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In this section: Drug Approvals and Databases The drug establishments current registration site is a publication of currently registered establishments which manufacture, prepare, propagate, compound or process drugs that are distributed in the U.S. or offered for import to the U.S. This file is updated each business day. Any establishment is automatically removed from the database if its registration is inactivated by FDA due to a compliance case. Registrations that expire, deregister or are otherwise dropped from submission are also removed from the database. Establishments must be registered within five days of beginning operations. Additionally, establishments must renew registration annually between October 1 and December 31 of each year. Establishments that send initial or annual registrations during the October 1 to December 31 period are considered registered until the end of following calendar year. Any registration submission received outside of this timeframe does not extend the registration expiration date beyond the current calendar year. Example 1: A new, updated or annual establishment registration structured product labeling (SPL) is received on October 1, 2020. Registration is current through December 31, 2021. Example 2: A new, updated or annual establishment registration SPL is received on September 30, 2020. Registration is current through December 31, 2020. The updated establishment registration must be submitted between October 1, 2020, and December 31, 2020 to remain current through December 31, 2021. Download and Search About the registration database This database does not contain establishments registered as human drug compounding outsourcing facilities An outsourcing facility may appear in the database if it also registered under other business operations This database does not contain wholesale drug distributors and third-party logistics providers that report licensure annually to the FDA as required by the Drug Supply Chain Security Act Questions ContacteDRLS@fda.hhs.gov with questions on the electronic registration and listing requirements. See points of contact for drug registration and listing for more information. Back to Top Domestic and foreign establishments that manufacture, repack, or re-label animal drug products in the United States are required to register with the FDA. Domestic and foreign drug manufacturers, repackers or re-labelers are also required to list all of their commercially marketed drug products. This process is done in conjunction with the human drug registration process. Cosmetics FDA stopped accepting and processing both electronic and paper submissions to the voluntary registration program for cosmetics establishments and products on March 27, 2023. We are developing a program for submission of the facility registrations and product listings mandated by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) and will provide further updates on its forthcoming availability. For more information, please visit: Modernization of Cosmetics Regulation Act of 2022. Drugs Domestic and foreign establishments that manufacture, repack, or re-label drug products in the United States are required to register with the FDA. Domestic and foreign drug manufacturers, repackers or re-labelers are also required to list all of their commercially marketed drug products. This information helps the FDA maintain a catalog of all drugs in commercial distribution in the United States. Food Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S. are required to register the facility with the FDA. Registration of Food Facilities Medical Devices Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration. Device Registration and Listing Radiation-Emitting Products Filing Radiation Safety (Product) Reports for radiation emitting products is required by law. The FDA eSubmitter software replicates several reporting guides and forms. The electronic templates currently available in eSubmitter represent most forms industry is required to submit to FDA. eSubmitter: Radiological Health Program Tobacco Products Under section 905 of the Tobacco Control Act, every person who owns or operates any domestic establishments engaged in the manufacture, preparation, compounding, or processing of a regulated tobacco product must register those establishments with FDA by December 31 of each year. All registrants must also submit a list of all tobacco products which are being manufactured by that person for commercial distribution, along with certain accompanying information including all labeling. FDA strongly encourages electronic submission. For electronic submission of such information, FDA utilizes the Tobacco Registration and Product Listing Module - Next Generation (TLRM NG). Alternatively, you may use Form FDA 3741 for Establishment Registration and Product Listing. Persons with disabilities having problems accessing the above pdf file may call 1-877-CTP-1373 for assistance. Vaccines, Blood, Biologics If you are an establishment that manufactures human cells, tissue, and cellular and tissue-based products (HCT/TPs), FDA regulations require you to register with the agency and list your HCT/TPs. Manufacture includes any or all steps involved in the recovery, processing, storage, labeling, packaging or distribution of HCT/TPs, and the screening or testing of the cell or tissue donor. See below for information on how to register with FDA. FDA regulations require all blood establishments that collect, manufacture, prepare, store under controlled conditions for further distribution or process blood and blood products to register. See below for detailed information on blood establishment registration: Domestic and foreign establishments that manufacture, repack, or re-label drug and biologic products, including vaccines, are required to register with the