

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 1 of 29</p>

## Sections in This Document

1. Purpose .....	1
2. Scope .....	2
3. Responsibility .....	2
4. Background .....	4
5. References .....	8
6. Procedure.....	9
6.1. Communications/Points of Contact.....	9
6.2. Registration information.....	12
6.3. Maintenance of Registration Files.....	13
6.4. Registration Numbers.....	14
6.5. Procedures for Registration/Re-registration/Renewals .....	15
6.5.1. Center for Biologics .....	15
6.5.2. Center for Drug Evaluation and Research/Center for Veterinary Medicine...	18
6.5.3. Center for Devices and Radiological Health.....	21
6.5.4. Center for Food Safety and Applied Nutrition.....	23
6.5.5. Center for Tobacco Products .....	24
6.6. Verification of Registration by an Investigator during an inspection .....	25
7. Glossary/Definitions .....	26
8. Records .....	27
9. Supporting Documents .....	27
10. Document History .....	28
11. Change History .....	28
12. Attachments.....	29

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### 1. Purpose

Establishes consistent instructions for processing and monitoring firm registrations from any Center. It summarizes Office of Regulatory Affairs (ORA) Office and Division responsibilities and ensures Establishment Registration information in the Center files are reconciled with ORA's Official Establishment Inventory (OEI) and integrated registration files.

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<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>Office of Strategic Planning and Operational Policy</i>	<b>Document Number:</b> <b>SOP-000353</b>	<b>Revision #: 00</b> <b>Revised:</b> 12/11/2019
<b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b>		Page 2 of 29

## 2. Scope

Process for updating Registration information for all commodities in FMS.

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## 3. Responsibility

- A. Centers (maintain their own internal procedures; this section for ORA information only)
    - 1. Maintain the registration systems or electronic registration portals accessible by the public
    - 2. Answer field inquiries regarding registration procedures and requests for registration and listing requirements
    - 3. Process registrations as per their internal procedures/practices, and distribute the information as described below
    - 4. Centers may issue untitled letters and/or Warning Letters to firms who fail to register or re-register their establishment
  
  - B. National OEI Coordinator:
    - 1. Acts as the liaison between the Centers and the Programs/Divisions
    - 2. Responsible for revising this procedure and associated work instructions
    - 3. Performs data analysis of registration data in Firm Management Services (FMS) to provide information to ORA for continuous improvement
  
  - C. Division Office
    - 1. Identifies one or more persons as Registration Monitor(s) for the Division
      - A. This role is part of the Program/Division OEI Coordinator position
    - 2. Notifies the IOM workgroup immediately of changes to Registration Monitors using the [IOM Change Request/Notice \(ICR/N \(FDA-3651\)\)](#).
  
  - D. Investigations Branch
    - 1. Determines within ten (10) working days whether a newly identified establishment, from a source other than a Center (for example
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<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 3 of 29</p>

complaints, investigations, inspections, etc.), is required to register, either by an inspection of, or telephone conversation, with the establishment.

- A. Provides Center registration resources to the establishment for further action
- 2. Supplies the appropriate Program/Division OEI Coordinator with basic information about the status of the new establishment, including the types of products produced.
  
- E. Program/Division OEI Coordinator or designee
  - 1. Ensures all registration information and associated information in Center registration systems for firms in their program area(s) are updated in FMS
  - 2. Provides information to the Program/Division OEI coordinators for merging duplicate firms (if the Registration Monitor is not also the Program/Division OEI coordinator)
  - 3. Ensures that all work on new registrants is processed and the appropriate Center is notified within fifteen (15) working days after paper forms or electronic information is received from the Center or Center accessible computer systems
  - 4. Generates or identifies the FEI number in FMS for the facility registration as required and provides this information to the Center as described below
  - 5. Manually updates FMS with annual registration information (for those systems that are not automated)
  - 6. Acts as the point of contact for all inquiries about registration for their program area(s)
  - 7. Maintains a current and accurate OEI for their program area(s)  
Encourages firms to register if required
  - 8. If paper copies of registration documents exist, maintains a Public Information File for the current calendar year of all registrants located within the district boundaries per 21 CFR Part 807.37 (Note: firms are geographically based)
  
- F. Investigators/Inspectors

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 4 of 29</p>

1. Verifies during all inspections/investigations the completeness and accuracy of all registration data held by FDA as set forth in the corresponding CPGM

G. Compliance Branch

1. Initiates appropriate action as set forth in the Compliance Policy Guides Manual, Current version on web, [Chapter 4 \(400.100; Drugs-General, 7132.07\)](#), and [Chapter 6 \(625.500, Veterinary Medicine, 7125.25\)](#) against those establishments which fail to register or to re-register in accordance with the law.

#### 4. Background

The Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act (the Act) require, among other things, that every person who owns or operates any establishment, in any state or territory engaged in manufacturing, preparation, propagation, compounding or processing of a drug or drugs shall register with the Secretary (FDA) annually.

##### Center for Biologics

Beginning with the mailing of registration forms for calendar year 1976, the Bureau of Biologics (renamed the Center for Biologics Evaluation and Research, CBER) assumed the responsibility for mailing forms and for updating and maintaining a registration file for all blood banks and blood product handling establishments.

In 2001, a registration and listing final rule was published that requires human cells, tissue, and cellular and tissue-based product (HCT/P) establishments to register with FDA and list their products.

Under the August 31, 2016 final rule, manufacturers of HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act or under the Food, Drug, and Cosmetic Act, must register and list their products in accordance with 21 CFR Part 207 or 807, as applicable, rather than 21 CFR Part 1271.

