

FDA Website: Resources Available to You

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CDER | US FDA

Electronic Drug Registration and Listing
Using CDER Direct – October 13, 2021

A Walkthrough of the FDA Website



- [The National Drug Code \(NDC\) Directory](#)

- Inclusion in the NDC Directory does not indicate that FDA has verified the information provided. The content of each NDC Directory entry is the responsibility of the labeler submitting the SPL file.
- The NDC Directory does not contain all listed drugs. It does not include animal drugs, blood products, drugs manufactured under contract or drugs that are marketed solely as part of a kit or combination product or inner layer of a multi-level packaged product not marketed individually.
- Assignment of an NDC number does not in any way denote FDA approval of the product.

NDC Directory



National Drug Code Direct... Preprod Dashboard New tab National Drug Code Direct... Drug Approvals and Datab... eCFR — Code of Federal R... DQCP Home

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Home > Drug Databases > NDC

National Drug Code Directory

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The National Drug Code (NDC) Directory is updated daily.
Current through: 10/3/2021

- [NDC Application Programming Interface \(API\)](#) (Firefox and Chrome recommended)

Finished Products Unfinished Products

NDC finished products search

Search the NDC database for finished drug products

Select Type

Enter at least three characters

Search Clear

100%



Search FDA

Home > Drug Databases > NDC

National Drug Code Directory

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The National Drug Code (NDC) Directory is updated daily.
Current through: 10/3/2021

- [NDC Application Programming Interface \(API\)](#) (Firefox and Chrome recommended)

Finished Products Unfinished Products

NDC finished products search

Select Type
Proprietary Name
Application Number
Nonproprietary Name
NDC Code
Labeler
aspirin

Search Clear

NDC Directory II



[National Drug Code Direct...](#)
[Preprod Dashboard](#)
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[Drug Approvals and Datab...](#)
[eCFR — Code of Federal R...](#)
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Current through October 03, 2021

You have searched Finished drug products

Search Results: 'aspirin'

Only the first 1,000 results are displayed. Consider refining your search by entering more specific terms.

[Back to Search Page](#) | [Search Again](#)

Display records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
365 everyday value aspirin	42881-7075-1	325 mg/1	TABLET, FILM COATED	ORAL	part343	Whole Foods Market, INC.	42881-7075	Aspirin	ASPIRIN	HUMAN OTC DRUG	08/23/2018	N/A	OTC MONOGRAPH NOT FINAL	100 TABLET, FILM COATED in 1 BOTTLE (42881-7075-1)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	0363-1320-12	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	part343	WALGREENS CO.	0363-1320	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN; ASPIRIN; CAFFEINE	HUMAN OTC DRUG	05/24/2019	N/A	OTC MONOGRAPH NOT FINAL	120 TABLET in 1 BOTTLE (0363-1320-12)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	0363-1320-23	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	part343	WALGREENS CO.	0363-1320	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN; ASPIRIN; CAFFEINE	HUMAN OTC DRUG	05/24/2019	N/A	OTC MONOGRAPH NOT FINAL	20 TABLET in 1 BOTTLE (0363-1320-23)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	0363-1320-80	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	part343	WALGREENS CO.	0363-1320	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN; ASPIRIN; CAFFEINE	HUMAN OTC DRUG	05/24/2019	N/A	OTC MONOGRAPH NOT FINAL	80 TABLET in 1 BOTTLE (0363-1320-80)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	69842-591-20	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	part343	CVS Pharmacy	69842-591	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN; ASPIRIN; CAFFEINE	HUMAN OTC DRUG	02/01/2021	N/A	OTC MONOGRAPH NOT FINAL	200 TABLET in 1 BOTTLE (69842-591-20)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	69842-591-23	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	part343	CVS Pharmacy	69842-591	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN; ASPIRIN; CAFFEINE	HUMAN OTC DRUG	02/01/2021	N/A	OTC MONOGRAPH NOT FINAL	20 TABLET in 1 BOTTLE (69842-591-23)

100%

DECRS



- Drug Establishments Current Registration Site (DECRS)

The screenshot shows the FDA website's Drug Establishments Current Registration Site (DECRS). The page features a dark blue header with the FDA logo and navigation menu. Below the header, there is a search bar and a navigation menu with categories like Home, Food, Drugs, Medical Devices, etc. The main content area is titled "Drug Establishments Current Registration Site" and includes a search form for firm names. The search form has a label "Search for Firm Name*", a text input field with the placeholder "Search for an Firm Name", and "SUBMIT" and "CLEAR" buttons. Below the search form, there is a link to "DECRS Home" and a note about data current through Friday, Oct 1, 2021. There are also links to "Points of Contact for Questions Regarding Registration and Listing for Human and Animal Drugs and Biologics" and "Guidance for Industry: Providing Regulatory Submissions in Electronic Format -Drug Establishment Registration and Drug Listing (PDF - 776 KB)". At the bottom, there is a note about language assistance available in various languages.

