FDA Website: Resources Available to You

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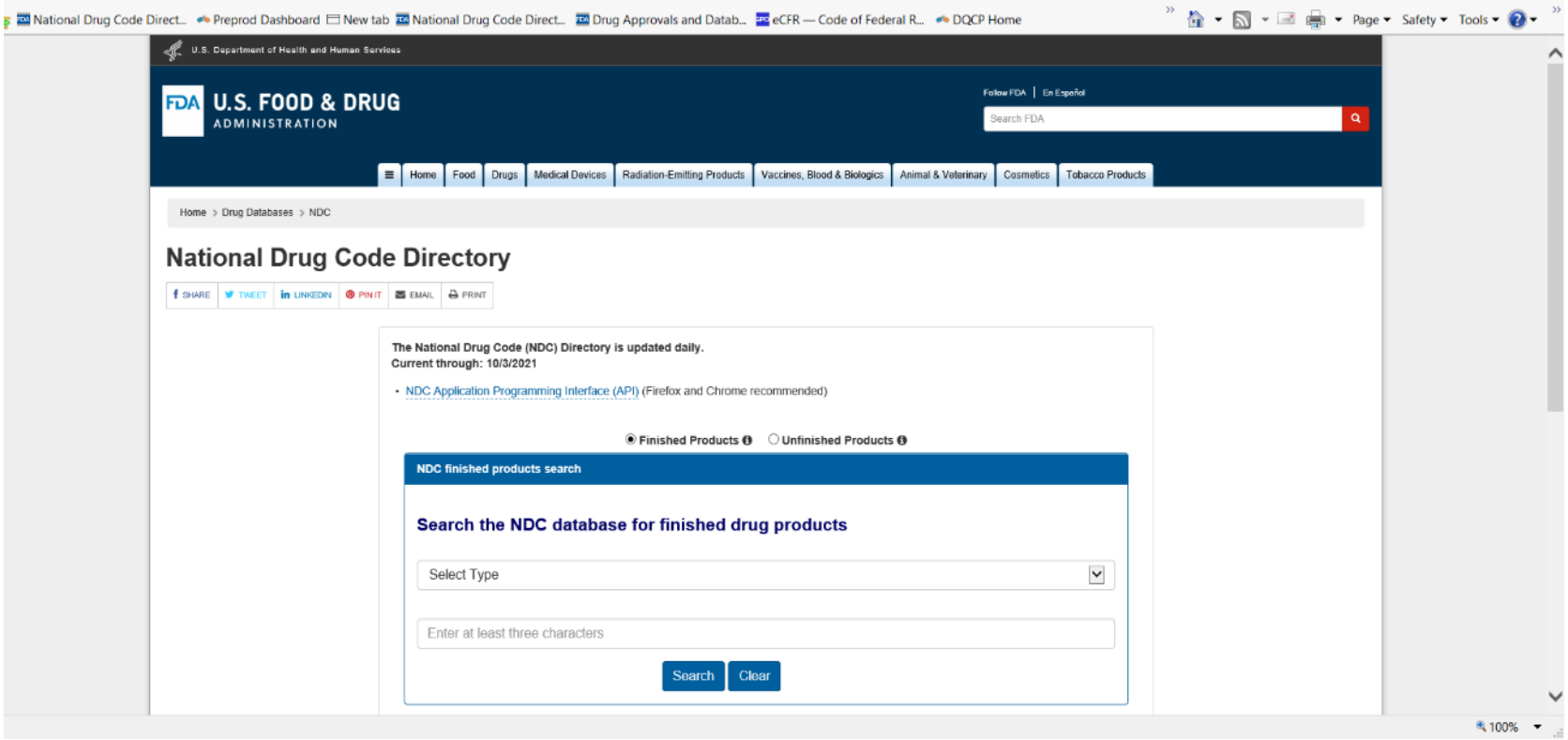
DLRUD/DRLB, Office of Compliance
CDER | US FDA