##### Center for Drug Evaluation and Research

Since the implementation of the Drug Registration regulations in 1963, the Drug Listing regulations in 1972, and the establishment of the Bureau of Biologics and the Bureau of Medical Devices within FDA, the procedures and responsibilities for maintaining the Drug Registration file have changed significantly. In January of 1977 the Bureau of Drugs began a staggered, January through July, registration procedure. Vaccines, allergenics, and other

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 5 of 29</p>

non-blood biological manufacturers continue to register and list with the Bureau of Drugs (renamed the Center for Drugs Evaluation and Research, CDER).

Sections 701 and 702 of FDASIA also directed the Secretary to specify the unique facility identifier (UFI) system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act, as amended, requires that each initial and annual drug establishment registration include a UFI. In November 2014, FDA finalized “Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration: Guidance for Industry” which states that for drug establishment registration, the preferred UFI for a drug establishment is the Data Universal Numbering System D-U-N-S (DUNS) number, assigned and managed by Dun and Bradstreet. The Field Establishment Identifier (FEI) number, the ten-digit number assigned to the establishment by the District or DFFPOI/DMPTOP, is considered the registration number for device, tobacco, blood component and HCT/P establishments. Field Establishment Identifiers (FEIs) continue to be used by ORA (along with the DUNS) to identify drug registered facilities. In past years, the registration number was the seven-digit Central File Number (CFN) assigned to the establishment by the district or DFFPOI/DMPTPO.

The August 2016 revision to 21 CFR 207 included the requirement that Registration number of each establishment, if previously assigned by FDA and a Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. The *Establishment registration number* is the number assigned to the establishment, as identified by FDA, after the establishment registration required in this part

#### Center for Devices and Radiological Health

In 1976, Section 510 of the Act was amended to require the annual registration of certain medical device and diagnostic product establishments and the Bureau of Medical Devices (renamed the Center for Devices and Radiological Health, CDRH) began separate registration and listing procedures. The Safe Medical Devices Act of 1990 directed FDA to establish MDR problem reporting requirements for users and distributors. To facilitate reporting by foreign manufacturers, CDRH modified 21 CFR Part 807 to require foreign manufacturers to identify a U.S. Designated Agent.

There have been many legislative and regulatory changes impacting medical device registration and listing since Section 510 was first amended. The following are some of the legislative and regulatory changes. On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA I) was signed into law. MDUFMA I amended the FD&C Act authorizing FDA to

<p align="center"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p align="center"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p align="center"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p align="center">Page 6 of 29</p>

collect fees from companies who submit certain applications for marketing of medical devices. The re-authorization of User Fees per MDUFMA II as part of the Food and Drug Administration Amendments Act (FDAAA) of 2007 mandated the use of an electronic registration and listing system known as the FDA Unified Registration and Listing System (FURLS) and introduced the annual registration user fee for certain types of establishments for FY 2008 through FY 2012. FURLS/DRLM was launched on October 1, 2007 for Fiscal Year (FY) 2008. All medical device firms are required to pay the annual registration user fee prior to submitting their registration and listing information electronically via FURLS/DRLM unless a waiver is granted. Medical device firms are required to review their registration and listing information annually between October 1<sup>st</sup> and December 31<sup>st</sup> each year. Medical Device User Fee Amendments of 2012 (MDUFA III) as part of the FDA Safety and Innovation Act (FDASIA) re-authorized annual registration user fees for all types of establishments and was signed into law on July 9, 2012.

On August 1, 2012, FDA published the revised version of Part 807 to reflect the statutory amendments to the device registration and listing provisions of the Federal Food, Drug and Cosmetic Act (the Act). The statutory amendments included requiring domestic and foreign device establishments to submit their registration and device listing information electronically via the FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM) and specified the timeframes when establishments are required to submit such information. The revised regulations facilitate collection of additional registration and listing information from foreign establishments and initial importers as required by the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act) and FDAAA. It also updated certain provisions in Part 807 to improve the quality of registration and listing information available to FDA.

Center for Food Safety and Applied Nutrition

The Center for Food Safety and Applied Nutrition (CFSAN) maintains two registration systems: Cosmetics and Low Acid Canned Foods (LACF). These registration systems are not processed or handled in the same manner as other Center registration files. The cosmetic registration/ listing is strictly voluntary at this time. There is no requirement for registration. LACF registration/process filing is required by regulation [21 CFR 108.35(c)].

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

<p align="center"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p align="center"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p align="center"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p align="center">Page 7 of 29</p>

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

- Food Facilities register with FDA, and
- FDA be given advance notice on shipments of imported food.

These regulations became effective on December 12, 2003. The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C), in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA renew such registrations every other year and provides FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

Created, caused, or was otherwise responsible for such reasonable probability; or

Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food

In 2016, the “FSMA Final Rule on Amendments to Registration of Food Facilities” was issued. This included additional information that an email address is now required, the type of activity conducted at the facility for each food product category; expands the definition of a retail food establishment which are not required to register but are still have the responsibility to ensure that their food is safe.

### Center for Tobacco

In 2009, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31) granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act added section 905 to the Act, establishing requirements for tobacco product establishment registration and product listing. Section 905(b) of the Act requires that “every person who owns or operates any establishment in any State engaged in the

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 8 of 29</p>

manufacture, preparation, compounding, or processing of a tobacco product or tobacco products” register with FDA the name, places of business, and all establishments engaged in these activities owned or operated by that person. Every person must register by December 31 of each year. The Center for Tobacco Products (CTP) maintains tobacco establishment registration and product listing information.

### Center for Veterinary Medicine

Beginning in 1986, CDER gave the authority to the Center for Veterinary Medicine, CVM, to list Veterinary Drug products including pharmaceutical dosage forms and Type A medicated articles. CDER still performs registration duties for producers of animal drug products. Also in 1986, the Second Generation Medicated Feed Program of the CVM was finalized by regulation requiring producers who use Type A medicated articles to manufacture Type B and C medicated feeds containing category II drugs to complete a Medicated Feed Application (MFA). Subsequently, with the passage of the Animal Drug Availability Act (ADAA) in 1996, medicated feed applications were abolished and replaced with a single medicated feed mill facility license. Section 510 of the Federal Food, Drug, and Cosmetic Act (the Act) also requires these licensed medicated feed producing sites to register with CDER.

