

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Policy and Operational Planning</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>WI-000020</b></p>	<p style="text-align: center;"><b>Revision #: 05</b>  <b>Revised:</b>  03 May 2022</p>
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## 1. Purpose

Establishes instructions for conducting activities to gather information for developing and maintaining a uniform, accurate, and complete record of a firm in the Official Establishment Inventory (OEI), also referred to as the inventory.

In addition, it provides a process to verify the integrity of an establishment's data with Firm Management Services (FMS), and to support the procedures for managing the OEI, as described in [SOP 000051](#) "OEI Development and Maintenance Procedure".

## 2. Scope

Applies to ORA Domestic and Foreign inventory and is followed by users of FMS.

## 3. Responsibility

### A. OEI Coordinators

1. Follow this procedure to gather and identify information related to a firm
2. Maintain and update the firm record in FMS for information collected from a variety of sources

### B. Supervisors/State Liaisons

1. Review and update FMS firm information through the work activities of their subordinates/state partners, in-program monitoring, and during work planning

### C. Consumer Safety Officers (CSOs)/Consumer Safety Technicians (CSTs)/Consumer Safety Inspectors (CSIs)

1. Follow this procedure to gather and identify information related to a firm
2. Obtain accurate information regarding establishments during their work activities
3. Enter accurate information related to the firm through various computer systems (FMS, eNSpect, etc.)

### D. All Employees

1. Manage establishment information in accordance with this work instruction

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**NOTE:** All employees that can make changes to the FMS OEI information should follow this work instruction. Those employees that do not have the capability to make changes should contact the Program/Division OEI Coordinator for the related program area

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#### 4. Background

The Official Establishment Inventory (OEI) is a database of firms that engage in activities of interest to the Food and Drug Administration. The OEI information is stored in Firm Management Services (FMS). The data from FMS is used by other agency application systems which include Field Accomplishments and Compliance Tracking System (FACTS), eNSpect (Electronic Inspection system), Operational and Administrative System for Import Support (OASIS), Foreign Inspection Planning and Scheduling System (FIPSS), Electronic State Access to FACTS (eSAF), and Compliance Management Services (CMS). Center processes often include this information in their work planning risk models.

FACTS inspection module has been replaced by eNSpect, an ORA system that is currently used to document the results of certain ORA operations (inspections, investigations, remote regulatory assessments, etc.). eNSpect includes data fields which correlate to data fields in FMS. During or at the completion of an assigned operation in eNSpect, investigators should always update the data fields relating to firm information within eNSpect. Some of the information transfers to FMS within two hours of the systems synchronizing on-line. Other information transfers to FMS after the activity has been endorsed and the systems have synchronized.

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#### 5. References

- A. [CBER home page: Blood Establishment Registration \(BER\) Intranet Query link](#) (bottom left of page)
- B. [CBER: Blood Establishment Registration \(BER\) Intranet Query](#)
- C. [CBER home page: Human Cell and Tissue Establishment Registration \(HCTERS\)](#) (bottom left of page)
- D. [CBER: Human Cell and Tissue Establishment Registration System \(HCTERS\) Query](#)
- E. [CBER: Human Cell and Tissue Establishment Registration System \(HCTERS\) Query alternative](#)

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- F. [CDER home page: Drug Quality and Compliance Portal \(DQCPortal\)](#) (lower left of middle of page)
- G. [CDER: Electronic Drug Registration and Listing System \(eDRLS\)](#)
- H. [DUNSLink: Link to Dun & Bradstreet \(D&B\) business information \(top left of page\)](#)
- I. [FURLS: FDA Unified Registration and Listing System](#) (middle of page)
- J. [Investigations Operation Manual \(IOM\): Chapter 3 – Federal and State Cooperation](#)
- K. [United States Postal Service \(USPS\)](#)

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## 6. Procedure

The procedure provides information/directions on different data sources which may be used to collect information/data about establishments that should be used to update the firm record in FMS. Information in a firm’s record is used to determine if the establishment is under the jurisdiction of FDA and is a workload obligation as defined by [SOP 000051](#) “OEI Development and Maintenance Procedure”.