FDA. Domestic and foreign drug and biologics manufacturers, repackers or re-labelers are also required to list all of their commercially marketed drug and biologic products. This information helps the FDA maintain a catalog of all drugs and biologics in commercial distribution in the United States. Drug Registration and Listing System Drug Firm Annual Registration Status There are three steps, or submissions, that are needed to register an establishment and list a drug with FDA. Each of these steps requires an initial submission followed by periodic updates to maintain an accurate and current status: Establishment registration Labeler code Drug product listing(s) FDA has adopted extensible markup language (XML) files in the structured product labeling (SPL) format for users to submit registration and listing data. Users may transmit the SPL-formatted submission through FDA's electronic submission gateway (ESG). Tools for registration and listing submissions Any SPL authoring software may be used to create registration and listing SPL files including CDER Direct and Xforms. Xforms and other third-party tools used to create SPL files require the creation of a FDA WebTrader account in order to submit the files. All registration and listing submissions, regardless of the source and tool used to create and submit, must pass the same rigorous set of validation rules. Do I need to register? Any establishment, with certain exemptions, engaged in manufacturing, repackaging, relabeling or salvaging drug products for U.S. distribution is required to register with FDA. Some exemptions include: Operate in conformance with local laws regulating the practice of pharmacy and medicine Regularly engage in dispensing prescription drugs to fill patients prescriptions Do not manufacture, repack, relabel or salvage drugs other than in the regular course of their business of dispensing or selling drugs at retail hospitals, clinics, other health care entities and public health agencies that Operate establishments in conformance with all applicable local laws regulating the practice of pharmacy and medicine Regularly engage in dispensing prescription drugs upon a valid order or prescription Do not manufacture, repack, relabel or salvage drugs other than in the regular course of their practice of pharmacy, including dispensing Licensed practitioners who prescribe or administer drugs and who manufacture, repack, relabel or salvage drugs for use only in their professional practice Companies or individuals that manufacture, repack, relabel or salvage drugs solely for use in research, teaching or chemical analysis and not for sale Manufacturers, repackers and relabelers of certain inactive ingredients such as excipients, colorings, flavorings, emulsifiers, lubricants, preservatives or solvents that become components of drugs Carriers in their receipt, carriage, holding or delivery of drugs in their usual course of business Storage facilities that do not perform any manufacturing function When to register? Registration is required within five days of introducing drugs into commercial distribution. Annual registration renewal must occur between October 1 and December 31 each year. Registration process Create and submit an establishment registration SPL document to register with FDA. Be sure to save a copy of your submission. Remember to include: The name and Dun and Bradstreet verification, or Data Universal Numbering System (DUNS) number of the establishment (not one linked to the corporate headquarters) Contact information of someone responsible for receiving FDA communications related to that establishment All applicable business operations that establishment performs For foreign establishments, the name and DUNS of a U.S. agent and all importers To renew, update or deregister a registration: How do I renew a registration with no changes? FDA is sharing training and additional resources below to assist in submission questions. To submit No Change Notification using CDER Direct: Open the previously submitted and accepted Establishment Registration Click Create New Version Enter the new address/DUNS or contact information that needs to be updated Submit Structured Product Labeling (SPL). To submit a change using other applications: Create a copy/new version of the most recent submission Do not change the SetID. Retain the original SetID from the previous version Generate a new DocumentID/RootID Enter an appropriate effective date and version number (generally, one number higher than the previous submission) Modify all establishment and contact information as appropriate and submit. How do I de-register? FDA is sharing training and additional resources below to assist in submission questions. To de-register using CDER Direct: Open the previously submitted and accepted Establishment Registration Click Create New Version Change the document type to Establishment De-Registration and Submit SPL. To de-register using another application: Create an establishment deregistration SPL document. Fill in the SetID with the SetID from your previous submission Enter the appropriate effective date and version number (generally, one number higher than the previous submission) Submit. How do I know if my registration notification was successful? Check the status of your registration at the Drug Establishment Current Registration Site (DECRS). Once your submission is successful, your firm's name and information will appear with the expiration date of 12/31/2022 within 24 business hours. Do I need a labeler code? Labeler codes are only used for generating National Drug Code (NDC) numbers for drugs. Generally, if you do not have to list any drugs with FDA, you do not need to apply for a labeler code. Under most circumstances, an assigned labeler code that does not have any NDCs listed with FDA within two years will be deactivated. A company is not required to obtain