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## 5. References

1. 21 CFR PARTS [207](#), [607](#), [807](#), [1107](#), and [1271](#)
2. Inspection operations manual, section 951
3. Instruction publications for registration and listing (furnished upon request by the appropriate center)
4. COMPLIANCE PROGRAMS
  - i. [CBER](#): 7341.002, 7341.002A, 7342.001, 7342.002, 7342.008, 7345.848
  - ii. [CDER](#): 7356.014
  - iii. [CDRH](#): 7382.845
  - iv. [CFSAN](#):
  - v. CTP
  - vi. [CVM](#):
5. [Compliance policy guides manual](#), Section 100.250 (CFSAN), Section 400.100 (Pharma), Section 625.500 ( CVM)



<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 9 of 29</p>

6. Blood Establishment Registration (BER) Intranet Query:
  - a. [External](#)
  - b. [Internal](#)
7. Device Establishment Registration & Device Listing
  - a. [External](#)
  - b. [Internal](#): under FURLS/DRLM
8. Drug Registration and Listing System (DRLS & eDRLS)
  - a. [External](#):
  - b. [Internal CDER](#): Drug Quality and Compliance Portal under Frequently-Used CDER Links
  - c. [Internal: ORA](#): under DRLS/eDRLs
9. Food:
  - a. External
  - b. [Internal](#): under FURLS/FFRM
10. [Generic Drug User Fee Amendments of 2012](#):
11. Human Cell and Tissue Establishment Registration System (HCTERS) Query:
  - a. [External](#)
  - b. [Internal](#)
12. Tobacco
  - a. External:
  - b. [Internal](#): under FURLS/TRLM

## 6. Procedure

### 6.1. Communications/Points of Contact

6.1.1 Registrations and re-registrations may be received by the Programs and Divisions (including foreign components of the Programs) from several sources as described in this procedure.

**NOTE:** If the Program receives registration or listing information directly from the registrants, they are to be referred to the appropriate Center (below).

6.1.2 All inquiries from the Centers and ORA about registration procedures should be directed to the National OEI Coordinator.

<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>Office of Strategic Planning and Operational Policy</i>	<b>Document Number:</b> <b>SOP-000353</b>	<b>Revision #: 00</b> <b>Revised:</b> 12/11/2019
<b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b>		Page 10 of 29

6.1.3 Registration problems that are related to the mechanics of data processing should be referred to:

A. ERIC; [eric@fda.hhs.gov](mailto:eric@fda.hhs.gov); (866) 807-3742; (301) 827-3742

B. APPS Desk: [APPSSDesk@fda.hhs.gov](mailto:APPSSDesk@fda.hhs.gov); (240) 241-5636

6.1.4 All other routine registration problems and communications should be directed to the Centers (mail or telephone).

**NOTE:** The Centers' registration responsibilities may be performed in whole or in part by outside contractors. The Centers, however, still maintain staff to oversee these activities. Communications regarding registration should be directed to the Center's staff listed in section below, and not the contractors.

Center	Email and Phone	Address
<b>CBER Blood Establishments</b>	<a href="mailto:bloodregis@fda.hhs.gov">bloodregis@fda.hhs.gov</a>  T: (240) 402-8360	Food and Drug Administration Center for Biologics Evaluation & Research  Document Control Center 10903 New Hampshire Avenue, Building 71, Room G112 Silver Spring, MD 20993-0002 ATTENTION: Blood Registration Coordinator
<b>CBER HCT/P Establishments</b>	<a href="mailto:tissuereg@fda.hhs.gov">tissuereg@fda.hhs.gov</a>  T: (240) 402-8369 F: (301)-595-1303	Food and Drug Administration Center for Biologics Evaluation and Research  Document Control Center 10903 New Hampshire Avenue, Building 71, Room G112 Silver Spring, MD 20993-0002 ATTENTION: Tissue Establishment Registration Coordinator

<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>Office of Strategic Planning and Operational Policy</i>	<b>Document Number:</b> <b>SOP-000353</b>	<b>Revision #: 00</b> <b>Revised:</b> 12/11/2019
<b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b>		Page 11 of 29

<b>CBER Biological Products with CDER registration and listing</b>	CBERSPL@fda.hhs.gov  T: (301) 827-0373	
<b>CDER</b>	<a href="mailto:edrls@fda.hhs.gov">edrls@fda.hhs.gov</a> No phone listed GDUFA inquiries: <a href="mailto:AskGDUFA@fda.hhs.gov">AskGDUFA@fda.hhs.gov</a> <u>v</u>	Food and Drug Administration Center for Drug Evaluation and Research  Drug Registration and Listing Staff 10903 New Hampshire Ave Silver Spring, MD 20993
<b>CDRH</b>	<a href="mailto:reglist@cdrh.fda.gov">reglist@cdrh.fda.gov</a> <a href="mailto:device.reg@fda.hhs.gov">device.reg@fda.hhs.gov</a>  T: (301) 796-7400	Food and Drug Administration Center for Devices and Radiological Health  CDRH Registration and Listing Policy Helpdesk 10903 New Hampshire Avenue Silver Spring, MD 20993
<b>CFSAN (Food Facility and Shell Egg Registration)</b>	<a href="mailto:Furls@fda.gov">Furls@fda.gov</a>  T: (800) 216-7331 T: (240) 247-8804 F: (301) 436-2804	U.S. Food and Drug Administration  Food Facility Registration 5100 Paint Branch Pkwy HFS-681 College Park, MD 20993
<b>CFSAN (LACF)</b>	<a href="mailto:LACF@FDA.HHS.GOV">LACF@FDA.HHS.GOV</a>  T: (240) 402-2411	U.S. Food and Drug Administration  LACF Registration Coordinator 5100 Paint Branch Pkwy HFS-303