At Program Discretion, [Form 173](#) “Official Establishment Inventory (OEI) Data Collection Form” MAY be used by any ORA employee to collect and document information as the employee is collecting and reviewing firm information. This information shall be used to update the FMS record. The Program/Division should decide which employees should review all data for accuracy and perform the actual updates of the FMS record in a timely matter. The review should follow existing procedures and include:

- determination of operational status
- workload obligation
- establishment types
- industry codes
- percent wholesale

which are used to determine inspectional obligations for the program.

It is preferable that employees update firm information through the firm information screens accessed during their operations in eNSpect.

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At Program discretion, [Form 173](#) “Official Establishment Inventory (OEI) Data Collection Form” MAY be used instead of, or in conjunction with a memo, to capture information when an attempted inspection (OP12) washes out due to the firm being inactive, out of business or relocated. The FACTS/eNSpect OP12 assignment **should be** converted to a FACTS/eNSpect OP13 investigation assignment.

The Program should develop a process to maintain the forms once they are created.

**NOTE:** Fields on Form 173 are defined in SOP-000051 “OEI Development and Maintenance Procedure”, WI-000022 “Date Entry Fields in Firm Management Services (FMS)”, and WI-000024 “Establishment Types and Industry Code”.

Otherwise, notes for the below activities can be documented in any method which allows the firm record in FMS to be updated.

## 6.1. Overview of the Data Collection Process

- A. Using FMS, determine what is already known about an establishment and any potentially duplicate Firm Establishment Identifiers (FEI) associated with the establishment. The search options in [6.2](#) may be used independently or in combination to obtain potential duplicate FEIs.
- B. Collect data from multiple sources, documenting the results on [Form 173](#) “Official Establishment Inventory (OEI) Data Collection Form” or other alternative data collection method (e.g., e-mail, memo, Compliance Management System (CMS), etc.). Each FEI may be associated with a Registration number, DUNS number, and/or possible points of contact ([6.3-6.7](#)).
- C. Contact the establishment ([6.8](#)) if:
  1. This is their initial interaction with FDA or ORA,
  2. The information in FMS is not correct, and/or
  3. The information in FMS needs to be updated (for example changing an establishment’s workload obligation from “Bioterrorism” (“B”) or “Potential” (“P”) to “Yes” (“Y”) or “No (“N”)).
- D. If being used, complete and sign the [Form 173](#) “OEI Data Collection” Form electronically unless specifically directed otherwise.
- E. Forward the [Form 173](#) through the recommending official (supervisor, contracting official, state liaison, or other supervising authority) to the OEI Coordinator for data verification and approval.

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**NOTE:** ORA employees are responsible for updating establishment information in FMS through an operation in FACTS/eNSpect.

## 6.2. Firm Management Services (FMS) search

- A. Follow [WI-000021](#) "Searching in Firm Management Services (FMS)"
  1. Search by establishment name using "Basic Search" function:
  2. Use one or two unique key words of the establishment name
  3. Do not include punctuation or legal status and avoid using words that may be abbreviated or are common words, such as "company"
- B. Search by address:
  1. If searching by name in the "Basic Search" does not locate the establishment, search by address
  2. Use a unique part of the address, such as the building number or unique street name, in combination with the state
  3. Do not include punctuation and avoid using words that may be abbreviated or are common words, such as direction (North or N) or street designation (Place or Ave)
  4. Include the city to narrow the search.
- C. Sort the results in FMS by selecting the hyperlink at the top of the results table, such as "Firm Name," "Address Line 1" or "City.") See [WI-000021](#) "Searching in Firm Management Services (FMS)" for additional search information and determine if the establishment has multiple entries in FMS
- D. If multiple FEIs are identified, document the duplicate numbers in box 40 of [Form 173](#). The OEI coordinator or designee will merge as appropriate.
- E. If one of the multiple FEIs is identified as Workload Obligation "Yes" or Workload Obligation "No" (Operational Status OPR or SEA), complete the [Form 173](#) with all information known and route to the OEI Coordinator or designee for further evaluation.

