Sections in This Document

1. Purpose

This procedure provides instructions for entering data and maintaining the Official Establishment Inventory (OEI) maintained in Firm Management Services (FMS). It summarizes ORA Field and ORA Headquarters responsibilities to ensure information in the OEI is uniform, accurate, complete and current.

The Food and Drug Administration (FDA) depends on the accuracy, completeness, and uniformity of the OEI data. FDA uses the information from the OEI to provide Congress, other government agencies, and the public with the type and number of regulated establishments. The data from the OEI is also utilized for budget purposes to justify resources received and to request additional resources to accomplish FDA's obligations under the Federal Food, Drug and Cosmetic (FD&C) Act and other related Acts. The Office of Partnerships and Operational Policy/Office of Strategic Planning and Operational Policy/Division of Planning and Evaluation (OPOP/OSPOP/DPE) as well as the Centers, use the information in the OEI to allocate resources for the annual ORA work plans, often using a risk-based model. These obligations assist in determining each ORA Division's staffing and are used by the field to plan their inspections or other regulatory activities. Scope

Comments or proposed changes are solicited from all employees of FDA on a periodic basis.

2. Scope

This standard operating procedure applies to all FDA personnel engaged in the OEI process.

3. Responsibility

This procedure should be followed by all FDA employees modifying data within FMS, including FDA contractors and partners.

A. Office or Regulatory Affairs (ORA)

1. ORA – All Employees:

a. Responsible for following the procedures outlined in this document for modifying data within FMS.

NOTE: An employee that holds the position of OEI Coordinator may work for either a District or a Program/Division and may function in either the domestic or foreign inventory.

B. ORA Program Offices (OHAFO, OPQO, OBPO, OBIMO, OMDRHO, and OEIO):

1. Maintain accuracy and completeness of the OEI in the firms' physical and electronic files within their assigned area of responsibility (domestic and foreign)

2. Appoint an OEI coordinator/contact person knowledgeable of OEI/FMS. This person serves as the liaison to DPE on national OEI projects. The OEI Coordinator's contact information should be provided to DPE at ORAOEI@fda.hhs.gov and the IOM editorial staff at IOM@FDA.HHS.GOV. For firms within the area of their responsibility, the OEI Coordinator will:
    a. Maintain the accuracy and completeness of the OEI
    b. Identify and verify prospective new establishments to determine Operational Status and Workload Obligation for firms in the OEI
    c. Input initial firm data using established reference systems
    d. Merge duplicate firms in FMS using FIDA
    e. Update/cancel registration status of a firm in FMS and notify the Centers as described in FMD 92 "Agency Establishment Registration and Control Procedures"
    f. Verify and correct data in FMS identified during work activities
3. Using established procedures, ensure FDA investigators, and state inspectors (and all others entering data into the OEI) verify and correct firm data identified during work activities (including through eNSpect) Office of Strategic Planning and Operational Policy (OSPOP)

C. The National OEI Coordinator
    a. Direct oversight over the OEI (including, but not limited to procedures, quality data analysis, computer systems, support, etc.)
    b. Maintains a list of District/Division OEI Coordinators
    c. Manages:
        i. OEI website
        ii. The dedicated OEI mailbox: ORA OEI: ORAOEI@fda.hhs.gov
        iii. Hosts regular OEI meetings used to communicate information and activities related to maintaining the OEI
    d. Performs data analysis of information in the OEI to provide information to ORA for continuous improvement
    e. One of the business owners of Firm Management Services (FMS) and FDA Inventory of Data Assets (FIDA)

i. Business liaison with FMS and FIDA (and other systems as requested)
ii. Suggests and develops User Interface (UI) improvements
iii. Identifies data discrepancies and provides oversight to fixing the data and preventing reoccurrence

f. Determines the criteria for including establishments in the OEI
g. Collaborates with other offices to develop policies, procedures, and definitions
h. Liaison between ORA and the Centers

D. Office of Information Systems Management /Division of System Solutions (OISM/DSS):
   1. Import Systems Branch (ISB)
      a. Business owner for Field Accomplishments and Compliance Tracking System (FACTS) and Operational and Administrative System for Import Support (OASIS)
      b. Merge duplicate firms as needed in FMS using FDA Inventory of Data Assets (FIDA)
   2. Enforcement Systems Branch (ESB)
      a. Communicates information and issues related to firm records between ORA and Centers.

