

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 1 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

Sections in This Document

1. Purpose	1
2. References	2
3. Procedure	2
3.1. Overview of the Data Collection Process.....	2
3.2. MARCS Firm Management Services (FMS) search.....	3
3.3. Registration search: Center databases.....	4
3.3.1.CBER: Blood Establishment Registration (BER).....	5
3.3.2. CBER: Human Cell and Tissue Establishment (HCTERS).....	5
3.3.4. CDRH: FURLS (FDA Unified Registration and Listing System)	5
3.3.5. CFSAN: FURLS.....	5
3.4. DUNS search	6
3.5. United States Postal Service (USPS)	7
3.6. Secretary of State, State Licensing and/or State Department of Revenue website Search	8
3.7. Internet searches for company	8
3.8. Contacting the establishment	9
3.8.1. Prior to contracting the establishment.....	9
3.8.2. Contacting the establishment.....	9
3.9. Record Keeping and Communications	10
4. Records	11
5. Document History	11
6. Change History	11
7. Attachments.....	12
Attachment A – Official Establishment OEI Data Collection Form	Error! Bookmark not defined.

1. Purpose

This document provides instructions for conducting searches to gather information for developing and maintaining a uniform, accurate, and complete Official Establishment Inventory (OEI), primarily for establishments in Workload Obligation “B” or “P” status. In addition, it provides a process to verify the integrity of an establishment’s data with Firm Management Services (FMS), to support the procedures for managing the OEI, as described in SOP.000051 SOP 130 “OEI Development and Maintenance Procedure”.

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 2 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

This procedure applies to domestic inventory and is followed by ALL ORA district offices, the Office of Food and Feed Operations (OFFO)/Division of Food and Feed Program Operations and Inspections (DFFPOI), and the Office of Medical Products and Tobacco Operations (OMPTO)/Division of Medical Products and Tobacco Program Operations (DMPTPO) in maintaining data within FMS.

2. References

- A. SOP.000051, SOP 130 OEI Development and Maintenance Procedure

3. Procedure

The following sections provide information on different data sources which may be used to collect information and data about establishments to update the OEI. This information is used to make a determination as to whether the establishment is under the jurisdiction of FDA and is a workload obligation as defined by SOP.000051, SOP 130 "OEI Development and Maintenance Procedure".

At District Discretion, the 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.eINspect OP12 assignment can be converted to a FACTS/eINspect OP 13 investigation assignment.

3.1. Overview of the Data Collection Process

- A. Determine what is already known about an establishment and any Firm Establishment Identifiers (FEI) associated with the establishment starting with FMS. The search options in step 6.2 may be used independently or in combination to obtain the FEIs.
- B. Collect data from multiple sources, documenting the results on the OEI Data Collection Form. Each FEI may be associated with a Registration number, DUNS number, and/or possible points of contact (steps 6.3-6.7).
- C. Contact the establishment if:
 - This is their initial interaction with FDA or ORA;
 - The information in FMS is not correct or;

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 3 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

- The information in FMS needs to be updated (for example changing an establishment's status from "B" or "P" to "Y" or "N").

- D. Complete and sign the OEI Data Collection Form electronically unless specifically directed otherwise.
- E. Forward the OEI Data Collection Form through the recommending official (supervisor, contracting official, state liaison, or other supervising authority) to the OEI Coordinator for data verification and approval, after research described in 6.2 through 6.8 of this procedure has been completed.
- F. NOTE: FDA employees are responsible for updating establishment information in FMS through an inspection (OP12) or investigation (OP13) activity in FACTS/eINSpect.