Operational Status Code	Workload Obligation	Actions
OPR	Y, N	Document Establishment information and duplicate FEI(s) on the OEI Data

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		Collection Form and submit to OEI Coordinator
SEA	Y, N	Document Establishment information and duplicate FEI(s) on the OEI Data Collection Form and submit to OEI Coordinator
OPR	B, P	Continue with research described in <a href="#">6.3-6.8</a>
SEA	B, P	Continue with research described in <a href="#">6.3-6.8</a>
OAS	P, N	Continue with research described in <a href="#">6.3-6.8</a>
OOB	N	Continue with research described in <a href="#">6.3-6.8</a>
INA	Y	Continue with research described in <a href="#">6.3-6.8</a>
NOE	N	Continue with research described in <a href="#">6.3-6.8</a>

### 6.3. Registration search: Center databases

#### 6.3.1. Access to Center databases

- A. Request access to [FURLS](#) (Food Facility Registration (FFR), Acidified/Low-Acid Canned Foods Registration and Filing (AF/LACF), Shell Egg Producer Registration (SEPR), and/or Medical Device Registration and Listing Module (DRLM))) through Employee Resource and Information Center (ERIC).
- B. Request access to [eDRLS](#) (Human and Animal Drugs) through the “Request Access” on the Drug Quality & Compliance Portal ([DQCPortal](#)).
- C. Search the various Center registration databases to determine registration information and contact information for an establishment.
- D. Document the date of the most recent registration and the Official Correspondent/Reporting Official/Point of Contact information on the OEI Data Collection Form.

**Note:** Sometimes this information (contact and address) may be for the establishment’s agent or legal counsel.

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**6.3.2. CBER: Blood Establishment Registration (BER)**

- A. Location: [CBER home page: Blood Establishment Registration \(BER\) Intranet Query link on bottom left of page](#) or [Blood Establishment Registration \(BER\) Intranet Query](#)
- B. Registration Number: FEI
- C. Follow the links. System uses information typed in by the user. No additional instruction needed.

**6.3.3. CBER: Human Cell and Tissue Establishment (HCTERS)**

- A. Location: [CBER home page: Human Cell and Tissue Establishment Registration System \(HCTERS\) Query](#) or [Human Cell and Tissue Establishment Registration System \(HCTERS\) Query alternative](#)
- B. Registration Number: FEI
- C. Follow the links. System uses information typed in by the user. No additional instruction needed.

**6.3.4. CDER/CVM (Electronic Drug Registration & Listing System eDRLS)**

- A. Location: [CDER home page: Drug Quality and Compliance Portal \(DQCPortal\) lower left of middle of page](#) or [ORA Applications: DRLS: eDRLS](#)
- B. Registration Number: FEI and DUNS
- C. See [SOP 353](#) "ORA Establishment Registration and Control Procedures" and [WI-000214](#) "ORA Management of Human and Animal Drug Registrations in Firm Management Services (FMS)" for search assistance. No additional instruction needed.

**6.3.5. CDRH: FURLS (FDA Unified Registration and Listing System)**

- A. Location: [FURLS home page](#) (Online Account Administration - for FDA): CDRH: Device Registration and Listing Module (DRLM)
- B. Registration Number: Original FEI assigned when firm first registered with CDRH. May be the current FEI or a previous FEI (due to merging)  
**NOTE:** CDRH/DRLM captures both the registration number (which never changes) and the FEI (which may change due to a merge by ORA)
- C. Search Registration and Listing (R&L) information. System uses information typed in by user. No additional instruction needed.