E. Office of the Commissioner (OC)/Office of Operations (OO)
   1. Office of Information Management and Technology (OIMT), Office of Information Management (OIM), Office of Technology and Delivery (OTD), Division of Application Services (DAS)
      a. Furnishes technical assistance and systems analysis support to ORA regarding data processing problems or needs and instructions for data entry and access.
   2. Office of International Programs (OIP)/foreign posts/employees that work with firm data in FMS
      a. Verify and correct firm data in FMS identified through other IT systems such as eNSpect
      b. Communicate information identifying duplicate firms to Foreign OEI Coordinators

4. Background

In 1961, ORA issued instructions to ORA field staff on how to assign Central File Numbers (CFNs) to establishments as they were inspected. Those instructions were the beginning of the OEI. Since then, there have been changes, that have required revisions to the instructions, assignments and definitions of CFNs. Major milestones in the development of the current OEI are captured in Appendix A.

5. References

A. ORA Production Applications: ORADSS link home page: ORADSS Help available if user has an ORADSS account

B. ORA Production Applications: FACTS link home page: FACTS and FMS Help available if user has a FACTS account

C. FMD 92 Registration and Control Procedures "Agency Establishment Registration and Control Procedures"

D. Investigations Operations Manual (IOM)

6. Procedure

There may be unique situations that are not addressed in this document that should be discussed with the National OEI Coordinator for resolution.

6.1. Database Design and User Roles

Note: When entering establishments in the OEI, document the decision-making process within the Establishment File (paper or electronic) and the Comments section in FMS.

For specific directions on coding establishments as a Workload Obligation, see Establishment Types/Industry Codes: Definitions, workload obligations (WI.000024).

6.1.1. Establishment Data

A. Establishment data in the OEI is stored in a series of tables in a relational database within the "Firms' module" in FMS (previously known as the "Firms' Database"). Knowledge of the inter-relationship of data tables within the firm's system, columns with tables, and the lists of values associated with columns are essential for querying multiple

records using SQL or Business Objects. See ORA Reporting Analysis and Decision Support System (ORADSS) help folders/data dictionary in ORADSS for inter-relationship and table information.

To ensure consistency and maintain data integrity, specific user roles are assigned in Field Accomplishments and Compliance Tracking System (FACTS). Unique capabilities for each of these roles include:

Role in FACTS	Held By	Unique Capabilities	Comments
DO_OEI_COOR	Held by, at minimum, the National OEI Coordinator, and ORA OEI Coordinators. At Management discretion and training, others may be granted this role within FACTS.	Update Firm Legal Name through FMS Set firm Workload Obligation indicator to Yes Add/Update District Use Codes (DUC)	
OEI Coordinator in FDA Inventory of Data Assets (FIDA)	Held by, at minimum the National OEI Coordinator, ORA OEI Coordinators, and their back ups	Merge and unmerge firms	
DO_REG_MNTR	Held by, at minimum, the National OEI Coordinator, ORA OEI Coordinators, and Program Registration Monitors	Enter Registration Data Update Registration Data Record Re-Registration Inactivate/Cancel/Flag for Cancellation Registration Add/Update District Use Codes (DUC)	(See FMD 92 for additional information)

6.1.2. Firm Data Entry and Review

A. Data enters FMS through:

a. Automated computer systems such as OASIS/ Automated Commercial Environment (ACE) and FDA Unified Registration and Listing System (FURLS)

b. Direct entry by ORA/authorized FDA personnel

c. Electronic State Access to FACTS (eSAF): information entered by state staff

d. eNSpect: Consumer Safety Officers (CSOs) can update firm information through their inspections and investigations in eNSpect. The information will transfer to FMS when the CSO is on-line and synchs.

B. New establishments to be manually added to the inventory may be identified through:

a. Surveillance by ORA/contracted personnel: observation while traveling, advertisements, inspections, state government directories, newspaper financial pages, trade publications, or allegations of regulatory misconduct (previously known as trade complaints)

b. Newly registered establishments (identified through Center registration systems such as the electronic drug registration and listing system (eDRLS), device registration and listing module (DRLM), or through other communication with the Centers).