<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>Office of Strategic Planning and Operational Policy</i>	<b>Document Number:</b> <b>SOP-000353</b>	<b>Revision #: 00</b> <b>Revised:</b> 12/11/2019
<b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b>		Page 12 of 29

		College Park, MD 20993
<b>CFSAN</b> <b>(Cosmetics: Voluntary)</b>	<a href="mailto:VCRP@fda.gov">VCRP@fda.gov</a> Phone not available	Food and Drug Administration  Voluntary Cosmetics Registration Program  5100 Paint Branch Parkway College Park, MD 20740-3835
<b>CTP</b>	<a href="mailto:CTPRegistrationandListing@fda.hhs.gov">CTPRegistrationandListing@fda.hhs.gov</a>  Phone not available	Food and Drug Administration Center for Tobacco Products  Division of Enforcement and Manufacturing  10903 New Hampshire Avenue Silver Spring, MD 20993
<b>CVM</b>	<a href="mailto:AskCVM@fda.hhs.gov">AskCVM@fda.hhs.gov</a>  T: (240) 276-9300	Food and Drug Administration Center for Veterinary Medicine  Division of Surveillance, HFV-210 7519 Standish Place Rockville, MD 20855

## 6.2. Registration information

Registrations may be received by the Programs and Divisions (domestic and foreign) from Center contacts via email, and from several sources as follows:

Center for Biologics Evaluation and Research (CBER):	Blood Registration and Product Listing for Manufactures of Blood Products and Licensed Device” <a href="#">Blood Establishment Registration (BER)</a>  Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Summary Reports
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<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>Office of Strategic Planning and Operational Policy</i>	<b>Document Number:</b> <b>SOP-000353</b>	<b>Revision #: 00</b> <b>Revised:</b> 12/11/2019
<b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b>		Page 13 of 29

	<a href="#">Human Cell and Tissue Establishment Registration System</a> (HCTERS)
Center for Drug Evaluation and Research (CDER):	<a href="#">Electronic Drug Registration and Listing System</a> (eDRLS):
Center for Devices and Radiological Health (CDRH):	<a href="#">FDA Unified Registration and Listing System (FURLS)</a> Device Registration and Listing Module (DRLM)
Center for Food Safety and Applied Nutrition (CFSAN)	<a href="#">FDA Unified Registration and Listing System (FURLS)</a> Food Facility Registration (FFRM) Shell Egg Producer (SEP) Low Acid Canned Foods (LACF) Form 2511 "Registration of Cosmetic Product Establishment" Form FDA 2512 (Cosmetics Product Ingredient Statement) Form 2512 A (Cosmetic Product Ingredient Statement)
Center for Tobacco Products (CTP)	<a href="#">FDA Unified Registration and Listing System (FURLS)</a> Tobacco Registration and Product System (TRLM)
Center for Veterinary Medicine (CVM)	<a href="#">Electronic Drug Registration and Listing System</a> (eDRLS):

**NOTE:** If the Programs or Divisions receive registration or listing information directly from the registrants, they are to be referred to the appropriate Center ([6.1](#)).

### 6.3. Maintenance of Registration Files

6.3.1 The Centers (following their own internal policies and procedures) maintain registration files for:

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 14 of 29</p>

- A. Addition of new registrants
  - B. Removal of registrants who are not required to register or are "Out of Business," following receipt of information from ORA
  - C. Tracking or monitoring "late" registrants (i.e. registered for the previous year but not re-registered for the current year)
  - D. Inactivating registrations of firms who did not register during the registration period. This does not mean that the firm is out of business or no longer involved in the regulated commodity and must be confirmed by ORA before FMS is updated
- 6.3.2 The registrant should save a copy of all registration, re-registration or renewal files
- 6.3.3 The OEI in FMS should contain all current registrants that are statutory inspectional obligations, as well as the voluntary registrants. When these files are current, detailed information is available on the status of registered establishments.
- 6.3.4 Electronic registration information should be reviewed monthly for medical devices, drugs, animal (veterinary) drugs, biologics and food facilities as described in [Section 5](#) (References) and [Section 9](#) (Supporting Documents). The Cosmetics Registration File is entirely composed of voluntary registrants.

#### 6.4. Registration Numbers

- 6.4.1 **CDER, CVM, and CBER-regulated drugs (other than blood components):** The nine-digit DUNs number assigned by Dun and Bradstreet is the current drug establishment Unique Facility Identifier (UFI). The FEI number is not required during the initial registration as the FEI is not usually known by the firm at that time. Per 21 CFR 207, firms are required to enter the FEI/registration number once it is known to them. eDRLS has not yet made this a mandatory field, but it is available to the registrants for data entry. FEI continues to be used by ORA as the identifier for these firms.
- 6.4.2 **CDRH, CBER (blood components, HCT/Ps, and licensed devices) and CTP:** The registration number is the ten-digit FEI assigned to the establishment by Program/Division. Some registration numbers continue to be the legacy seven-digit CFN (Central File Number) (now preceded by "000") that was issued to older firms prior to the conversion to a ten-digit FEI.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 15 of 29</p>

6.4.3 **CFSAN:** The food facility registration (FFR) number is generated by FFRM. An FEI number is matched to the FFR or is generated by FIDA.

## 6.5. Procedures for Registration/Re-registration/Renewals

The Centers' registration responsibilities may be performed in whole or in part by outside contractors. The Centers, however, still maintain staff to oversee these activities. Communications regarding registration should be directed to the Center's staff listed in section [6.1](#), not the contractors. Process Maps of each commodity are included in [Attachment A](#).

There are separate work instructions which provide guidance/directions on how to merge firms, what fields to update in FMS, etc.