a different labeler code for each manufacturing establishment under the same ownership since the labeler code identifies a company marketing a product. Process for requesting a labeler code Create and submit a labeler code SPL document to request a new labeler code including all necessary data (e.g., name and DUNS number of the company, contact information of someone responsible for receiving FDA communications related to drug listings with NDCs under that labeler code) Leave the NDC labeler code field blank FDA will email the contact person on the request with the assigned number Submit an updated labeler code form SPL as described below with the newly assigned number filled in to complete the process To update labeler code information, including contact information and name changes of the company or changes in ownership of the labeler code: Create a copy/new version of the most recent submission Do not change the SetID Generate a new DocumentID/RootID Enter an appropriate effective date and version number (generally, one number higher than the previous submission) Modify all establishment and contact information as appropriate Submit If a labeler code transfers to another company through a merger or acquisition, or if there is a name change, all product listings under that labeler code must be updated with the new labeler name. The new information captured in the labeler code request submission does not automatically populate or propagate to drug listing files under that labeler code. Requesting Label Coder using CDER Direct Listing All registered establishments must list all drugs they produce for U.S. commercial distribution under their own labeler code. This includes active pharmaceutical ingredient manufacturers, other bulk drug manufacturers, contract manufacturers, repackers and relabelers. A single product listing SPL may include multiple NDCs (products and packages) provided that they all use the same content of labeling/package insert. What data do I need to list a product? When creating a product listing, be sure to include: Full 10-digit NDC Proprietary and non-proprietary name If a drug does not have a proprietary name, the established name of the drug should be included in the proprietary name field Dosage form and route of administration The name with unique ingredient identifier (UNII) code and amount/strength (with appropriate unit of measure such as grams, milliliters, etc.) of each active ingredient Active ingredient strength sometimes has to be converted to SPL acceptable values (see strength conversion in drug listing for more information) Each inactive ingredient (name and UNII) The amount/strength of each inactive ingredient may be included A copy of the most up-to-date labeling, including a .jpg file of the outer packaging and principal display panel of each drug product in the SPL submission The name and DUNS number for each establishment involved in manufacturing the product When do I list? Initial drug listings should be submitted within three days after initial registration of the establishment. Updates to listing data are required to be made no later than June or December following a change in the information. However, FDA requests they be made as soon as possible. A company may submit a single blanket no changes certification once a year during the October 1 to December 31 renewal period for products that do not require any updates. Listing process To list a product: Select the appropriate SPL document type for the product (human Rx drug, human OTC, bulk ingredient, etc.) Fill out all required listing data elements Create a section within the SPL file for each section of content for labeling (e.g., highlights, warnings, how supplied) and enter the text for each The .jpg file(s) of the outer packaging/front label belongs in the section entitled Package Label. Principal Display Panel Submit Product Listing using CDER Direct Updates to listing To update a listing: Create a copy/new version of the most recent submission Do not change the SetID Generate a new DocumentID/RootID Enter an appropriate effective date and version number (generally, one number higher than the previous submission) Modify all listing data elements and labeling as appropriate Submit Blanket no change certification for product listing data There is an annual requirement to either update listings or certify that no changes have occurred for drugs that were not initially listed or updated during the current calendar year. The period for product listing certifications is October 1 through December 31 each year. Any drug listing that is required to be certified but is not certified may be considered inactive and removed from the NDC Directory and other publications of listing data. Outside this three-month window an update of the listing SPL submission for each NDC is required to certify the product. Blanket No Changes Certification of Product Listing using CDER Direct Use of the National Drug Code Drugs are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as the FDA's universal product identifier for drugs. NDCs should not be assigned to non-drug products such as medical devices and medical foods. Submission of NDC is required at the time of drug listing with FDA. Registration of a drug establishment or drug wholesaler or assignment of a registration number or assignment of NDC number does not in any way denote approval of the company or its products. Any representation that creates an impression of official approval because of registration or possession of registration number or NDC number is misleading and violates federal law. Related Links Introduction to eDRLS Product listing certification guide National Drug Code Directory Drug establishments current registration site Structured product labeling resources CDER direct Electronic submissions gateway Xforms

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