Note: New establishments registering through FURLS/Food Facility Registration Module (FFRM) and Shell Egg Producer Registration (SEP) which don't match to an existing firm in FMS will automatically be assigned an FEI in FMS and have an operational status of "B" (FFRM) or "P" (SEP) in FMS.

c. Domestic or foreign sample collected (and documented in FACTS) which was ultimately found to be from an establishment that was not in the OEI (no assigned FEI)

d. Referral by state, county, country, other agency, or other FDA office

e. Incoming product applications (e.g., PMAs, 510(k)s, NDAs, ANDAs, etc.) to the Centers. Centers may contact ORA OEI Coordinators or Program Monitors for assistance in identifying or adding these firms into FMS

f. Special assignments and surveys which require the inspection of establishments not regularly maintained as Workload Obligations in the OEI file.

g. Other sources not specifically listed.

C. ORA OEI Coordinators/designees/contractors verify new establishments through telephone calls, e-mail, visits, information obtained from local or state agencies, FDA Foreign Offices, or any other appropriate means selected by a Program Area. The following work instructions provide more specific directions:

a. "Official Establishment Inventory (OEI) Data Collection": Instructions for conducting searches to gathering information" (WI.000020)

b. "Search Firm Management Services (FMS)": instructions on searching for establishments in FMS (WI.000021)

c. "Data Entry Fields in Firm Management Services": descriptions of the data fields in FMS (WI.000022)

D. General information

a. In the event a duplicate establishment is entered and identified in FMS, the OEI Coordinator will merge the duplicate establishments using FIDA.

b. A decision to change establishment information (i.e. workload obligation, operational status, etc.) may be documented in the comment field in FMS. ORA Management may also choose to document these decisions (or provide more details) in the factory file jacket or other Program files (including electronic files). Documentation should include at a minimum: date of decision to include the establishment, method and source of information leading to the inclusion, a list of the establishment types and associated industry codes for the establishment, and the name of the employee making the decision. A Form FDA 457, Product/Establishment Surveillance Report, or the form "Official Establishment Inventory (OEI) Data Collection" (FORM-000173) listed, or other Program form, memo, or checklist may be used.

c. CSOs, Consumer Safety Inspectors (CSIs), or others documenting regulated activities in FACTS/FMS or eNSpect are responsible for reviewing, verifying, filling in incomplete or missing information, and updating **ALL** establishment information through the work activities (e.g. inspections, investigations,

sample collections, etc.) in FACTS/FMS via the “FIRMS” button on the toolbar or through Firm Overview” and “Firm Additional Detail” screens in eNSpect.

d. Supervisors should review firm's data within the firm’s maintenance screen in FMS during routine review/endorsement of inspections, sample collections and other work activities of FDA employees.

   OR

e. Supervisors should review firm's data within the “Firm Overview” and “Firm Additional Detail” screens in eNSpect during routine review/endorsement of inspections and other work activities of FDA employees (though not all information in FMS is automatically updated through eNSpect (registration, BSE), and may need to be manually updated directly in FMS).

f. Supervisors should bring any visible inaccuracies or inconsistencies to the attention of the employee who conducted the operation for verification/correction of the data. At the time of endorsement, the Supervisor or other reviewer also has the capability to go directly to FMS to update information directly in FMS or update the information in eNSpect. The information to be verified, **at minimum** (this information is used in many of the risk models by the Centers), includes:

   i. Establishment Name
   ii. Physical and Mailing Address including Zip Code
   iii. Telephone number
   iv. County
   v. Registration Information
   vi. Workload obligation
   vii. Operational status
   viii. Size
   ix. Establishment type(s) and related Industry code(s) (reflect current activity of the firm)
   x. Products covered/manufactured

xi. Percent (%) Interstate

xii. Percent (%) Wholesale (Food firms only)

g. The process described above should be used to review the work products submitted by any state investigators (e.g. state liaisons for food, MQSA/rad health specialists for mammography and x-ray, regional specialists for seafood and milk, etc.).

6.1.3. Workload Obligation

Firm identified as Workload Obligation "Yes" may consist of:

Operational Status	Details

Operational (OPR)	• Establishment is in operation
	• FDA is required by statute to inspect on a risk-based schedule
	• Registered food, biologics, human drug, veterinary drug, medical device, and tobacco establishments
	  • **Note**: There are firms that are inspectional obligations that do not have a registration requirement
	  • **Note**: Not all registered firms need to be inspected depending on the risk of the product and program determinations
	• FDA inspects on a recurring cycle not pre-determined by statute (e.g. Bioresearch Monitoring (BIMO) establishments such as Clinical Investigators)
	  o While BIMO firms may be changed to a Workload Obligation "No" after a Center final classification of NAI or VAI is received, their status may be updated to become a Workload Obligation "Yes" any time there is an assignment
	• Other selected establishments, which are by statute subject to FDA regulations, but are not inspected on a recurring basis per FDA discretion (e.g., Class I devices)