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### 6.3.6. CFSAN: FURLS

- A. Location: [FURLS home page](#) CFSAN: Food Facility Registration Module (FFRM)
- B. Registration Number: FFR
  1. If an FFR is associated with an FEI, the FFR will be observed in the “Registration” section of the FMS record
- C. Search FURLS/FFRM
  1. “Search Facility Registrations” radio button:
    - a. Use this search for all registrations including current, invalid, and cancelled registrations
    - b. Select the “Search Registration by Facility Information”, and then specify the facility location for the search by selecting from the drop-down menu
    - c. Check the “Include Cancelled Registrations” and “Include Invalid-Failed to Renew Registrations” boxes to include cancelled and invalid registrations in the search results
  2. The FFR can be found in FMS:
    - a. “Registration” section on the “Firm Details” page
    - b. “Registrations” link on the top right of the “Firm Details” page
  3. If the establishment has multiple FEI’s in FMS with registration numbers, use one to two unique key words of the establishment name in combination with the state or by a unique part of the establishment’s address in combination with the state
  4. Search Incomplete Registration: Use this search to determine if the establishment has an incomplete registration in draft status, which has not been officially submitted to the agency
  5. Search Failed to Renew Registration: Use this search if the establishment failed to renew their registration within the current renewal timeframes

### 6.4. DUNS search

#### 6.4.1. General Information

- A. Dunn & Bradstreet (D&B) is a privately owned company which assigns a free, unique nine-digit number for each physical location of a business

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- B. A DUNS number may provide confirmation of the establishment status, either Active or Inactive and may indicate the establishment has moved. DUNS may provide additional information about an establishment
- C. There may be multiple DUNS numbers for one FEI, as DUNS numbers are assigned to a specific building or department, where FEI numbers are assigned to a business entity, which may contain a campus of several buildings. Each time an establishment moves locations, it may be assigned a new DUNS number. A recent change with DUNS allows the DUNS number to move with the firm at the firm's request
- D. DUNS may be accessed: [FDA DUNSLink](#)
- E. If a DUNS number is not available, FDA DUNSLink can still be searched using the firm's name and address

#### **6.4.2. Search Options**

- A. By DUNS Number - The DUNS number is found in FMS on the "Firm Details" page for the specific FEI in the DUNS Information section.
- B. Search by business name and business address.
- C. Search Tips: When searching by business name and business address, use a combination of one or two unique key words of the establishment name (required) and the state. Use a unique part of the address to narrow the search.

#### **6.5. United States Postal Service (USPS)**

- A. If an establishment is not at the identified location, it is possible the establishment has moved to a new location. Visiting the USPS and submitting the appropriate documented request may allow identification of the new location of the establishment.
- B. Identify the local United States Post Office which services the identified location using USPS "Locations"
- C. Follow [IOM](#) 3.2.15.1- Change of Address Information
- D. Complete the "Address Information Request" form ([IOM](#) Chapter 3: Exhibit 3-3)
- E. Go to the local Post Office and present the "Address Information Request" form and appropriate identification to the Postal Clerk or Postmaster
- F. It is preferred that the "Address Information Request" form is completed while present, but the "Address Information Request" form may be mailed back

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G. Per [IOM](#) 3.2.15.3, the authority for providing forwarding address information to government agencies is defined in 39 CFR 265.6(d)(5)(i). Additionally, 39 CFR 265.6(d)(7) may apply for address verification

**6.6. Secretary of State, State Licensing and/or State Department of Revenue website Search**

- A. Provides status of establishment, current Business License status and may provide an updated address. Be cautious with the addresses listed on these sites as occasionally the addresses are for the establishment representative/agent/legal counsel and not the actual facility/plant.
- B. State databases may also provide information on registered trade names that can be used to search in FMS or the Center registration databases. Some establishments register under their “Doing business as” (DBA), alternative name, or assumed business name instead of legal name.
- C. Internal [Official Establishment Inventory \(OEI\)](#) website has potential links to the state sites under “State Government Sites for Reference”
- D. Search Tips: When searching by business name and/or business address, query using one or two unique key words of the establishment name only. Add a unique part of the address and/or city to narrow the search.

