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1. Purpose

This procedure establishes consistent instructions for processing and monitoring firm registrations from any Center. It summarizes field and headquarters responsibilities and ensures Establishment Registration information is in the Center files and the field's Official Establishment Inventory (OEI) and Registration files.

2. Scope

This document applies to all district offices, the Office of Food and Feed Operations (OFFO)/Division of Food and Feed Program Operations and Inspections (DFFPOI) and Office of Medical Products and Tobacco Operations (OMPTO)/Division of Medical Products and Tobacco Program Operations (DMPTPO).

3. Guidelines

This document supplements commodity specific regulations regarding firm registrations, as described in Background.

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.

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 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.

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 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 1st and December 31st 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.

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, received, 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:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food

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 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.

5. Procedures/Responsibilities

5.1 Responsibilities

A. Centers
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 re-register their establishment.

B. DFFPOI/DMPTPO
1. Maintains a master roster of all Registration Monitors, by program area (included in the blue pages of IOM).
2. Identifies one or more persons as Registration Monitor(s) for the various foreign program areas.
3. Functions as the district office for all foreign firms and performs the duties described herein for foreign firm registration.

C. National OEI Coordinator:
1. Acts as the liaison between the Centers and the districts.
2. Responsible for revising FMD 92 and associated work instructions.

D. District Office
1. Identifies one or more persons as Registration Monitor(s) for the various program areas.

2. Ensures DFFPOI/DMPTPO is notified immediately of changes to district Registration Monitors using the IOM Change Request/Notice (ICR), http://inside.fda.gov:9003/ORA/OfficeofRegionalOperations/DivisionofFieldInvestigations/default.htm.

E. District Investigations Branch
1. Determines within ten (10) working days whether or not a newly identified establishment, from a source other than a Center (for example complaints, investigations, inspections, etc.), is required to register, either by an inspection of or telephone conversation with the establishment.
2. Supplies the appropriate program area Registration Monitor with the basic information about the status of the new establishment, including the types of products produced.

F. Registration Monitors or designee
1. Ensures all registration information and associated information for firms in their program area(s) are updated in FMS.
2. Merges duplicate firms.
3. Ensures that all work on new registrants is processed and the appropriate Center is notified within fifteen (15) working days after the forms or electronic information is received from the Center or Center accessible computer systems.
4. Generates or identifies the FEI for the facility registration as required and provides this information to the Center as described below.
5. Updates FMS with annual registration updates.
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), along with the OEI Coordinator. 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 Parts 207.37, 607.37, 807.37, 1271.37.

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

H. 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.

5.2 Communications/Points of Contact

A. Registrations and re-registrations may be received by the district and DFFPOI/DMPTPO from several sources as described in this FMD.
NOTE: If the districts or DFFPOI/DMPTPO receive registration or listing information directly from the registrants, they are to be referred to the appropriate Center (below).

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

C. Registration problems that are related to the mechanics of data processing should be referred to:
   1. ERIC ; eric@fda.hhs.gov; (866) 807-3742
   2. APPS Desk: APPSDesk@fda.hhs.gov; (240) 241-5636

D. 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 5.2(D), not the contractors.

Center	Email and Phone	Address
CBER Blood Establishments	bloodregis@fda.hhs.gov 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
CBER HCT/P Establishments	tissuereg@fda.hhs.gov Telephone: 240-402-8369 Fax: 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
CDER	edrls@fda.hhs.gov No phone listed GDUFA inquiries: AskGDUFA@fda.hhs.gov	Food and Drug Administration Center for Drug Evaluation and Research Drug Registration and Listing Staff 10903 New Hampshire Ave Silver Spring, MD 20993