Operational Status	Details
Seasonal (SEA)	• Establishments involved in seasonal activities, usually only operating during several weeks or months in a year, such as small maple syrup manufacturers, which operate only in the spring • See OPR definition for additional information

Pre-Production (PRP)	• Establishment plans to process FDA regulated products within six months*
	• May be used for any commodity
	• OEI maintenance directions*:
	  • It is recommended that these establishments be monitored by the Program Monitor or the OEI Coordinator, document the monitoring activities in the FMS comment field
	  • Document date of initial "PRP" status in the "QA Date" field in FMS
	  • Re-evaluate (by telephone or email) every six months to determine the status of the establishment
	  • The purpose of the re-evaluation is to determine a permanent status for the establishment so that it may be included in a risk based inspectional scheduled as soon as the establishment begins an FDA regulated activity
	  •

Inactive (INA)	• Temporarily not in operation but are expected to resume operations (e.g. a firm undergoing renovation or repair due to storm damage or another catastrophic event)
	• OEI Maintenance Directions*
	  • It is recommended that these establishments be monitored by the Program Monitor or the OEI Coordinator, document the monitoring activities in FMS comment field
	  • Document date of initial "INA" status "QA Date" field in FMS
	  • Re-evaluate (by telephone or email) every six months to determine the status of the establishment*

Operational Status	Details
	• The purpose of the re-evaluation is to determine a permanent status for the establishment so that it may be included in a risk-based inspectional schedule as soon as the establishment begins an FDA regulated activity

*__Note__: If an establishment does not begin operation within the registration cycle of that commodity (e.g., two years for foods, one year for drugs, devices and biologics) consider putting the firm as a workload obligation "No". Provide the establishment with the registration requirements for that commodity and encourage them to cancel their registrations with the appropriate Center until the firm meets the registration requirements for that commodity.

A. Interstate Commerce

a. Establishments that receive or ship raw materials or finished products (i.e., at least one product) directly or indirectly in interstate commerce) are Workload Obligation "Yes".

NOTE: An establishment must be involved in producing at least one product that moves in interstate commerce or use an ingredient that moved in interstate commerce to qualify the establishment as a Workload Obligation "Yes" in the OEI. That establishment remains as a Workload Obligation "Yes", even though it may produce other products that are not under FDA regulation.

b. **EXCEPTIONS** to the interstate commerce rules:

i. There are several establishment types that are regulated by FDA, are Workload Obligations "Yes" AND are exempt from the interstate commerce rule above. These include, but are not limited to, Blood Banks, Bioresearch Monitoring establishments (Clinical Investigators (CIs), Institutional Review Boards (IRBs)), MQSA facilities, etc. See "Establishment Types and Industry Types and Industry Code Attachment to OEI Development" for specific Workload Obligation requirements for these establishment types.

ii. All juice sold as juice, or for use as an ingredient in other beverages, except juice produced at retail establishments, is subject to the juice HACCP regulations and are "Workload Obligation", "Yes". This includes juice sold in both intrastate and interstate commerce (21 CFR 120.1).

6.1.4. Workload Obligation "No" (N):

Firm identified as Workload Obligation "No" may consist of:

Operational Status	Details
Operational (OPR)	• Establishments which are involved in an FDA regulated activity but have been identified as a type of firm not inspected on a risk-based schedule (e.g., third party audit inspected only under MDSAP). **Note:** There are firms that may have an obligation to register but may still be a workload obligation "No" within this category. • Establishments which have previously been Workload Obligations "Yes" but are now classified as Workload Obligation" No" due to FDA resource constraints, low inspectional priority status, or are no longer inspected by FDA (e.g., methadone clinics, some swine and poultry feed mills) • Establishments no longer subject to inspection or other FDA activities on a recurring cycle/risk-based schedule because they are only marginally regulated under the Act and regulations that FDA administers. Individual establishments in this category may periodically be of interest but are not considered as Workload Obligation "Yes" for ORA work planning. • Reclassified from manufacturer, repacker, or labeler/relabeler to dealer/retailer • FDA may still choose to inspect these firms at any time or may enter them "For Cause" • **Exception:** Establishments which are only inspected during certain assignments (e.g., tissue