**6.7. Internet searches for company**

- A. Search engine: Provides additional verification of the establishment’s status from one or more of the below resources. (Search Tips: search using one or two unique key words of the establishment name or a combination of business name and state. Add a unique part of the address and/or city to narrow the search.) Consider searching for the following:
  1. Establishment website
  2. Industry group web sites the establishment may belong to, such as AFDO, WAFDO, Seafood Processors Association, etc.
  3. Phone number and or Address from phone directories
  4. Establishment reviews
  5. Newspaper articles related to the establishment
  6. Facebook or other social media
  7. Other source not listed

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- B. Internet Map: Search for the address(s) found during research using an Internet mapping website, such as Google Maps or MapQuest. The street view and/or satellite view may provide additional verification of the establishment status.

## 6.8. Contacting the establishment

### 6.8.1. Prior to contracting the establishment

- A. Determine the following information from FMS or other sources: legal name, FEI number, address, city, state, county, telephone number and point of contact
- B. Review, if available, the establishment type and industry codes
- C. If the requirements of [section 6.1\(C\)](#) are met, contact the establishment

### 6.8.2. Contacting the establishment

- A. Initially, contact the establishment, or establishment representative (for example the U.S. Agent for foreign firms) by using the suggested scripts for telephone or e-mail ([Attachment A](#)).
- B. If the establishment questions the source of the inquiry and/or is reluctant to provide information prior to verification, offer to have them contact/call back the Division Office or provide them an FDA e-mail address. Contact an SCSO prior to proceeding.
- C. The FDA employee or designee collects the information as requested on [Form 173](#) or other data collection method and documents the results.
- D. Out of Business (OOB): If information suggests that the establishment might be out of business:
  - 1. Attempt to verify if the firm is out of business or has relocated following steps [6.2- 6.7](#)
  - 2. Contact Divisional Management to determine if a verification should be made to confirm the potential OOB status
  - 3. The DUNS National Change of Address system may be used in lieu of visiting the local post office ([6.4](#))
- E. After concluding contact with the establishment, determine:
  - 1. The operational status of the firm per [SOP-000051](#) "OEI Development and Maintenance Procedure"

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2. The workload obligation of the firm per [SOP-000051](#) “OEI Development and Maintenance Procedure” and [WI-000024](#) “Establishment Types and Industry Codes”
3. Establishment type(s) for the establishment Industry code(s) as described in [WI-000024](#) “Establishment Types and Industry Codes”
4. If the establishment is required to be registered, as well as whether the information in FMS reflect proper and current registration designation(s) for all commodities (biologics, drugs, food, medical devices, etc.).
5. If any of the information is not available, contact a Supervisor/Contracting Official for possible follow-up action.

#### **6.9. Update the firm record**

- A. An FDA employee should update the establishment information in FMS directly or through eNSpect when conducting an operation.
- B. [Form 173](#) or any other alternative documentation of the above procedures may be sent to the Division OEI Coordinator if the employee cannot update the name, workload obligation, or registration, or if merges of FEIs need to be conducted.
- C. If applicable (e.g., CSO, CSI, CST), capture time under OP92 or OP13, using the OEI Improvement PAC
  1. 03R876: Foods, CFSAN
  2. 42R876: Biologics, CBER
  3. 56R876: Pharmaceutical, CDER
  4. 71R876: Animal products, CVM
  5. 82R876: Medical Devices, CDRH
  6. 86R876: Radiological Health, CDRH
  7. 96R876: Tobacco, CTP
  8. 99R876: General
- D. Contact OEI coordinators with any questions regarding, [SOP-000051](#), “OEI Development and Maintenance Procedure”.

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## **7. Glossary/Definitions**

- A. **eNSpect**: a computer application that provides the Mission Accomplishment and Regulatory Compliance Services (MARCS)
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functionality for supervisors to create inspection assignments and assign them to investigators, who then complete the inspections and submit the results and documents back to supervisors. Inspections are then reviewed and endorsed by supervisors. Additionally, the application allows for use of intelligent questionnaires to produce analyzable data from inspection reports.