DECRS Continued

Drug Establishments Current Registration Site

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New Search

Search Results for **Abc**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
ABC Compounding Co., Inc.	3012553246	003284353	LABEL; MANUFACTURE; PACK;	2600 Dogwood Drive, Conyers, Georgia (GA) 30013, United States (USA)	12/31/2021
ABC INDUSTRIES LLC	3013661874	561180632	MANUFACTURE;	AL GHAIL, MAIN STREET, RAS AL KHAIMAH, 0427, United Arab Emirates (ARE)	12/31/2021
ABCO Laboratories	1000142677	029618279	MANUFACTURE;	2450 South Watney Way, Fairfield, California (CA) 94533, United States (USA)	12/31/2021
LabChemS Corp	3011238454	829884407	ANALYSIS;	2015 Jaime Rodriguez Street Guanajibo Industrial Park, Mayaguez, Puerto Rico (PR) 00680, United States (USA)	12/31/2021

Showing 1 to 4 of 4 entries

Previous Next

Data Current through: Friday, Oct 1, 2021

[Return to Drug Firm Annual Registration Status Home Page](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)



Registered Outsourcing Facilities

- [503B Facilities](#)

Registered Outsourcing Facilities

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- Human Drug Compounding
 - Compounding Quality Center of Excellence
 - Compounding Laws and Policies
 - Regulatory Policy Information
 - Compounding Risk Alerts
 - Compounding Oversight and Compliance Actions
 - Compounding: Inspections, Recalls, and other Actions
 - Information for Outsourcing

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Content current as of:
09/29/2021

Updated as of 9/24/2021

- [Information Concerning Outsourcing Facility Registration](#)
- [Outsourcing Facility Product Reporting Information](#)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility ¹	Date of Most Recent Registration as an Outsourcing Facility ¹	End Date of Last FDA Inspection Related to Compounding ²	Was a Form FDA-483 issued? ³	Other Action, if Any, Based on Last Inspection ^{4,5}	Intends to Compounds Sterile Drugs From Bulk Drug Substances ⁶

Information for Outsourcing Facilities

- [Information for Outsourcing Facilities](#) – link to reporting

Home > Drug Databases > Outsourcing

Outsourcing Facility Product Report

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Outsourcing facilities are required to provide FDA with a list of drugs they compounded during the previous six-month period upon initial registration and in June and December each year. This database contains information reported to FDA within the last two years (last four reporting periods). This information may be used to identify outsourcing facilities that have produced certain drugs. This retrospective information does not identify drugs that outsourcing facilities intend to produce in the future.

Outsourcing Facility Product Report search

Search the Outsourcing Facility Product Report database

Select Reporting Year

- 2019-1
- 2019-2
- 2020-1
- 2020-2

Enter at least three characters

Search Clear

100%

Example

Outsourcing Facility Product Report

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Outsourcing facilities are required to provide FDA with a list of drugs they compounded during the previous six-month period upon initial registration and in June and December each year. This database contains information reported to FDA within the last two years (last four reporting periods). This information may be used to identify outsourcing facilities that have produced certain drugs. This retrospective information does not identify drugs that outsourcing facilities intend to produce in the future.

Outsourcing Facility Product Report search

Search the Outsourcing Facility Product Report database

2020-2

Active Ingredients

aspirin

[Search](#) [Clear](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).
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Outsourcing Facility Product Report

Home > Drug Databases > Outsourcing

Outsourcing Facility Product Report

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Current through October 03, 2021

You have searched for Active ingredients: 'aspirin'

[Back to Search Page](#)

Show 10 rows [CSV](#)

Search for text in the table:

Active Ingredients	Active Ingredients Info	Dosage	Estab. Name	Package Description	NDC Package Code	Report Year
Aspirin	10 mg/1 mL	suspension	Epicur Pharma(802110531)	120 MI in 1 Bottle		2020-2

Showing 1 to 1 of 1 entries

Previous **1** Next

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Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

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Points of Contact

- [Points of Contact for Drug Registration and Listing](#)

[Home](#) / [Drugs](#) / [Guidance, Compliance, & Regulatory Information](#) / [Electronic Drug Registration and Listing System \(eDRLS\)](#) / [Points of Contact for Drug Registration and Listing](#)

Points of Contact for Drug Registration and Listing

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Electronic Drug Registration and Listing System (eDRLS)

[Electronic Drug Registration and Listing Instructions](#)

[Electronic Registration and Listing Compliance Program](#)

[Dun and Bradstreet Verification](#)

[Points of Contact for Drug Registration and Listing](#)

Following are points of contact for specific questions about registration and listing for human drugs, animal drugs and biologics.