Operational Status	Details
	residue). At the completion of the assignment, the Workload Obligation is changed to "No". • See Supporting Documents WI.0000024 for additional information regarding marginally regulated firms, retail food firms, etc.
Seasonal (SEA)	• Establishments involved in seasonal activities, usually only operating during several weeks or months in a year, such as small maple syrup manufacturers, which operate only in the spring. • See OPR definition for additional information

Not OEI Establishment (NOE)	• Establishment that is not engaged in activities, or does not manipulate products, subject to FDA regulation, but still remains in business.
	• No longer engages in activities or manipulates products subject to FDA regulation.
	  • e.g., Establishment manufactured sterile gloves for surgery, but now only manufactures gloves for auto mechanics
	• **Exception**: Establishments against which FDA is actively pursuing a regulatory action or on-going investigation to assist states or other agencies.
	  • When this occurs: Change the Operational Status to "OPR" and the Workload Obligation" to "Yes"
	  • When the FDA activity is completed: Change the Workload Obligation from "Yes" to "No"

OASIS/NEC (OAS)	• Establishments that are automatically entered into the firms' database through OASIS/ACE as a result of import entries. • These may be duplicate entries of existing firms in the OEI. Routine quality control will identify the duplicates and merged into existing firms or each other as appropriate.
Out of Business (OOB)	• The establishment goes out of business (OOB) entirely.

Operational Status	Details
	Note: See 6.1.5. below for additional notes

6.1.5. Out of Business (OOB):

A. An establishment is considered OOB **ONLY IF** the establishment no longer exists anywhere or anyplace.

Note: Firms remain District based. However, the work process described below may be completed, or requested to be completed, by a Program /Division OEI Coordinator in coordination with the Administration Branch (or whoever is involved with the firms physical/electronic files).

B. An establishment that has been purchased by another firm is not considered "OOB". The FMS record is updated to reflect the name and ownership change (as well as new location if applicable).

C. If a firm ceases operations in one District and moves to another District, the losing District does not put the firm out of business. The losing District updates the address, state, zip code, and county to the new location to transfer ownership of record to the receiving District where the firm is relocating. The receiving District checks for duplicate FEIs and merges as appropriate.

a. The losing District's OEI coordinator (or Program/Division OEI Coordinator) sends an email to the receiving District's OEI coordinator (or Program/Division OEI Coordinator), and the firm's factory jacket/electronic record and any other information is forwarded to the receiving District. The losing District is not required to maintain any paper/electronic records of the transfer.

b. Compliance files may stay with the original District or be sent to the receiving District at District's discretion, as most of the pertinent documents are maintained in either the firm's factory jacket or the electronic Compliance Management Services (CMS).

6.1.6. Changing a Firm's Workload Obligation from "Yes" to "No":

A. Establishments are changed to Workload Obligation = "No" when Program personnel determines that the establishment changes its

activities to meet the definitions under section 6.1.4 “Workload Obligation “No” (N)”.

B. Maintain documentation in the establishment file jacket (paper or electronic) or FMS Comment field, which provides an explanation for the change in an establishment’s Workload Obligation status to “No”.

C. FMS automatically changes the Workload Obligation of an establishment from “Yes” to “No” when the Operational Status is changed to OOB or NOE.

D. Cancel (most registration types) or Flag for Cancellation (FFR, SEG) registrations and profiles, as appropriate, before updating the Workload Obligation.

6.1.7. Multiple Establishment Types

A. Activities accomplished by an establishment may meet the definition for more than one establishment type. Specific examples include:

a. If an establishment manufactures one product and repacks another manufacturer's product, code the establishment with both (M) manufacturer and (R) repacker establishment types.

b. If the establishment stores their own finished products (either that it manufactures or repacks), code it as a manufacturer (M) or repacker (R) only, since the warehousing activity is part of the establishment's normal business operations.

c. If an establishment stores finished products manufactured by other establishments for distribution, add the appropriate warehouse establishment type (WA, WR, WF, or WZ) to the establishment’s list of establishment types.

d. If a distribution center is not located at the manufacturing site, code the distribution center as a separate establishment with the appropriate warehouse establishment type: WA, WZ, WR, or WF

e. If the establishment is a Control Lab which performs testing for other customers, code it as a “C”. If testing is performed only for its own product, the establishment would NOT receive an establishment type of “C”.