CDRH	device.reg@fda.hhs.gov (301) 796-7400	Center for Devices and Radiological Health CDRH Registration and Listing Policy Helpdesk 10903 New Hampshire Avenue Silver Spring, MD 20993
CFSAN (General)	CFSAN Food Facility Registration@fda.gov 1-800-216-7331 or 301-575-0156	U.S. Food and Drug Administration Food Facility Registration 5100 Paint Branch Pkwy HFS-681 College Park, MD 20993
CFSAN (LACF)	LACF@FDA.HHS.GOV 240-402-2411	U.S. Food and Drug Administration LACF Registration Coordinator 5100 Paint Branch Pkwy HFS-303 College Park, MD 20993
CFSAN* (Cosmetics)	http://www.fda.gov/Cosmetics/RegistrationProgram/PaperRegistration/default.htm http://www.fda.gov/Cosmetics/RegistrationProgram/OnlineRegistration/default.htm Phone not available	Voluntary Cosmetics Registration Program Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835
CTP	CTPRegistrationandListing@fda.hhs.gov Phone not available	Center for Tobacco Products Division of Enforcement and Manufacturing 10903 New Hampshire Avenue Silver Spring, MD 20993
CVM	AskCVM@fda.hhs.gov (240) 276-9300	Food and Drug Administration Center for Veterinary Medicine Division of Surveillance, HFV-210 7519 Standish Place Rockville, MD 20855

*The Voluntary Cosmetic Registration Program (VCRP) is handled by CFSAN's Office of Cosmetics and Colors, Division of Programs and Enforcement Policy. VCRP forms can be faxed to the Office of Cosmetics and Colors at (301) 436-2975. VCRP filers may obtain printed forms from their nearest FDA District Office or by contacting the Office of Cosmetics and Colors. They also may download forms from the FDA Web site, or may participate in the VCRP using our online system at: http://www.fda.gov/cosmetics/registrationprogram/onlineregistration/default.htm.

5.3 Overview

Registrations may be received by the Districts and DFFPOI/DMPTPO from several sources as follows:

Center for Biologics Evaluation and Research	Form FDA 2830 (Blood Establishment Registration and Product Listing)

(CBER):	Form FDA 3356 (Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps))
Center for Drug Evaluation and Research (CDER):	Electronic Drug Registration and Listing System (eDRLS)
Center for Devices and Radiological Health (CDRH):	FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM)
Center for Food Safety and Applied Nutrition (CFSAN)	FURLS/Food Facility Registration (FFR) FURLS/Shell Egg FURLS/Acidified/Low Acid Canned Foods 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)	FURLS/Tobacco Registration and Product Listing Module (TRLM) Form FDA 3741 (Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments)
Center for Veterinary Medicine	Electronic Drug Registration and Listing System (eDRLS)

NOTE: If the districts or DFFPOI/DMPTPO receive registration or listing information directly from the registrants, they are to be referred to the appropriate Center (5.2).

5.4 Maintenance of Registration Files

A. The Centers (following their own internal policies and procedures) maintain registration files for:
   1. Addition of new registrants.
   2. Removal of registrants who are not required to register or are "Out of Business," following receipt of information from the field.
   3. Tracking or monitoring "late" registrants (i.e. registered for the previous year but not re-registered for the current year).
   4. 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.

B. The registrant should save a copy of all registration and re-registration files.
C. The OEI 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.
D. Electronic registration information should be reviewed monthly for medical devices, drugs, animal (veterinary) drugs, biologics and food facilities as described in Section 6. References/Supporting Documents for related Work instructions). The Cosmetics Registration File is entirely composed of voluntary registrants.

5.5 Registration Numbers

A. 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 registration Unique Facility Identifier (UFI). The FEI number is an optional data element included with this type of registration. Firms are encouraged to include it with their registration submission if they know it, but it is not required. FEI continues to be used by ORA as the identifier for these firms.
B. CDRH, CBER (blood components, HCT/Ps, and licensed devices) and CTP: The registration number is the ten-digit FEI assigned to the establishment by the district or DFFPOI/DMPTPO. 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.
C. CFSAN: The food facility registration (FFR) number is generated by FURLS, along with an FEI number matched or generated from FMLS.

5.6 Procedures for Registration/Re-registration

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 5.2(D), 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.

5.6.1 Center for Biologics

A. Initial Registration

1. Blood establishments register through the Electronic Blood Registration System (eBER) or by submitting Form 2830 via postal mail/FAX.
2. HCT/P establishments register through the Electronic Human Cell and Tissue Establishment Registration System (eHCTERS) or by submitting Form 3356 via mail or FAX.
3. Using their own internal procedures/policies, CBER personnel screen the information for new registrants.