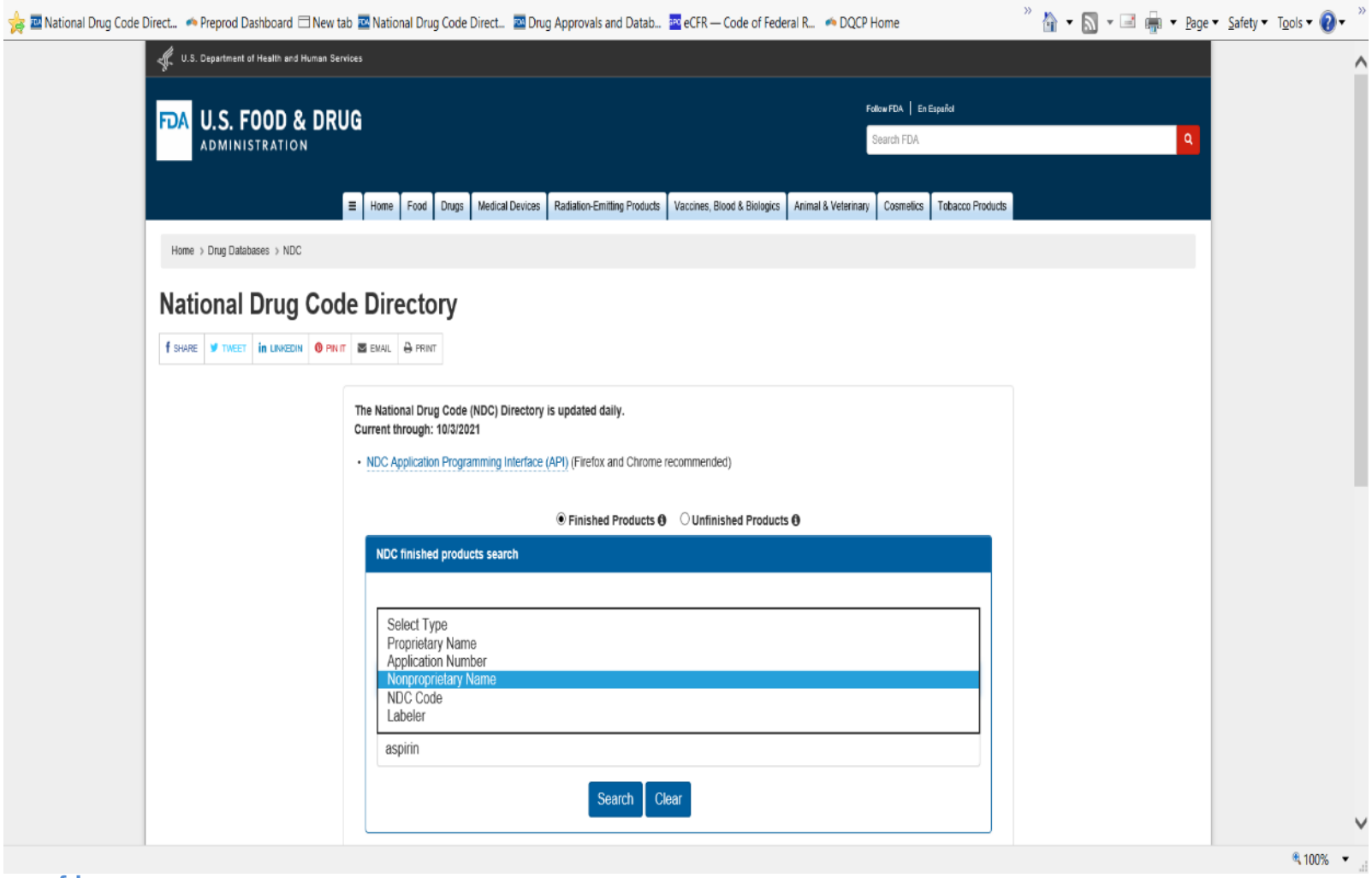
Electronic Drug Registration and Listing
Using CDER Direct – October 13, 2021