**NOTE:** There may be instances when newly registered establishments are not required to register, but which are an FDA obligation under the FD&C Act. In this case, follow the procedure for the registration information returned to the Center, but add the establishment to the OEI as any other non-registered obligation would be added.

**NOTE:** An establishment is a "Voluntary Registrant" if it is not required to register but does so for its own purposes. The establish may state that it is a voluntary registration during the registration process, or this may be identified during the verification process. The Program/Division OEI Coordinator should update FMS by indicating a "Voluntary" registration in the registration fields. The appropriate Center should be notified of the firm's voluntary status.

Assign FEI numbers following [Firm-FDA Establishment Identifier \(FEI\) \(WI-000026\)](#)

### 6.5.1. Center for Biologics

#### A. Initial Registration

1. Blood establishments register through the Electronic Blood Registration System (eBER)
2. HCT/P establishments register through the Electronic Human Cell and Tissue Establishment Registration System (eHCTERS)
3. Using their own internal procedures/policies, CBER personnel screen the information for new registrants.
4. CBER personnel emails the Program/Division OEI Coordinator the "Blood Establishment Registration Summary Report" (Biologics) or the "Tissue Registration Summary Report for HCT/Ps (HCT/P).

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 16 of 29</p>

5. The Program/Division OEI Coordinator verifies that the registration is for a new establishment in the inventory, a previously identified establishment that is registering for the first time (firm may be in FMS for another commodity), or re-registering after a lapse in registration. Verification should be done via a check in FMS using the search function. Sometimes searching using a variety of search inputs will identify the firm. (see [Searching in Firm Management Services \(FMS\) \(WI-000021\)](#))
6. The Program/Division OEI Coordinator assigns an FEI number (or uses one that has previously been assigned to that firm) and returns the email with the PDF and FEI/registration number, to the Center contact. The FEI/Registration number may be either handwritten on the form which is scanned or typed into an Excel spreadsheet or Word document.
7. If duplicate registration information for an establishment is received, the Program/Division OEI Coordinator returns any information received from the Center, including that the information indicating duplicate information, and provides the registration number. No other action is required.
8. If, in the opinion of the Program/Division OEI Coordinator, the establishment does not meet the registration requirements of the regulations:
  - a. The Program/Division OEI Coordinator should not generate an FEI number/assign a registration number.
  - b. Indicate on the email containing the PDF file that the firm is "NOT REQUIRED TO REGISTER" and attach the appropriate documentation for the decision. The reasons should be clearly stated. The reasons may be either handwritten on the form which is scanned or typed into an Excel spreadsheet or word document.
9. **Registration of Blood Establishments Eligible for CMS Exemption under 21 CFR 607.65(f)** - CBER will review the initial submission and notify the establishment and the appropriate district if the establishment is exempt from registration under 21 CFR 607.65(f)<sup>1</sup> and instead covered under the interagency agreement

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<sup>1</sup> 21 CFR 607.65(f) provides an exemption for transfusion services which are a part of a facility that is certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and which are engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components. The collection and processing of blood and blood components in an emergency situation



<p align="center"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p align="center"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p align="center"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p align="center">Page 17 of 29</p>

with CMS. A copy of the registration form will be sent to the district office stamped EXEMPT. If the establishment is not in the OEI, assign an FEI to it. The registration record must have the code for Center for Medicare & Medicaid Services (CMS) (previously known as the Health Care Financing Administration (HCFA)) obligation, "H" in the Voluntary Registration (Vol. Reg.) field.

**B. Re-Registration/Cancelled/Inactive registrations**

1. Center sends an email in November (blood establishments) or October (HCT/P establishments) to notify all current registrants of their requirement to re-register each year between November 15 and December 31.
2. Blood establishments update information in eBER
3. HCT/P establishments update information in eHCTERS
4. CBER provides Summary Reports to the Program/Division OEI Coordinator via email (one or several emails may be sent).
5. Program/Division OEI Coordinator updates information in FMS. Information to be updated includes, but is not limited to merging duplicates, and updating name, address, establishment types, industry codes, registration information, contacts, etc.
6. Any blood establishments or HCT/P establishment registration not received by CBER by the end of February are considered late.
7. HCT/P and Blood establishments for firms that fail to submit their annual registration:

In March, a list of "Failure to Register" (FTR) establishments is sent to the Program/Division OEI Coordinator by the Center. The Program/Division OEI Coordinator follows up with the firms and responds to the Center as to why the firm did not register (Tissue and Blood registration coordinators and the CBER Office of Compliance and Biologics Quality [OCBQ]).

If a firm is out-of-business, the Program/Division OEI Coordinator cancels the registration in FMS and documents this action on the "Failure to Register" list. CBER will then inactivate the firm's

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as determined by a responsible person and documented in writing, therapeutic collection of blood or plasma, the preparation of recovered human plasma for further manufacturing use, or preparation of red blood cells for transfusion are not acts requiring such transfusion services to register.

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<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 18 of 29</p>

registration in their systems according to their internal procedures. If the Program identifies a firm as out-of-business throughout the year, cancel the registration as described and send an email to CBER.

If a firm is in business and continues to meet the requirements of registration, the Program/Division OEI Coordinator will provide the registration contact information to the firm and document the actions on the “Failure to Register” list.

8. Additionally, the Program/Division OEI Coordinator may access the [Blood Establishment Registration \(BER\)](#) and [Human Cell and Tissue Establishment Registration System \(HCTERS\)](#) to verify firm registration information.

**C. Re-registration batch update option (Spring)**

1. National OEI Coordinator will contact CBER Registration contact to ask for a download of firms that have re-registered
2. National OEI Coordinator will work with FMS IT staff to utilize the list to update the registration status for Biologic and HCT/P firms in FMS
3. As data discrepancies are identified (FEIs don’t match, FEIs match to firms that are out-of-business or OASIS, etc.), reports will be sent to the Program for evaluation and action.