6.1.8. Establishment

A. In general, an FDA regulated establishment is a business or other entity under one owner(s) (including multiple shareholders or partner) and at one geographic location or address (see 6.1.8.C) that handles products

or performs activities subject to FDA regulation (e.g. processes, manufactures, labels, repacks, stores, distributes, tests, performs services or otherwise manipulates products regulated by FDA). Any individual, or group of individuals, whose activities fall under the regulation of the FDA and for which an establishment type is defined, is an establishment. Establishment types are defined in "Establishment Types and Industry Types and Industry Code Attachment to OEI Development".

B. Document the decision to change establishment information (i.e. workload obligation, operational status, etc.) in the comment field in FMS. Programs may also choose to document these decisions (or provide more details) in the factory file jacket or other physical or electronic files.

C. The activities at one establishment may be in more than one product or program area and thus the responsibility of more than one Program or Center.

D. "One geographic location or address" is to be reasonably construed to include separate buildings within close proximity (see definition below 6.1.8.D.a) if the activities in them are closely related to the same business enterprise, under the supervision of the same local management, and are capable of being inspected at the same time.

   a. Close Proximity:

      i. Within a campus setting

      ii. Within three miles driving distance of each other

      iii. The buildings MUST be within the same State and the United States Judicial District Court area

   b. Program Domestic and Foreign OEI Coordinators may use their discretion for unique situations. Documentation as to the unique situation **MUST** be documented in the comment field in FMS for all potentially related FEIs. Programs may also choose to document these decisions (or provide more details) in the factory file jacket or other electronic files.

      Some examples include:

      i. Unmanned warehouses may be associated with the main firm FEI

ii. Establishments at two locations, three miles or less apart may be assigned one FEI if they are always inspected (or capable of being inspected) at the same time, under the supervision of the same local management, and in-process material from one location is used to make the final product in a second location.

iii. Criteria to determine whether international sites are "Capable of being inspected at the same time" may be determined on a case-by-case basis.

iv. Some country tax laws may prohibit multiple sites from having one shared FEI number. In this case, it may be appropriate for the firms to be assigned separate FEI numbers, but the FEI for the sister sites should be notated in the comment field so that they may possibly be inspected at the same time.

c. Two or more business enterprises (separate legal entities) with different management, although using the same facility or the same address, are to be identified as separate establishments and therefore should have separate FEI numbers.

6.1.9. Industry Codes

Establishment Types and Industry Code Attachment to OEI Development:

A. Industry codes in the OEI record represent" finished" products that are the responsibility of the establishment.

a. Ingredients/components used to manufacture a finished product do not receive an industry code

b. "Finished" products may include products such as APIs, unsterilized medical devices, etc. as defined within a Program.

B. Do not enter an industry code when inspecting products in process, raw materials or ingredients such as vitamins, food/color additives (unless the material is distributed in this state or are stored in an independent warehouse).

C. This does not include conveyances inspected on premises.

6.1.10. District Use Codes (DUCs)

A. Reserved for District or Program use to provide clarification or additional detail to an establishment types (e.g. acidified foods, juice HAACP).

Also used to develop National DUC to be used to identify a subset of firms within a Program.

B. DUCs are created in the FACTS system. Once created, the DUCs will become available in FMS to be assigned to a firm.

C. The National OEI Coordinator may develop a standardized national DUC which will be applied in certain global situations.

6.1.11. Registration Activities (ORA and Centers)

A. Centers are responsible for maintaining their registration systems and receiving registration information from establishments.

B. Registration information:

a. Food registrations (FFR and SEG) are automatically updated through a limited information transfer from the Food Facility Registration Module (FFRM) to FIDA/FMS.

b. Medical Device (DEV) and Tobacco (TBC) renewals are automatically updated through an automatic data transfer from the Medical Device Registration and Listing Module (DRLM)/Tobacco Registration and Listing Module (TRLM) and FIDA/FMS. ORA personnel manually assign an FEI to new firms and follow up on firms that cancel their registrations in the Center registration e systems

c. Biologic (BIO) and HCTP (BHT) renewals may either be manually updated in FMS as information is received from the Center, or batch updated by the National OEI coordinator in the spring of each calendar year (this may be an automated process in the future). ORA personnel manually assign an FEI to new firms and follow up on firms that cancel their registrations in the Center registration systems

d. Human (DRG) and Animal (VET) drug registrations are manually updated annually by ORA personnel (this may be an automated process in the future). ORA personnel manually assign an FEI to new firms and follow up on firms that cancel their registrations in the Center registration systems. The OEI Coordinator should provide the registered human and animal drug firms of their FEI number so that the FEI can be entered into eDRLS during the renewal/re-registration process.

