statutory firms, and stated that our sample did not differentiate between the two. Our sample did not make the distinction between statutory and non-statutory firms because, when we requested information in this format, FDA was unable to provide it. We proceeded with our review using the available OEI data because we understood from FDA officials and available statistics that the statutory firms accounted for only about 16,000 of the 135,885 total establishments (approximately 12 percent) in the OEI. Another important consideration was FDA's inspection workload, which FDA statistics for FY 1999 identified that the majority of inspections were conducted at non-statutory establishments by a 2 1/2:1 ratio over statutory establishments. Further, the FDA FMD No. 130, which established the

95 percent accuracy goal for the OEI, states that the agency must assure that the information about *each establishment* in the OEI, regardless of whether there is a statutory requirement for its inspection, is complete and accurate.

The FDA suggested that the report include a statement that the OEI is sufficiently accurate for medical products (i.e. statutory establishments) to plan inspections and request resources necessary to meet statutory requirements. We do not believe that we can include such a statement. Our sample showed that of the 16 establishments that are out of business and were still included in the OEI, 8 were firms that manufactured or stored medical products including 4 medical device firms and one each for human drugs, biologics, cosmetics, and a warehouse for surgical supplies. The 8 remaining firms were food-related establishments.

The FDA did not disagree that there are firms in the OEI that are no longer in business and should be removed, but stated that there is a good possibility that other firms are in business and not in the inventory. We agree with this statement and urge the agency to use the methods suggested in FMD No. 130 to identify prospective new establishments for inclusion in the OEI. These methods include telephone calls, visits, information obtained from other local or state agencies, or any other appropriate means selected by the FDA district offices.

Finally, FDA suggested that the report show the number of establishments included in our sample by type of industry, and whether the firm was required to register with FDA. Our sample of 100 establishments included firms from the following industries: Foods and Cosmetics-52; Devices and Radiological Health-24; Human Drugs-11; Animal Drugs and Feed-8; Biologics-3; and Multiple Storage-2. The OEI data provided by FDA for our sample did not identify those establishments that are required to register (statutory establishments), so we are unable to report this information.

Thomas D. Roslewicz

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

DATE: December 31, 2001

TO: Assistant Inspector General for
Public Health Service Audits

FROM: Acting Principal Deputy Commissioner

SUBJECT: Agency's Response for the Office of Inspector General's Report, "Review of the Accuracy of the Food and Drug Administration's Official Establishment Inventory," (CIN: A-15-01-20001).

Thank you for the opportunity to review and submit the Agency's response for the OIG's Report, "Review of the Accuracy of the Food and Drug Administration's Official Establishment Inventory," (CIN: A-15-01-20001). The attached document contains the Agency's comments and implementation plans for your consideration.

If you need additional information, please contact Loretta W. Davis, (301) 827-4809.

BA Schwetz

Bernard A. Schwetz, D.V.M., Ph.D.

Attachment

cc: Carol Lessans

Agency's Comments and Implementation Plans, "Office of Inspector General's Review of the Accuracy of the Food and Drug Administration's Official Establishment Inventory (OEI)," (CIN: A-15-01-20001) December 19, 2001

Comments:

The FDA agrees that an accurate OEI is an important tool. However, it is difficult to evaluate the significance of the audit without knowing the make up of the firms in the sample of 100. The audit appears to show that the OEI is far more accurate for statutory firms (devices, drugs, and biologics) than non-statutory firms (foods). This is most likely due to the fact that FDA currently lacks the statutory authority to require the registration of all food firms.

We do have concerns with the OIG's findings that state FDA's OEI is not accurate and could be reduced by sixteen percent, and that the error rate is higher than the goal FDA set for itself, which is accuracy within five percent. These findings mix data for statutory firms with non-statutory firms and apply the results to the whole OEI.

Based on the listing of the sixteen out-of-business firms in the sample, it seems clear that the highest error rate is for the listing of food establishments, which are currently not required to register with FDA. A projection that is largely influenced by the findings from the food/cosmetics industries should not be applied to the remainder of regulated industry, which is required to register with FDA.

Overall, FDA's error rate for medical product industries, which are required to register, is reasonable. OIG's data appears to show an error rate of about six percent (6%) for devices, drugs, and biologics as a whole (four devices, one drug, and one biologics firm found out of business). The OEI accuracy criteria appear, by the OIG's study, to be essentially met for those industries where biennial inspections are required. The OEI is sufficiently accurate for medical products to plan inspections and request resources.

The high inaccuracy rate found by OIG's sample for food firms is not as critical as it may seem. As the OIG recognizes, these firms do not have to register with FDA (with the exception of Low Acid Canned Food Process manufacturers). In the food industry, there are many small firms which start up, go out of business, and merge without informing the FDA. Many food firms are also seasonal. We do not disagree that there are firms in the inventory that are no longer in business and should be removed, but there is a good possibility that other firms are in business and not in the inventory. We believe, even with errors, the OEI is a good estimate of total workload. The OEI has never been 100% accurate. But, as an historical basis for estimates, we have been consistent in its use.

FDA suggests that the report include a statement that the OEI is sufficiently accurate for medical products to plan inspections and request resources to meet statutory requirements. In addition, we suggest that an attachment be included in the OIG report showing the number of firms reviewed by type of industry, whether the firm was required

to register, and the percent of firms which should or should not have been included in the OEI.

Implementation Plans:

Recommendation One: ***The importance of an accurate OEI and the need for its continuous review is communicated to all cognizant officials and staff.***

The Office of Regulatory Affairs held discussions on the importance of an accurate OEI and how to ensure obtaining and then maintaining this goal, at the Senior Staff Meeting held December 5-6, 2001. Also, a memo will be issued reminding the field offices that maintaining accurate information of the firms in the inventory is important.

Recommendation Two: ***The FDA district offices, under the direction of ORA headquarters, implement the periodic random sampling review procedures existing in FMD No. 130 to improve the accuracy of the OEI, and specifically to ensure that:***

(a) ***Establishments that are out of business and no longer subject to inspection are promptly removed from the OEI; and***

(b) ***Names, addresses, telephone numbers, and other information for establishments remaining in the OEI [are] correct.***

FDA will update existing procedures for OEI maintenance, strive to increase the accuracy of information on firms, and continue to remove out of business firms as resources permit. Toward this end, ORA has initiated an OEI Improvement pilot project in the Southeast Regional office with an external contractor to review the accuracy of its current inventory of selected firms in order to determine the utility of such a contract service.