4. CBER personnel emails the District Registration Monitor a PDF of Form 2830 (Blood) or Form FDA 3356 (HCT/P) for the registered firm.
5. The Registration Monitor 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. (WI for searches is being developed).
6. The Registration Monitor 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. The Registration Monitor maintains a hardcopy pdf of the registration form (if one is available) in the district's Public Information or appropriate Registration File.
7. If duplicate registration information for an establishment is received, the Registration Monitor 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 Registration Monitor, 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. 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.
    c. 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 that 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. If an establishment is a "Voluntary Registrant" because it is not required to register, but does so for its own purposes, the establishment registration form should be marked by the applicant. The Registration Monitor updates FMS by indicating a voluntary registration in the registration fields. The appropriate Center should be notified of the firm's voluntary status.
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)[1] and instead covered under the interagency agreement 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, DO NOT ASSIGN AN FEI TO IT. If the establishment is in the OEI, 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 or submit Form 2830 by mail.
3. HCT/P establishments update information in eHCTERS or submit Form 3356 via mail or fax.
4. CBER provides a PDF of Form 2830 or 3356 to the Registration Monitor via email (one or several emails may be sent).
5. Registration Monitor 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 shall be 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 each district by the Center. The Registration Monitor follow up with the firms and responds to the Center (Tissue and Blood registration coordinators and the CBER Office of Compliance and Biologics Quality [OCBQ]). The follow-up currently takes about a month.

[1] 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 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.

8. If a firm is out-of-business, the Registration Monitor cancels the registration in FMS, and documents this on the "Failure to Register" list. CBER will then inactivate the firm's registration in their systems according to their internal procedures. If the district identifies a firm as out-of-business throughout the year, cancel the registration as described and send an email to CBER.
9. Additionally, Registration Monitors may access the Blood Establishment Registration (BER) and Human Cell and Tissue Establishment Registration System (HCTERS) on Inside FDA at http://inside.fda.gov:9003/CBER/default.htm to verify firm registration information.

5.6.2 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 information is captured in eList and available for querying reports in eDRLS. eList may also be accessed for data verification.
2. Registration Monitor runs monthly queries against Establishment Registration Structured Product Labeling (SPL) available in eDRLS (See Attachment B for Work Instruction), including how to identify firms that have self-identified for Veterinary products.
3. The Registration Monitor 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. Registration Monitor assigns an FEI number to the firm and contacts firm management to provide them with the FEI number. The Registration Monitor will encourage firm management to update their registration information through the registration portals. Additionally, the Registration Monitor 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.
5. Registration monitors 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 are considered expire, and considered not current or valid until renewed.
4. Registration Monitor runs queries monthly against Establishment Registration Structured Product Labeling (SPL) available in eDRLS. (See Attachment B).
5. Firms that are in "Inactive" status in eDRLS should be followed up by the District Registration Monitor to determine if the firm is out-of-business, no longer involved an CDER/CVM regulated activity, or has forgotten to re-register.

   Registration Monitor 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 District Registration Monitor accesses the User Fee Facility Data Management (UFFDM) to query for self-identified firms (See Attachment B)
3. Alternatively, CDER publishes a fiscal year "Self-Identified Generic Drug Facilities, Sites, and Organizations Spreadsheet" http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm. This document is only updated annually.
4. The District Registration Monitor adds the GDUFA identifier in the Registration Screen in FMS.
5. The District Registration Monitor 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.

5.6.3 Center for Devices and Radiological Health

A. Initial Registration

1. Firms register through FURLS/DRLM.
2. CDRH personnel screen the information for new registrants.
3. CDRH sends an Excel spreadsheet for the firms that are still waiting for an FEI/Registration Number to be assigned and a snapshot of each firm's registration and listing information to each District Registration Monitor. (See Attachment C)
4. The Registration Monitor 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 Registration Monitor 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 Registration Monitor maintains a hardcopy 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 Registration Monitor should enter "Duplicate" and the FEI Number in the "Registration Number" column on the Excel Spreadsheet. No other action is required.
7. If, in the opinion of the Registration Monitor, 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 Registration Monitor should enter "NOT REQUIRED TO REGISTER" and attach a memo documenting why the firm is not required to register. The reasons should be clearly stated.
8. 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 this information to the District Device Registration monitor. The Registration Monitor should provide the firm with CDRH contact information and send an email to device.reg@fda.hhs.gov to alert CDRH to follow up with firm, include the registration number, firm name and address, and reason for change in status.