3.2. MARCS Firm Management Services (FMS) search

- A. Search by establishment name using "Basic Search" function: Use one or two unique key words of the establishment name. 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: If searching by name in the "Basic Search" does not locate the establishment, search by address. Use a unique part of the address, such as the building number or unique street name, in combination with the state. 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). Include the city to narrow the search.
- C. Sort the results in FMS by clicking the hyperlink at the top of the results table, such as "Firm Name," "Address Line 1" or "City.") See Work Instruction (WI) "Search Field Management Services (FMS)" for additional search information and determine if the establishment has multiple entries in FMS.
 1. If multiple FEIs are identified, document this information in Box 41 of the OEI Data Collection Form. The OEI Coordinator or designee will merge as appropriate.
 2. If one of the multiple FEIs is identified as Workload Obligation "Yes" or Workload Obligation "No" (Operational Status OPR, SEA), complete the OEI Data Collection Form with all information

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 4 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

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 Collection Form 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 steps 6.3-6.8
SEA	B, P	Continue with research described in steps 6.3-6.8
OAS	P, N	Continue with research described in steps 6.3-6.8
OOB	N	Continue with research described in steps 6.3-6.8
INA	Y, N	Continue with research described in steps 6.3-6.8
NOE	N	Continue with research described in steps 6.3-6.8

3.3. Registration search: Center databases

- A. Request access to FURLS (Food, Tobacco, Devices) 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.
- 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 on the OEI Data Collection Form. Note: sometimes this information (contact and address) may be for the establishment’s agent or legal counsel.

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 5 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

3.3.1. CBER: Blood Establishment Registration (BER)

- A. Location: CBER home page: Blood Establishment Registration (BER) Intranet Query link on right hand side 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.

3.3.2. CBER: Human Cell and Tissue Establishment (HCTERS)

- A. Location: CBER home page: Human Cell and Tissue Establishment Registration (HCTERS) Query link on right hand side of page or Human Cell and Tissue Establishment Registration System (HCTERS) Query
- B. Registration Number: FEI
- C. Follow the links. System uses information typed in by the user. No additional instruction needed.

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

- A. Location: CDER home page: Drug Quality and Compliance Portal lower center of page
- B. Registration Number: FEI and DUNS
- C. See FMD 92 and associated work instructions for search assistance. No additional instruction needed.

3.3.4. 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: FEI
- C. Search Registration and Listing information. System uses information typed in by user. No additional instruction needed.

3.3.5. CFSAN: FURLS

- A. Location: Location: FURLS home page (Online Account Administration - for FDA) : CFSAN: Food Facility Registration (FFRM)
- B. Registration Number: FFR
- C. Search FURLS/FFRM.

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 6 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

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” radio button, and then specify the facility location for the search by selecting one of the radio buttons.
 - c. Check the “Include Cancelled Registrations” and “Include Invalid-Failed to Renew Registrations” radio buttons to include cancelled and invalid registrations in the search results.
2. If an FFR is associated with an FEI in FMS, there will be a date in the “Last Firm Registration Date” column of the FMS search results page.
3. Find the FFR number in FMS on the “Firm Details” page for the specific FEI in the “Cross References” and “Registration” sections.
4. The FFR status is displayed in FMS in the “Registration” section.
5. 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.
6. 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.
7. Search Failed to Renew Registration: Use this search if the establishment failed to renew their registration within the current renewal timeframes.

3.4. DUNS search

3.4.1. 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.
- 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, where FEI numbers are assigned to a business entity, which may contain a campus of several buildings.

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 7 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

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
 - 1. Using the link in FMS
 - 2. FDA DUNS Link through inside FDA
 - 3. FDA Duns Link: direct link
- E. If you don't have the DUNS number you can still search for the firm in FDA DUNSLink using the firm's name and full address.

3.4.2. 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.
- D. Using the FEI in the "Optimizer Search" may provide a United States Postal Service (USPS) National Change of Address Information (NCOA) for certain establishments.

3.5. 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](#).
- C. Complete the "Address Information Request" form (Exhibit 3-3 of the Investigation Operations Manual).
- D. Go to the local Post Office and present the "Address Information Request" and appropriate identification to the Postal Clerk or Postmaster.
- E. It is preferred that the "Address Information Request" form is completed while present, but the "Address Information Request" form may be mailed back.

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 8 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

- F. 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 (IOM 3.2.15.3).

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

- A. Provides current 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. 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.

3.7. 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
- B. Internet Map: Search for the address(s) found during research using an Internet mapping website, such as Google Maps or MapQuest.

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 9 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

The street view and/or satellite view may provide additional verification of the establishment status.

3.8. Contacting the establishment

3.8.1. 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(3) are met, contact the establishment.