**D. Biologics and HCT/P District Use Codes (DUCs)**

1. District Use Codes will be applied to firms as described in [District Use Codes for Biologics and Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\) in Firm Management Services \(FMS\) \(WI-000213\)](#)
2. District Use Codes are assigned to assist Divisions with work planning and in determining the types of inspections to conduct at a firm.

**6.5.2. Center for Drug Evaluation and Research/Center for Veterinary Medicine**

**A. Initial Registration**

1. Firms register through the portals on CDER or CVM external website. For human drugs, FDA adopted the use of Extensible Markup Language (XML) files in the Structured Product Labeling (SPL) format. To transmit the SPL formatted submission, firms must use the FDA’s Electronic Submission Gateway (ESG). The

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 19 of 29</p>

information is captured in eList and available for querying reports in eDRLS. eList may also be accessed for data verification.

2. Program/Division OEI Coordinator run monthly queries against Establishment Registration Structured Product Labeling (SPL) available in eDRLS to firms without an FEI and might be new firms, ([ORA Management of Human and Animal Drug Registrations in Firm Management Services \(FMS\) \(WI-000214\)](#)), including how to identify firms that have self-identified for Veterinary products.
3. The Program/Division OEI Coordinator verifies that the registration is for a new establishment in the inventory, a previously identified establishment that is registering for the first time (firm may be in FMS for another commodity), or re-registering after a lapse in registration. Verification should be done via a check against the FMS.
4. Program/Division OEI Coordinator assigns an FEI number to the firm and provides firm with the FEI number. The Program/Division OEI Coordinator will encourage firm management to update their registration information (if incorrect, missing or an incorrect FEI, etc.) through the registration portals. Additionally, the Program/Division OEI Coordinator should determine if the firm manufactures human pharmaceuticals (DRG), animal (veterinary) drug products (VET) or both (DRG and VET) and assign the correct registration(s) to the firm in FMS.
5. Program/Division OEI Coordinator should flag whether the operations of the firm include sterile preparations or other appropriate flags.

## **B. Re-Registration/Cancelled/Inactive and Registration Maintenance**

1. CDER/CVM sends an email to notify all current registrants of their requirement to re-register each year October 1 through December 31.
2. All firms are required to submit an updated registration or “No Changes” notification in that time frame to renew registration for the following year through the electronic portals on CDER and CVM websites.
3. Any drug registration not renewed through CDER’s or CVM’s electronic portal by December 31 is considered expired and considered not current or valid until renewed.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 20 of 29</p>

4. Program/Division OEI Coordinator runs queries monthly against Establishment Registration Structured Product Labeling (SPL) available in eDRLS to identify firms that have re-registered ([ORA Management of Human and Animal Drug Registrations in Firm Management Services \(FMS\) \(WI-000214\)](#)).
5. Firms that have a status of “Dropped”, “Expired”, “Out of Business”, or “De registered” eDRLS should be followed up by the Program/Division OEI Coordinator to determine if the firm is out-of-business, no longer involved an CDER/CVM regulated activity, or has forgotten to re-register.

Program/Division OEI Coordinator updates information in FMS. Information to be updated includes, but is not limited to merging duplicates, and updating name, address, establishment types, industry codes, registration, contacts, etc. This includes canceling the registration if appropriate.

### C. GDUFA Firms

1. This is a self-identification code, NOT a registration code, even though the information is entered into the Registration screens in FMS.
2. In June, after the self-identification portal closes, and then at least annually, the Program/Division OEI Coordinator accesses the User Fee Facility Data Management (UFFDM) to query for self-identified firms ([ORA Management of Human and Animal Drug Registrations in Firm Management Services \(FMS\) \(WI-000214\)](#)).
3. Alternatively, CDER publishes a fiscal year “[Self-Identification of Generic Drug Facilities, Sites, and Organizations Spreadsheet](#)” under the “User Fee Lists” section. This document is only updated annually.
4. The Program/Division OEI Coordinator adds the GDUFA identifier in the Registration Screen in FMS.
5. The Program/Division OEI Coordinator compares the previous year’s list with the current year’s list and delete the GDUFA identifier for those firms no longer on the list. The previous year’s list may also be queried through UFFDM.
6. Alternatively, the National OEI Coordinator will extract the annual GDUFA list from UFFDM. Th National OEI Coordinator will work with FMS IT staff to utilize the list to update the registration status GDUFA self-identified firms in FMS. As data discrepancies are identified (FEIs don’t match, FEIs match to firms that are out-of-

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 21 of 29</p>

business or OASIS, etc.), reports will be sent to the Program for evaluation and action.

**D. CVM District Use Codes (DUCs)**

1. District Use Codes will be applied to firms as described in [District Use Codes for Veterinary Drug and Medicated Feed Mill Facilities in Firm Management Services \(FMS\) \(WI-000212\)](#)
2. District Use Codes are assigned to assist Divisions with work planning and in determining the types of inspections to conduct at a firm.