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

1. CDRH personnel send an email to notify all current registrants of their requirement to re-register each year. These are sent November and December of each year.
2. CDRH has a Business Objects report titled, "Device Registration Maintenance Info By District v1". This report should be run monthly (November through January) and quarterly for the remainder of the year to update the registration and listing information for re-registrant. (See Attachment C).
3. Firms that are in "Inactive" status in FURLS/DRLM should be followed up by the District Registration Monitor to determine if the firm is out-of-business, no longer involved an CDRH regulated activity, or has forgotten to re-register.
4. Registration Monitor 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 and District Use Codes

1. Annually, CDRH/Office of In Vitro Diagnostics and Radiological Health (OIR)/ Division of Radiological Health (DRH) will send the National OEI coordinator a list of firms that will need to be assigned District Use Codes (DUC).
2. District Use Codes are assigned to assist districts in determining the types of inspections to conduct at a firm.
3. District Registration Monitors should follow the directions in Attachment D when assigning district use codes for Radiological products.

5.6.4 Center for Food Safety and Applied Nutrition

A. Initial Registration

1. Firms register through FURLS/FFRM.
2. Information is automatically transferred from FURLS/FFRM to FMS.
3. New firms will enter FMS as workload obligation “Bioterrorism” (“B”) status.
4. Sometimes the IT connection between FURLS/FFRM and FMS does not identify that a firm exists in FMS, and will create a duplicate firm record in FMS with a workload obligation “Bioterrorism” (“B”) status.
5. Registration Monitors run ORADDS report FIR 002 “Firm Listing” monthly to identify firms with a workload status of “B” (“Bioterrorism”).
6. Registration Monitors check the lists for duplicates, and merge.
7. The Registration Monitors 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 registrations of their requirement to renew each even-numbered year. The reregistration window is from October 1 to December 31.
2. Information is automatically transferred from FURLS to FMS. Existing firm registration information will be updated automatically.

C. Cancelled/Inactive Registrations

1. Firms that are listed as “Invalid” or “Cancelled” in FURLS/FFRM should be followed up by the District Registration Monitor to determine if the firm is out-of-business, no longer involved in a CFSAN regulated activity, or has forgotten to re-register.
2. Registration Monitor 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.

5.6.5 Center for Tobacco Products

A. Registration

1. CTP receives tobacco product establishment registration information and notifies the appropriate District Registration Monitor via email of any new registrations.

B. Re-registration

1. All inspections of tobacco product establishments are performed by the Tobacco Cadre in DMPTPO/OMPTO. CTP will work with DMPTPO/OMPTO, the appropriate District Tobacco Monitor, and Registration Monitor to ensure that tobacco product establishment registration information is electronically entered into the relevant ORA system(s).

5.7 Verification of Registration by an Investigator during an inspection

A. The Investigator verifies the firm's registration status during an inspection and takes actions as follows:
   1. Currently registered: no action needed
   2. Required to register or re-register: the investigator will provide the firm contact information from Section 5.2 of this FMD.
   3. In business, but not obligated to register:
      a. If no longer engaged in activities that require registration, encourage the firm to update their electronic registration, and provide contact information from Section 5.2 of this FMD.
      b. For CDER, CVM, and CTP: If voluntarily registered, DO NOT send notification to the Center, but make certain that the registration is flagged as a voluntary registrant ("V" in "Vol. Reg" field in FMS)
      c. For CBER: If voluntarily registered, send notification to the Tissue Establishment Registration Monitor who will update HCTERS accordingly. Flag the registration a voluntary registrant ("V" in "Vol. Reg" field in FMS)
   4. For those establishments that are not required to register, but are an active FDA obligation, classify these firms as per FMD-130, and provide contact information from Section 5.2 of this FMD to update the electronic registration.
   5. 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 5.2 of this FMD.
   6. "Pre-Production Registration" or "Not Yet Operational": update FMS

