



U.S. Food and Drug Administration

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Drug Registration and Listing (DRLS)

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What is DRLS?

- The Who, What, and Where of drugs on the market in the United States.
 - Drug establishments must **Register** annually with FDA, providing names, addresses, contact information, and manufacturing roles
 - Each establishment must **List** with FDA all drug products being marketed in the United States, providing names, ingredients, approved NDA or BLA, manufacturer, labeling, etc.

Regulatory Authority

- Section 510(b) of Food Drug and Cosmetic Act (FD&C)
 - On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs ... shall register with the Secretary his name, places of business and all such establishments.
- Section 510(i) of FD&C
 - On or before December 31 of each year, any establishments within any foreign country engaged in the manufacture, preparation, ... of a drug that is imported or offered for import into the United States shall ... register with the Secretary the name and place of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug that is known to the establishment
- Section 510(j) of the FD&C
 - Every person who registers with the Secretary shall file a list of all drugs which are being manufactured, prepared, ...
- 21 CFR 207 Code of Federal Regulations
- Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Establishment Registration and Drug Listing
 - Establishes Structured Product Labeling (SPL) as standard

What Do I Do?

- Get your FDA WebTrader account set up so you can send things to FDA electronically.
 - <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>
 - For help: esgprep@fda.hhs.gov
- Send in a labeler code request SPL
 - Only have to do this once
 - FDA will notify you of your labeler code number
 - <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>
- Send in a Registration SPL for each facility
 - All facilities can be in one SPL
 - Contact information can be same or different for all facilities
 - Business operation(s) can be same or different for facilities
 - <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>
- Send in a Listing SPL for each product
 - Include content of labeling when appropriate
 - Multiple products allowed per SPL if they use the same content of labeling
 - <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

The National Drug Code (NDC)

- The NDC is a unique number assigned to drug products
- Three segments identify:
 - The company **12345**-6789-0
 - The product 12345-**6789**-0
 - The package 12345-6789-**0**
- Two main configurations:
 - 5-4-1 *example: 12345-6789-0*
 - 5-3-2 *example: 12345-678-90*

Labeler Code Requests

- Must do this once, even if already assigned a labeler code in old paper system
- For new requests, FDA may contact the person identified in the contact information
- Some companies do not require a labeler code
 - Medicated feed companies
 - Dietary supplement companies
 - Test labs
- The FDA will notify company by email of labeler code assignment
 - May take as much as 10 business days or more – depending on how long it takes to contact the company

Who Must Register?

- Business Operations to be claimed: (use all that apply)
 - ANALYSIS
 - API MANUFACTURE
 - IMPORT
 - LABEL
 - MANUFACTURE
 - MEDICATED ANIMAL FEED MANUFACTURE
 - OUTSOURCING HUMAN DRUG COMPOUNDING
 - PACK
 - PARTICLE SIZE REDUCTION
 - POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION
 - RECOVERY
 - RELABEL
 - REPACK
 - STERILIZE

Registration – Private Label Distributors (PLDs)

- What is a Private Label Distributor (PLD)?
 - A PLD is a company that markets a drug product under its own name, but does not perform any manufacturing, processing, or packaging.
 - A PLD must obtain a labeler code and list its products, ***but it does not have to register any establishments.***

Registration – US Agents

- All foreign establishments must specify in their registration one U.S. Agent who resides on U.S. soil.
- There can only be one US Agent at a time for each establishment. It may be changed at any time.
- Any US Agent can represent multiple establishments, from multiple companies.

Registrations

- **Must have a DUNS (Dunn and Bradstreet) number**
 - Do not use corporate HQ number. Must have one assigned to facility.
- **Include FEI (FDA Establishment Identifier) if known**
 - Not required.
 - Won't have one assigned yet for new registrations. When assigned, firm is notified via email of number.
 - Please include in future updates and annual renewals.
- **Must do this annually**
 - Either update information (including contact info) or certify no changes
 - There is no particular month/anniversary date to renew annually.
 - Anytime during calendar year covers that calendar year's obligation (don't wait until Dec 31st though!)
- **No confirmation is sent back**
 - Electronic gateway receipt can be used as confirmation that registration has been submitted.
 - Appearance on Drug Firm Annual Registration Status (DFARS) List can also be used. Usually appears in 2-3 business days.
 - If your submission has an error and does not pass validation, you will receive an error notice. The registration is not accepted.

What Should be Listed?

A drug is: (From the FD&C Act)

- (g)(1) The term “drug” means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) **articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals;** and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C).
- A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section Q:\COMP\FDA\FDA.002 December 19, 2002 5 FEDERAL FOOD, DRUG, AND COSMETIC ACT Sec. 201 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement

What Should be Listed?

- Prescription drugs
- Homeopathics
- Over-the-Counter (OTC) products such as:
 - Medicines
 - Toothpaste with fluoride
 - Sunscreens
 - Antacids
- Active pharmaceutical ingredients used in other drugs
- Drug products that still must undergo some manufacturing, labeling, or packaging. (bulks, drug products for further processing, etc)
- *Do not need to list:*
 - Foods and dietary supplements that do not make drug claims
 - Example: General iron supplement with no drug claims versus a high dose version used to treat anemia. The latter could be a drug and would need to be listed.
 - Intermediates – substances used in the synthesis of active ingredients

Listings

- Take care to choose appropriate product/document type and marketing category
 - Product/document type determines whether content of labeling is required.
 - If choosing and approved drug, double check the application number.
 - If choosing OTC Monograph, double check the monograph citation. (e.g. “part 341”)
- Use DUNS number to refer to any processing facilities
 - Can set confidentiality flag so manufacturing relationships are not released to public.
- To discontinue a product listing (NDC):
 - May use expiration date of last lot produced in the End Marketing Date
 - If listing only in paper, may send an email to edrls@fda.hhs.gov to discontinue. This will **NOT** remove it from DailyMed website if it is there through other means.
- Cannot change your NDC configuration!
- Keep your listings up to date

Listings – Private Label Distributors

- If you market a drug under your name, but do not do any of the manufacturing, your drug must still be listed under your labeler code.
 - Use the DUNS number to refer to the Manufacturer who supplies your product.
 - If you use multiple manufacturers to supply your product, the product must be identical in appearance, formulation, etc. If not, a new NDC with new product code is needed for the different versions.
 - Manufacturer will list under the category “Manufactured exclusively for Private Label Distributor”

Special Case: Company Name Changes

3 Steps to a Name Change:

- Submit a labeler code request with same labeler code but new name
- Update each registration with SPL to show new name as registrant
 - Update your DUNS information first!
- Update all product listings with new name in LabelerName field

Helpful Places to Get Information

A good place to start:

www.fda.gov/edrls

For business and regulatory questions:

edrls@fda.hhs.gov

For SPL technical issues:

spl@fda.hhs.gov

For Gateway and Webtrader account issues:

esgprep@fda.hhs.gov