**6.5.3. Center for Devices and Radiological Health**

**A. Initial Registration**

1. Firms register through FURLS/DRLM
2. CDRH Device Registration and Listing staff screen the information for new registrants.
3. CDRH Device Registration and Listing staff sends an Excel spreadsheet for the firms that are waiting for an FEI/Registration Number to be assigned and a snapshot of each firm’s registration and listing information to each Program/Division OEI Coordinator.
4. The Program/Division OEI Coordinator verifies that the registration is for a new establishment in the inventory, a previously identified establishment that is registering for the first time (firm may be in FMS for another commodity) or re-registering after a lapse in registration. Verification should be done via a check against FMS.
5. The Program/Division OEI Coordinator assigns an FEI number (or uses one that has previously been assigned to that firm) and enters the FEI number into the “Registration Number” column on the spreadsheet. The monitor sends the completed Excel Spreadsheet to the CDRH Registration Information email account (regnum@cdrh.fda.gov). The Program/Division OEI Coordinator maintains a hardcopy/electronic pdf of the registration in the district’s Public Information or appropriate Registration File.
6. If duplicate registration information for an establishment is received, the Program/Division OEI Coordinator should enter “Duplicate” and the FEI Number in the “Registration Number” column on the Excel Spreadsheet. No other action is required.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 22 of 29</p>

7. If, in the opinion of the Program/Division OEI Coordinator, the establishment does not meet the registration requirements of the regulations:
  - a. The monitor should not generate an FEI number/assign a registration number.
  - b. The Program/Division OEI Coordinator should enter "NOT REQUIRED TO REGISTER" and include a statement documenting why the firm is not required to register. The reasons should be clearly stated.
  - c. CDRH may request that the firm receive a registration number. The firm should be entered into FMS with a "Voluntary" status for the device registration.

**B. Re-registration/Cancelled/Inactive and Cancelled Registrations**

1. CDRH Device Registration and Listing staff send an email to notify all current registrants of their requirement to re-register each year. The emails are sent November and December of each year.
2. Limited information and registration information for firms which re-register through FURLS/DRLM will automatically transfer to FMS. Periodically, CDRH Device Registration and Listing staff will send periodic "Registration Change" Reports to each Division listing changes identified as firms update their registration information in FURLS/DRLM. The "Change Report" includes changes to firm information and registration status.
3. Changes should be followed up by the Program/Division OEI Coordinator to determine if the firm is out-of-business, no longer involved an CDRH regulated activity, or has forgotten to re-register.
4. Program/Division OEI Coordinator updates information in FMS. Information to be updated includes, but is not limited to merging duplicates, and updating name, address, establishment types, industry codes, registration, contacts, etc.

**C. Radiological Health District Use Codes (DUC)**

1. Periodically, CDRH/Office of In Vitro Diagnostics and Radiological Health (OIR)/ Division of Radiological Health (DRH) will send the National OEI coordinator or the Program a list of firms that will need to be assigned DUCs.
2. Radiological Health DUCs should be added to firms as applicable as they are inspected.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 23 of 29</p>

3. District Use Codes will be applied to firms as described in [District Use Codes for Radiological Health Products in Firm Management Services \(FMS\) \(WI-000147\)](#)
4. District Use Codes are assigned to assist Divisions in determining the types of inspections to conduct at a firm.

#### **6.5.4. Center for Food Safety and Applied Nutrition**

##### **A. Initial Registration**

1. Facilities register through FURLS/FFRM
2. Limited information is automatically transferred from FURLS/FFRM to FIDA
  - a. If the IT systems are unable to match a FFRM record to an existing FIDA record, a record is created in FIDA with a Workload Obligation “Bioterrorism” (“B”) status (which is then transferred to FMS).
3. Program/Division OEI Coordinator run [ORADDS](#) report FIR002 “Firm Listing” or FIR052 “Firms Registration by Commodity” monthly to identify firms with a Workload Obligation of “B” (“Bioterrorism”)
  - a. Program/Division OEI Coordinator check the lists for duplicates, and merge
  - b. Program/Division OEI Coordinator will determine information about the firm, update the information in FMS, and determine if the Workload Obligation should be “Yes” (“Y”) or “No” (“N”)

##### **B. Biennial Registration Renewal**

1. CFSAN personnel send an email to notify all current registrants of their requirement to renew each even-numbered year. The renewal window is from October 1 to December 31
2. As firms renew in FURLS/FFRM, limited registration information is automatically transferred from FURLS/FFRM to FIDA.

##### **C. Cancelled/Inactive Registrations**

1. Registrations that are listed as “Invalid” or “Cancelled” in FIDA/FMS should be followed up by the Program/Division OEI Coordinator to determine if the facility is out-of-business, no longer involved in a CFSAN activity which requires registration, or has forgotten to renew or re-register.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: right;">Page 24 of 29</p>

**Note:** While some firms are not required to register per CFSAN regulation ([Retail Food Establishment Exemption](#)), they may still be subject to inspection under certain regulations and may need to remain Workload Obligation “Yes”. These firms should NOT be updated to “Dealer/Retailer” and made a Workload Obligation “No” based solely on their registration status.

2. Program/Division OEI Coordinator updates information in FMS. Information to be updated includes, but is not limited to merging duplicates, and updating name, address, establishment types, industry codes, registration, contacts, etc.

### 6.5.5. Center for Tobacco Products

#### A. Registration

1. Firms register through FURLS/TRLM
2. CTP receives tobacco product establishment registration information and performs several quality checks. CTP personnel then notify the Program/Division OEI Coordinator via email of any new registrations, including a request for the assignment of an FEI.
3. The Program/Division OEI Coordinator verifies that the registration is for a new establishment in the inventory, a previously identified establishment that is registering for the first time (firm may be in FMS for another commodity) or re-registering after a lapse in registration. Verification should be done via a check against FMS.
4. The Program/Division OEI Coordinator assigns an FEI number (or uses one that has previously been assigned to that firm) and provides the FEI number in their response email to CTP registration.
5. If duplicate registration information for an establishment is received, the Program/Division OEI Coordinator provide this information in the response email to CTP Registration. No other action is required.

#### B. Re-registration

1. CTP Registration and Listing staff send an email to notify all current registrants of their requirement to re-register each year. These are sent December of each year. Tobacco firms can register any time within a calendar year to be considered registered for that calendar year.
2. Limited information and registration information for firms which re-register through FURLS/TRLM will automatically transfer to FMS.