C. Registration activities are conducted in FMS by personnel with the role of “DO_REG_MNTR” in FACTS.

D. Food registrations (FFR and SEG) may be "Flagged for Cancellation" in FMS if a firm is out - of business or has renewed and created a duplicate firm in FMS. All other registration types may be updated to "Canceled".

E. Review FMD 92 "Registration and Control Procedures" for further instructions.

F. If an establishment's registration conflicts with FMD 92, review the establishment's information to determine how the establishment should register. Consult with the National OEI Coordinator and/or the appropriate Center if necessary. Communicate to the establishment how they should be registered with FDA and request that they update information in the Center registration systems as appropriate.

7. Glossary/Definitions

A. **DUNS number:** Dun & Bradstreet (D&B) provides a DUNS Number, a unique nine-digit identification number, for each physical location of a business. An FEI for an establishment may be linked to several DUNS numbers.

B. **DRLM:** Device Registration and Listing Module

C. **eDRLS:** Electronic Drug Registration and Listing System

D. **Establishment Type(s):** Identifies the activity(s) accomplished by or at an establishment of interest to the FDA. Establishment type definitions are defined in "Establishment Types and Industry Code Attachment to OEI Development (WI.000024)" A, Establishment Types (definitions).

E. **FFRM:** Food Facility Registration Module

F. **Firms Database:** The firm's database contains information related to FDA regulated firms, both domestic and foreign, and other entities encountered during the course of conducting FDA operations. Domestic includes any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

G. **Firm Establishment Identifier or FDA Establishment Identifier (FEI):** 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.

H. **Firm Management Services (FMS):** A 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.

I. **FDA Inventory of Data Assets (FIDA):** FIDA is a Master Data Management (MDM) program initiated within ORA to establish and maintain integrated master data enabled by people, process, and technologies. The firms (establishment) master data within FIDA establishes a master copy of a unique firm record within ORA along with its associative information such as name, address, and DUNS. The firm's master data is managed through a collaborative process involving all stakeholders to standardize process, publish and protect the sharable information assets and is enabled by Data Governance and Stewardship. The firm's master data is managed through a coordinated data life cycle management process to create a 360 view of master and reference data governed by compliance policies and rules. FIDA technology in automation is supported by a multi-domain (MDM) hub and toolset, Informatica MDM.

J. **Industry/Product Code:** The first two-digits of the seven-character product code which describes a broad category of products regulated by FDA. For the purposes of the OEI, the industry code(s) associated with each establishment represents the final or finished product(s) of the establishment, not components of the final product(s). Industry codes and the product groups they represent are identified in the, "Establishment Types and Industry Code Attachment to OEI Development" work instruction (WI.000024).

K. **Operational and Administrative System for Import Support (OASIS):** An automated FDA system for processing and making admissibility determinations for shipments of FDA regulated products of foreign origin seeking to enter domestic commerce. Firm data from OASIS is automatically integrated into FMS.

L. **Official Establishment Inventory (OEI):** Includes information about establishments under FDA regulation. These include establishments determined to under the regulation of FDA, as well as establishments that have been determined not to be under the regulation of FDA. The electronic records are stored in the FMS module in the FACTS database.

M. **TRLM:** Tobacco Registration and Listing Module

8. Records

A. Documentation of firm entry and changes in FMS: (e.g. Form FDA 457, Product/Establishment Surveillance Report, the form listed in Official Establishment Inventory (OEI) Data Collection (WI-000020)" or other Program form, memo, or checklist; PDF of registration information from Centers.

9. Supporting Documents

A. Establishment Types/Industry Codes: Definitions, workload obligations (WI.000024).
B. Official Establishment Inventory (OEI) Data Collection (WI.000020)
C. Search Firm Management Services (FMS) (WI.000021)
D. Description of Data Entry Fields in Firm Management Services (FMS) (WI.000022)
E. Inventory Reconciliation and Adding District Use Codes for Molluscan Shellfish Cooperative Program (WI.000025).
A. Firm/FDA Establishment Identifiers How, why and when FEI are generated (WI.000026)
B. Official Establishment Inventory (OEI) Data Collection Form (FORM-000173)

10. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	10/16/2016	LORI LAWLESS, NATIONAL OEI COORDINATOR	Sarah Pichette, Work Planning Branch Chief
2.0	R	12/11/17	LORI LAWLESS, NATIONAL OEI COORDINATOR	Jessica Hopson, Work Planning Branch Chief
03	R	07/11/2018	JUSTIN R. CARR QSM	Justin Carr QSM
04	R	05/07/2019	LORI LAWLESS, NATIONAL OEI COORDINATOR	Mark Abdy, Division of Program Evaluation, Director