3.8.2. Contacting the establishment

- A. Initially, contact the establishment by phone or e-mail. Identify yourself as an employee from the U.S. Food and Drug Administration. "I am an FDA employee (or contractor) from the _____ District Office. 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".
- 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 to the District Office or provide them with an e-mail address. Contact the SCSO prior to proceeding.
- C. The FDA employee or contractor collects the information as requested on the OEI Data Collection Form 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. If possible, visit the establishment's last known location, and/or the local post office, to verify.
 3. The DUNS National Change of Address system may be used in lieu of visiting the local post office (See 6.4.2 (D)). For some firms, the DUNS system electronically pulls information from the USPS national change of address information database.

3.8.2. After concluding contact with the establishment

- A. Determine:
 1. If the establishment is a workload obligation per SOP.000051, SOP 130 "OEI Development and Maintenance Procedure"

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 10 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

2. Establishment type(s) for the establishment
 3. Industry code(s) for the establishment
 4. Workload obligation: Workload obligation “Yes”, Not a workload obligation “No”) per SOP.000051, SOP 130 “OEI Development and Maintenance Procedure”
 5. Operational Status: Operational (OPR), Seasonal (SEA), Inactive (INA) Out of Business (OOB) or Not-OEI Establishments (NOE) per SOP.000051, SOP 130 “OEI Development and Maintenance Procedure”
 6. If the establishment is required to be registered, does the information in FMS reflect proper and current registration designation(s) for all commodities (Biologics, drugs, food, devices, etc.)
- B. If any of the information is not available, contact a Supervisor/Contracting Official for possible follow-up action.
- C. An FDA employee has the ability to update the establishment information in FMS through an inspection or an investigation. Establishment information gathered through an inspection may be updated through eNSpect.

3.9. Record Keeping and Communications

- A. Recommending Official forwards the completed OEI Data Collection Form to the District OEI coordinator. The District OEI coordinator updates FMS independent of an investigation or an inspection.
- B. The district decides where to store the forms (in the physical establishment jackets, in the district’s electronic file, or the OEI coordinator’s file).
- C. Select the appropriate Program Risk identifier for data analysis. (XX indicates the Fiscal Year of the project and is designated in the Program Risk Identifier in FMS). Risk identifiers provide information for data analysis.
 1. OCXX FYXX OEI CFSAN B Firm Clean up: to be used when a CFSAN contractor performs the research on the establishment
 2. OSXX FYXX OEI State B Firm Clean up: to be used when a State contractor performs the research on the establishment
 3. OOXX FYXX OEI Coordinator B Firm Clean up: to be used when the OEI Coordinator/OEI Contractor performs the research on the establishment

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 11 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

- D. If applicable (e.g. CSO, CSI, CST), capture time under OP 92 or OP 13, 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
- E. Contact OEI coordinators with any questions regarding, SOP.000051, SOP 130 "OEI Development and Maintenance Procedure".
- F. Direct procedural questions to Management or Contracting Officials.

4. Records

- A. FORM-000173 Official Establishment Inventory (OEI) Data collection Form (Attachment A)

5. Document History

Version #	Status* (D,I, R, C)	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
3.0	R	4/20/18	MAREN FORSYTH, ACTING OSPOP QSM	JESSICA HOPSON, WORK PLANNING BRANCH CHIEF

* - D: Draft, I: Initial, R: Revision, C: Cancel

6. Change History

Version	Change

ORA-WIDE Work Instruction Food and Drug Administration Office of Regulatory Affairs	Document #: WI.000020 Revision 3	Page 12 of 12
Title: Official Establishment Inventory (OEI) Data Collection		

Version	Change
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
3.0	1. RECORDS SECTION: ADDED IN FORM IDENTIFICATION "FORM-000173" TO OEI DATA COLLECTION FORM 2. ATTACHMENT A: ADDED IN FORM IDENTIFICATION "FORM-000173" TO OEI DATA COLLECTION FORM AND UPDATED THE HYPERLINK

7. Attachments

List of Attachments

[Attachment A](#)- FORM-000173 Official Establishment Inventory (OEI) Data Collection Form