<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 25 of 29</p>

## 6.6. Verification of Registration by an Investigator during an inspection

**6.6.1** The Investigator verifies the firm's registration status in FMS during an inspection and takes actions as follows:

- A. Registration is current for the calendar (or for foods biannual) registration period: no action needed
  - B. Registration is NOT current for the calendar (or for foods biannual) registration period: the investigator will contact the Program/Division OEI Coordinator who will determine if the information corresponds to that in the Center registration database. If it does not, the Program/Division OEI coordinator will update as appropriate or provide the Center registration information to the Investigator to share with the firm (or contact the firm with the information themselves)
  - C. If a firm is in business, but not required to register:
    1. If the firm is no longer engaged in activities that require registration, encourage the firm to update their electronic registration if they are still registered with the Center. Investigator to provide contact information from [Section 6.1](#) of this procedure.
    2. If the firm is registering with the Center because they want to (and not required by regulation), confirm that the registration field in FMS is flagged as a voluntary registrant ("V" in "Vol. Reg" field in FMS). If not, provide information to the Program/Division OEI coordinator who will update the record.
  - D. For those establishments that are required to register, and are an active FDA obligation, classify these firms as per [SOP-51](#), and provide contact information from [Section 6.1](#) of this procedure to update the electronic registration.
  - E. Out-of-business: For those establishments which have gone "Out of Business" (OOB) since the last inspection, classify as OOB, update the OEI, provide information to the firm for updating their electronic registration, and contact the Centers as per [Section 6.1](#) of this procedure.
  - F. "Pre-Production Registration" or "Not Yet Operational": update FMS
- NOTE:** If, during any type of work performed by an FDA employee (or contractor), a firm is identified that should have been registered or requires a change in registration, the employee should provide

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: center;">Page 26 of 29</p>

this information to the Program/Division OEI Coordinator. The Program/Division OEI Coordinator should provide the firm with Center contact information or the external Center registration site. CDRH and CBER have also requested to be notified of these firms via an email which will include the registration number, firm name and address, and reason for change in status.

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## 7. Glossary/Definitions

- A. **EDRLS:** Electronic Drug Registration and Listing System
- B. **Food Facility:** Any establishment, structure, or, structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities. (21 CFR 1.227(b)(2))
- C. **FACTS:** Field Accomplishments and Compliance Tracking System
- D. **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.
- E. **FMS:** Field Management System, 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.
- F. **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

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>Office of Strategic Planning and Operational Policy</i></p>	<p style="text-align: center;"><b>Document Number:</b>  <b>SOP-000353</b></p>	<p style="text-align: center;"><b>Revision #: 00</b>  <b>Revised:</b>  12/11/2019</p>
<p><b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b></p>		<p style="text-align: right;">Page 27 of 29</p>

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.

- G. **Files:** these may either be electronic or paper
- H. **FURLS:** FDA's Unified Registration and Listing System
- I. **FURLS/DRLM:** FDA's Unified Registration and Listing System/Device Registration and Listing Module
- J. **FURLS/FFRM:** FDA's Unified Registration and Listing System/Food Facility Registration Module
- K. **FURLS/TRLM:** Tobacco Registration Listing Module
- L. **Official Establishment Inventory (OEI):** Includes information about establishments under FDA regulation. These include establishments determined to be 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. **Public Information File:** Copies of registration forms for establishments located within a particular geographic area are available for inspection at FDA district offices responsible for that geographical area. For additional information, see per 21 CFR Part 807.37

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## 8. Records

All OEI Records are stored in the Firm Management Services (FMS) application.

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## 9. Supporting Documents

- A. [Data Entry Fields in Firm Management Services \(FMS\) \(WI-000022\)](#)
- B. [District Use Codes \(DUC\) for Biologics and Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\) in Firm Management Services \(FMS\) \(WI-000213\)](#)
- C. [District Use Codes \(DUCs\) for Radiological Health Products in Firm Management Services \(FMS\) \(WI-000147\)](#)

<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>Office of Strategic Planning and Operational Policy</i>	<b>Document Number:</b> <b>SOP-000353</b>	<b>Revision #: 00</b> <b>Revised:</b> 12/11/2019
<b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b>		Page 28 of 29

- D. [District Use Codes \(DUCs\) for Veterinary Drug and Medicated Feed Mill Facilities in Firm Management Services \(FMS\) \(WI-000212\)](#)
- E. [Establishment Types and Industry Code \(WI-000024\)](#)
- F. [Firm-FDA Establishment Identifier \(FEI\) \(WI-000026\)](#)
- G. [OEI Development Maintenance Procedure \(SOP-000051\)](#)
- H. [Official Establishment \(OEI\) Data Collection \(WI-000020\)](#)
- I. [Official Establishment Data Collection Form \(FORM-000173\)](#)
- J. [ORA Management of Human and Animal Drug Registrations in Firm Management Services \(FMS\) \(WI-000214\)](#)
- K. [Searching in Firm Management Services \(FMS\) \(WI-000021\)](#)
- L. [Registration Process Maps](#)

## 10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	01/11/2017	Lori Lawless, National OEI Coordinator	Kate Bent, Director OPRM
02	R		Lori 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	This document replaces FMD-92 "Agency Establishment Registration and Control Procedures (FMD#92)".
2.0	THIS DOCUMENT REPLACES FMD 92 "ADDING DISTRICT USE CODES FOR RADIOLOGICAL HEALTH", FORMATTING UPDATED, NUMBERING UPDATED TO BE CONSISTENT WITH QMIS VERSION 11.6, AND SIGNIFICANT CHANGES THROUGHOUT DUE TO PROGRAM ALIGNMENT.

<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>Office of Strategic Planning and Operational Policy</i>	<b>Document Number:</b> <b>SOP-000353</b>	<b>Revision #: 00</b> <b>Revised:</b> 12/11/2019
<b>ORA Establishment Registration and Control Procedure (Formerly FMD# 92)</b>		Page 29 of 29

## 12. Attachments

List of Attachments

**No table of contents entries found.**