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

11. Change History

Version	Version
Draft	ORA J. GIVENS COMMENTS: 7-26-16
Draft	OIP CLEARANCE/NO COMMENTS: 8-16-16
Draft	CVM CLEARANCE/NO COMMENTS: 8-30-16
Draft	CFSAN EDITS: THOMAS: 9/3/16
2.0	1. DOCUMENT NUMBER CHANGED DUE TO OFFICE CHANGES DURING ORA PROGRAM ALIGNMENT. (OLD # OPRM-DPEM.002) 2. DOCUMENT PUT INTO NEW QMIS SOP TEMPLATE
03	MINOR: UPDATED THE LINK TO THE CURRENT DOCUMENT FOR "ATTACHMENT A" AND UPDATED THE VERSION CONVENTION.
04	UPDATED TO REFLECT CHANGES IN ORGANIZATIONAL STRUCTURE, COMPLETE REVIEW OF DOCUMENT. ADDED SECTION ON ESTABLISHMENTS AND CLOSE PROXIMITY

12. Attachments

List of Attachments

Appendix A: Major Milestones in the Development of the Current OEI

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In 1981, ORA assessed the current state of the OEI and several data clean-up activities were initiated.

In July 1993, via a Field Guidance memorandum, the Center for Drug Evaluation and Research (CDER) reclassified establishments which manufacture or manipulate compressed or liquefied medical gases from repackers to manufacturers.

In FY 1994, the Center for Biologics Evaluation and Research (CBER) transferred the inspectional responsibility for Military Blood Banks (Domestic and Foreign) to ORA.

In FY 1995, mammography facilities were added to the OEI. The Mammography Quality Standards Act (MQSA) of 1992 established the authority for the regulation of mammography services and radiological equipment.

In early FY 1997, ten new establishment type definitions and ten two-character establishment type codes were implemented. A new establishment type, entry filer (EF), was added and the current importer/broker establishment type was modified to accommodate the Operational and Administrative System for Import Support (OASIS).

Between 1996 and 2000, FDA developed and implemented Field Accomplishments and Compliance Tracking System (FACTS). FACTS was a replacement system for the Field Information System (FIS) used by the Agency for many years. The OEI formerly resided within FIS.

Data about firms could be entered directly into FACTS/FMS on data entry screens or indirectly through the (OASIS) system. Both FMS and OASIS automatically generate a Firm Establishment Identifier or FDA Establishment Identifier (FEI) number, which is a ten-digit number. The seven-digit CFN still appears on some firm records in FMS, and is referred to as an FEI number.

Under FIS, each district had its own OEI database (both active and auxiliary) stored on their local system. Monthly updates were consolidated into a single headquarters active and auxiliary file. Under FIS, the OEI database contained only domestic firms. With the implementation of FACTS and FMS, the Division of Field Investigation's (DFI) international inventory was loaded into the firm file in FMS, allowing access to foreign firm data. Under FIS, FMS is a national and international relational database which should contain the most current firm information.

eNSpect was released in September 2014 to New England District Office and later rolled out throughout the rest of the agency. It is currently the primary

location for creating, managing, endorsing assignments and/or working wth post-endorsement assignments. Firm information is transferred from FMS based on the FEI number. Firm information can be updated in FMS during the inspection. The updated information will transfer to FMS during an hourly transfer of data between the two systems when the eNSpect user is online and performs a synch. Additionally, information updated in FMS will be transferred to eNSpect during certain stages of the inspectional process when the eNSpect user is online and performs a synch.

The automatic transfer of registration data between CDRH/Device Registration and Listing (DRLM) system and FMS was implemented in October 2016. Information included updating the status to the current fiscal year, establishment types/industry codes, the highest classification of the device for re-registering firms and registration number. Reports were generated providing information about re-registering firms that were out of business, not official establishment inventory or FEIs did not match. These reports are reviewed by the National OEI coordinator to correct the data in either FMS or DRLM. A second version was released in November 2018 to add contact information, aliases, trade names, US Agent, and checking the boxes for “Registration Required” and “Profile Required”.

The automatic transfer of registration data between CTP/Tobacco Registration and Listing (TRLM) system and FMS was implemented in January 2017.