B. Update FMS and notify the Centers as follows:
   1. CBER: Email CBER Tissue Establishment Registration Coordinator or CBER Blood Registration Coordinator.
   2. CDER/CVM: no need to contact, District should work with firm
   3. CDRH: Email CDRH Registration Information at regnum@fda.hhs.gov and state the reason for the change in status in the email:
      a. If the registration information obtained during the inspection is different from the information in FFRM, send an email to CFSANFoodFacilityRegistration@fda.hhs.gov with the facility name, FEI or

registration number, and the specific registration information that is inaccurate (e.g., food categories, physical address).

b. If the facility is operating and has not submitted food facility registration, send an email to CFSANFoodFacilityRegistration@fda.hhs.gov with the facility name, FEI, and a statement that the facility is operating and has not submitted a valid food facility registration (e.g., operating with no registration, operating with a suspended registration, operating with an invalid registration, or operating with a cancelled registration). (IOM 5.4.1.5.3 - INSPECTIONAL GUIDANCE)

4. CTP: All inspections of tobacco product establishments are performed by the Tobacco Cadre in OMPTO/DMPTPO. CTP works with OMPTO/DMPTPO, the appropriate District Tobacco Monitor, and Registration Monitor to ensure that tobacco product establishment registration information is electronically entered into the relevant ORA system(s).

C. The investigator/inspector or Registration Monitor notifies the gaining district if the firm moves to another district.

D. **NOTE:** The Centers are the final authority for cancellation of registrations. If the Center does not agree with the decision to cancel the registration, the Center will notify the monitor.

6. References/ Supporting Documents

A. 21 CFR PARTS 207, 607, 807, and 1271

B. Inspection operations manual, section 951

C. Instruction publications for registration and listing (furnished upon request by the appropriate center)

D. COMPLIANCE PROGRAMS

1. CBER: 7341.002, 7341.002A, 7342.001, 7342.002, 7342.008, 7345.848
2. CDER: 7356.014
3. CDRH: 7382.845
4. CFSAN
5. CTP
6. CVM:

E. Compliance policy guides manual (March 1995), chapter 4 (7132.07) drugs, chapter 2 (7134.01) biologics and chapter 6 (7125.25) veterinary medicine

F. Blood Establishment Registration (BER) Intranet Query: http://inside.fda.gov:9003/ProgramsInitiatives/Biologics/EstablishmentRegistration/ucm013338.htm

G. Drug Registration and Listing System (DRLS & eDRLS) external: http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/drugregistrationandlisting/ucm2007058.htm

H. Drug Registration and Listing System (DRLS & eDRLS) internal: http://inside.fda.gov:9003/CDER/default.htm Electronic Drug Registration and Listing System under Frequently-Used CDER Links

I. eList: http://elist/prpllr/

J. Generic Drug User Fee Amendments of 2012: http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm

K. Human Cell and Tissue Establishment Registration System (HCTERS) Query: http://inside.fda.gov:9003/ProgramsInitiatives/Biologics/EstablishmentRegistration/ucm013341.htm

7. Definitions/Glossary

A. EDRLS: Electronic Drug Registration and Listing System
B. FACTS: Field Accomplishments and Compliance Tracking System
C. FMS: Field Management System
D. Files: these may either be electronic or paper
E. FURLS: FDA's Unified Registration and Listing System (http://www.access.fda.gov/)
F. FURLS/DRLM: FDA's Unified Registration and Listing System/Device Registration and Listing Module
G. OEI: Official Establishment Inventory
H. 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 Parts 207.37, 607.37, 807.37, 1271.37.
I. TRLM: Tobacco Registration Listing Module

8. Records

Records must be maintained and distributed in accordance with applicable requirements.

9. Attachments

A. Process Map
B. District Implementation of Drug (Human and Animal) Registrations
C. Adding District Use Codes for Veterinary Drug and Medicated Feed Mill Facilities
D. Adding District Use Codes for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)Feed Mill Facilities

E. District Implementation of Device Registrations

F. Adding District Use Codes for Radiological Health Products

10. Document History/Change History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	R	7/2/15	LORI LAWLESS, NATIONAL OEI MONITOR	KATE BENT, DIRECTOR OPRM

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

1.0 Previous versions of this document exist and are archived (http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061432.htm), however version numbering was not included. This is the first version in the new format.