Electronic Submission Gateway (ESG) account

Contact ESGHelpDesk@fda.hhs.gov for ESG technical inquiries regarding opening a new gateway account.

Examples of questions for this point of contact:

- How long does it take to open a new gateway account?
- What should I submit in my letter of non-repudiation?
- How do I obtain an x.509 digital certificate?

Structured Product Labeling (SPL)

Contact spl@fda.hhs.gov for technical help and inquiries regarding XForms.

Examples of questions for this point of contact:

- Why did I get an error message with my XForms submission? What does it mean?

Content current as of:
12/18/2020

Points of Contact contd.

- **Electronic Submission Gateway (ESG) account**
 - Contact ESGHelpDesk@fda.hhs.gov for ESG technical inquiries regarding opening a new gateway account.
- **Structured Product Labeling (SPL)**
 - Contact spl@fda.hhs.gov for technical help and inquiries regarding XForms.
- **Establishment registration status**
 - Contact edrls@fda.hhs.gov for questions and assistance with registration. See the [drug establishment current registration site](#) to check a facility's current registration.

Points of Contact I

- **Drug listing status**
 - See [NDC Directory](#) for human drugs and biologics listing status
 - Contact edrls@fda.hhs.gov with questions about human drug listings
 - Contact CBERSPL@fda.hhs.gov with questions about biologic listings
 - See [the electronic animal drug product listing directory](#) for animal drug listing status. Contact AskCVM@fda.hhs.gov or call 240-276-9300 with questions
 - Contact reglist@cdrh.fda.gov with questions about device registration or listing



Points of Contact II

- **Regulatory questions or request for general information**
- For human drugs, contact edrls@fda.hhs.gov
- For animal drugs, contact AskCVM@fda.hhs.gov or call 240-276-9300
- For biologics, contact CBERSPL@fda.hhs.gov or call 301-827-0373



SPL Resources

- [Structured Product Labeling Resources](#)
 - SPL Guidance Documents
 - SPL Terminology
 - SPL Implementation Guide and Validation Procedures
 - SPL Schema and Stylesheet information
 - GDUFA SPL Step-by-Step Instructions & Technical Specifications
 - Questions regarding SPL submissions should be directed to: spl@fda.hhs.gov.