- B. **FACTS: Field Accomplishments and Compliance Tracking System:** Client/Server Oracle application which is integrated with many other data systems within FDA and ORA.
- C. **FEI: Firm Establishment Identifier or FDA Establishment Identifier:** Firm Management Services (FMS) automatically generates a 10-digit FEI number under the firm build screen when a new firm is added. Firms previously in FIS retained their original 7-digit CFN which, in most cases, also became their FEI number. The historical CFN may be viewed under the cross-reference viewing screen in FMS.
- D. **FMS: Firm Management Services:** An ORA computer application which is used to manage and maintain firm related data such as Establishment Types, Industry Codes, Operational Status, Workload Obligation, Registration Information, etc.
- E. **IOM: Investigations Operations Manual:** Primary operational reference for FDA employees who perform field investigational activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations. Other FDA manuals and field instructions supplement, but do not supersede, the information in the IOM.
- F. **OEI: Official Establishment Inventory:** Includes information about establishments which have been encountered while conducting FDA operations. These include establishments determined to be under regulation by FDA, as well as establishments that have been determined not to be under regulation by FDA. The electronic records are stored in the FMS module in the FACTS database.

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## 8. Records

No records created from this procedure.

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## 9. Supporting Documents

- A. [Establishment Types and Industry Code](#) (WI-000024)
- B. [OEI Development Maintenance Procedure](#) (SOP-000051)
- C. [Official Establishment Inventory \(OEI\) Data Collection](#) (Form 173)
- D. [ORA Establishment Registration and Control Procedure](#) (SOP 353 [formerly FMD 92])
- E. [ORA Management of Human and Animal Drug Registrations in Firm Management Services](#) (FMS) (WI-000214)
- F. [Searching in Firm Management Services \(FMS\)](#) (WI-000021)

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## 10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	10/30/2016	LORI S. LAWLESS, NATIONAL OEI COORDINATOR	SARAH PICHETTE, WORK PLANNING BRANCH CHIEF
2.0	R	12/12/17	LORI S. LAWLESS, NATIONAL OEI COORDINATOR	JESSICA HOPSON, WORK PLANNING BRANCH CHIEF
03	R	05/02/2022	LORI S. LAWLESS, NATIONAL OEI COORDINATOR	MARK ABDY DIRECTOR, DIVISION OF PLANNING AND EVALUATION

\* - D: Draft, I: Initial, R: Revision

## 11. Change History

Revision #	Change
1.0	INITIAL
2.0	1. DOCUMENT NUMBER CHANGED DUE TO OFFICE CHANGES DURING ORA PROGRAM ALIGNMENT. (OLD NUMBER OPRM-DPEM-WI.001) 2. DOCUMENT PUT INTO NEW QMIS WORK INSTRUCTION TEMPLATE QMS-TMPL.055
03	MINOR CHANGES THROUGHOUT THE ENTIRE DOCUMENT TO PROVIDE CLARIFICATION OF LANGUAGE, TO IMPROVE GRAMMAR, AND PROVIDE CLARITY. TEMPLATE UPDATED TO THE LATEST VERSION.

## 12. Attachments

### List of Attachments

Attachment A - Example of a Telephone Script..... 16

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### **Attachment A - Example of a Telephone Script**

Suggested general Telephone template.

This can be adapted with additional information for specific programs.

My name is XXX. I am the OEI Coordinator for xxx Division of the Food and Drug Administration. We are updating some information regarding your registration with the Food and Drug Administration. The purpose of this inquiry is to update our files and I need to ask a few questions to confirm the information we have on file for your facility.

Location at xxxx, city, state, country (if international firm).

1. If you have moved from another location, what was the previous address?
2. Legal name and any doing business as (DBA)/alias of your business?
3. Current contact names, phone numbers, and e-mail addresses?
4. What is the percent wholesale sold by your firm (finished products sold to business customers as opposed to directly to the end consumer)?
5. What is the percent of your finished product that you place into interstate commerce? If none, what percent of incoming components or ingredients do you receive from across state lines?
6. Describe the activities conducted at xxx address (warehouse, manufacturer, repacker, labeler, etc) as well as which products.