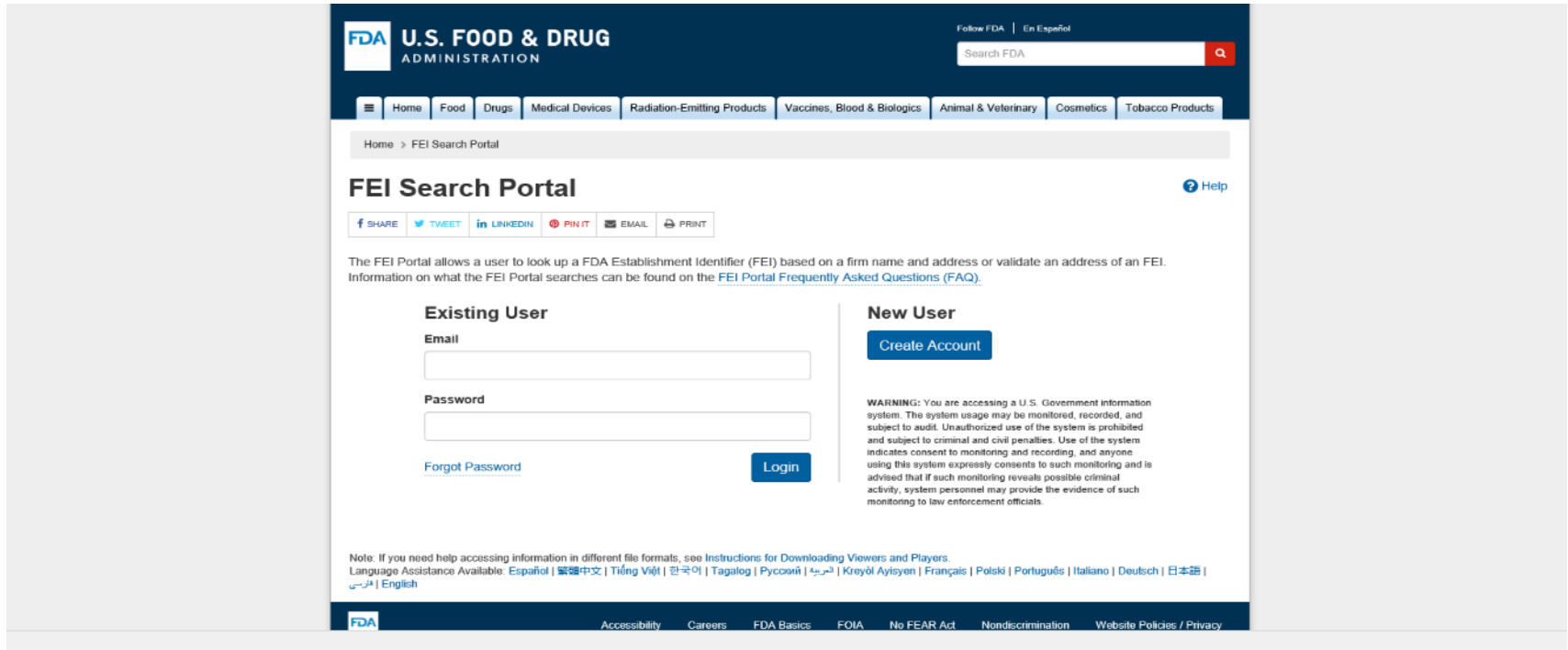


DRLS Instructions Page

- [DRLS Instructions Page](#)
- SPL Process
- SPL Authoring Tools
- Registration, Labeler Codes, Listing
- Updating SPL submissions
- Blanket No Change Certification for product listing data

FEI Search Portal

- [FEI Search Portal](#)



The screenshot shows the FEI Search Portal interface. At the top, there is the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". A search bar is located in the top right corner. Below the header, there is a navigation menu with links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled "FEI Search Portal" and includes a "Help" link. Below the title, there are social media sharing options for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print. A paragraph explains that the FEI Portal allows users to look up a FDA Establishment Identifier (FEI) based on a firm name and address or to validate an address. It also provides a link to the "FEI Portal Frequently Asked Questions (FAQ)".

Existing User

Email

Password

[Forgot Password](#)

New User

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

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Strength Conversion

- [Strength Conversion in Drug Listing](#)

Strength Conversion in Drug Listing

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Electronic Drug Registration and Listing System (eDRLS)

[Electronic Drug Registration and Listing Instructions](#)

[Electronic Registration and Listing Compliance Program](#)

[Dun and Bradstreet Verification](#)

[Points of Contact for Drug Registration and Listing](#)

A drug strength or concentration of its active ingredients can be expressed in many different ways. In order to standardize the expression of active ingredients in drug listing Structured Product Labeling (SPL) submitted to FDA, the agency has adopted a series of automated validation rules to allow for certain expressions.

For example, the strength of active ingredient is not allowed to be included as a percentage value but can be a concentration of an amount of solute in an amount of solution:

- As w/w - mass (grams) of solute in mass (100 gm) of solution, like topical creams and ointments
- As w/v - mass (grams) of solute in a volume (100ml) of solution, like oral liquids
- As v/v - volume (milliliters) of solute in a volume (100ml) of solution, like alcohol

The strength data element in a listing SPL is designed to accept submissions mostly in concentrations of w/w or w/v format, when the strength of an active ingredient is expressed as a percentage. Percentages must be converted into ratios of w/w or w/v with a value in the numerator and in the denominator including the correct units of measure in order to pass the SPL validation rules.

Content current as of:
02/06/2017



Resources

- [The National Drug Code \(NDC\) Directory](https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm)
 - <https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm>
- [Drug Establishments Current Registration Site \(DECRS\)](https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm)
 - <https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>
- [503B Facilities](https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities)
 - <https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>
- [Information for Outsourcing Facilities](https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities#reporting) – link to reporting
 - <https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities#reporting>

Resources I



- [Structured Product Labeling Resources](#)
 - <https://www.fda.gov/industry/fda-resources-data-standards/structured-product-labeling-resources>

- [DRLS Instructions Page](#)
 - <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions>

Resources II

- [Points of Contact for Drug Registration and Listing](https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/points-contact-drug-registration-and-listing)
 - <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/points-contact-drug-registration-and-listing>
- [FEI Search Portal](#)
- <https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login>
- [Strength Conversion in Drug Listing](https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/strength-conversion-drug-listing)
 - <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/strength-conversion-drug-listing>



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