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
Page
Safety
Tools
U.S. Department of Health and Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION
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Home
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Drugs
Medical Devices
Radiation-Emitting Products
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Tobacco Products
Home › Drug Databases › NDC
National Drug Code Directory
SHARE
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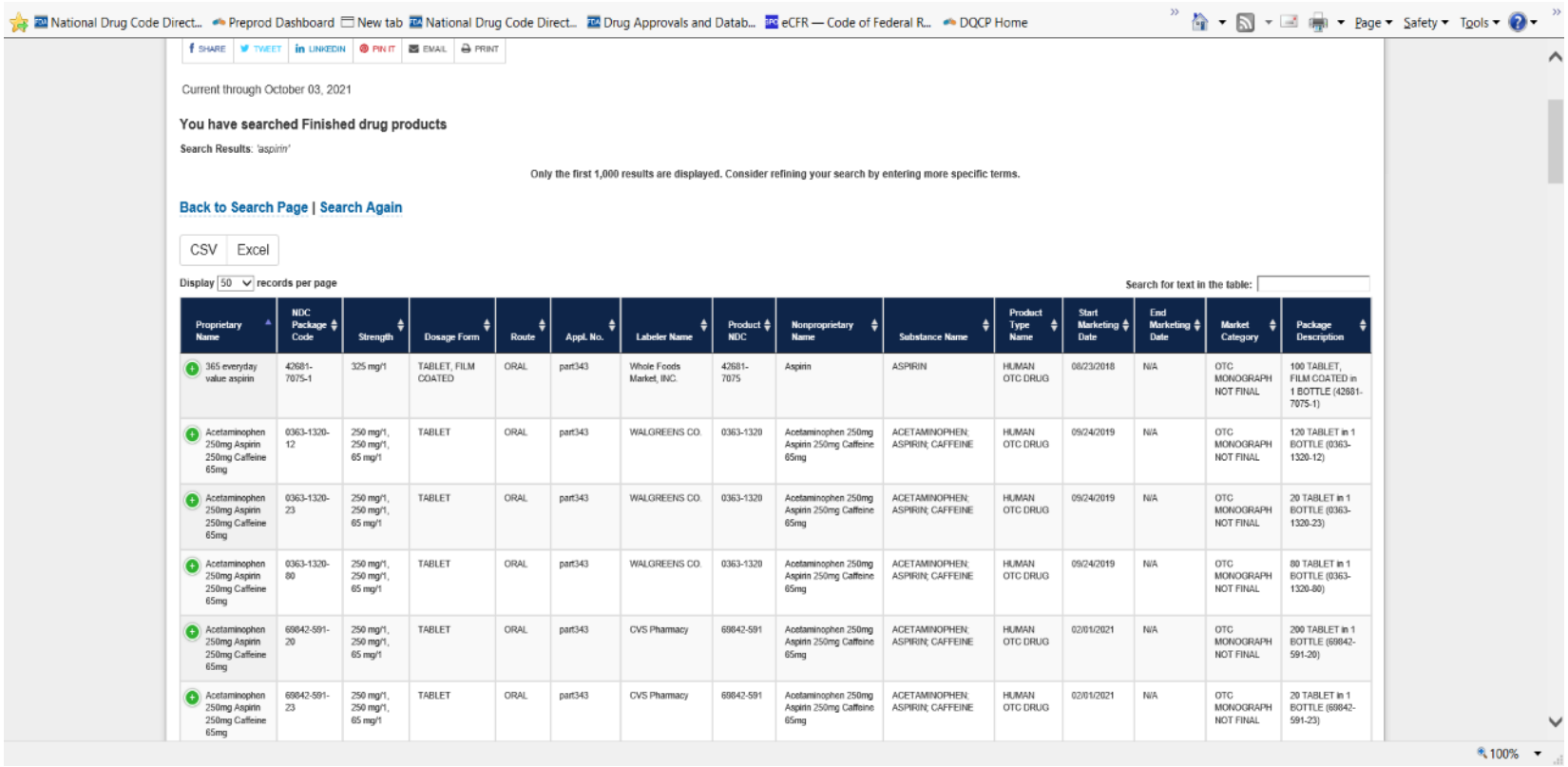
The National Drug Code (NDC) Directory is updated daily.
Current through: 10/3/2021
NDC Application Programming Interface (API) (Firefox and Chrome recommended)
Finished Products
Unfinished Products
NDC finished products search
Select Type
Proprietary Name
Application Number
Nonproprietary Name
NDC Code
Labeler
aspirin
Search
Clear
100%

NDC Directory II



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

Page | Safety | Tools

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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

CSV | Excel

Display 50 records per page

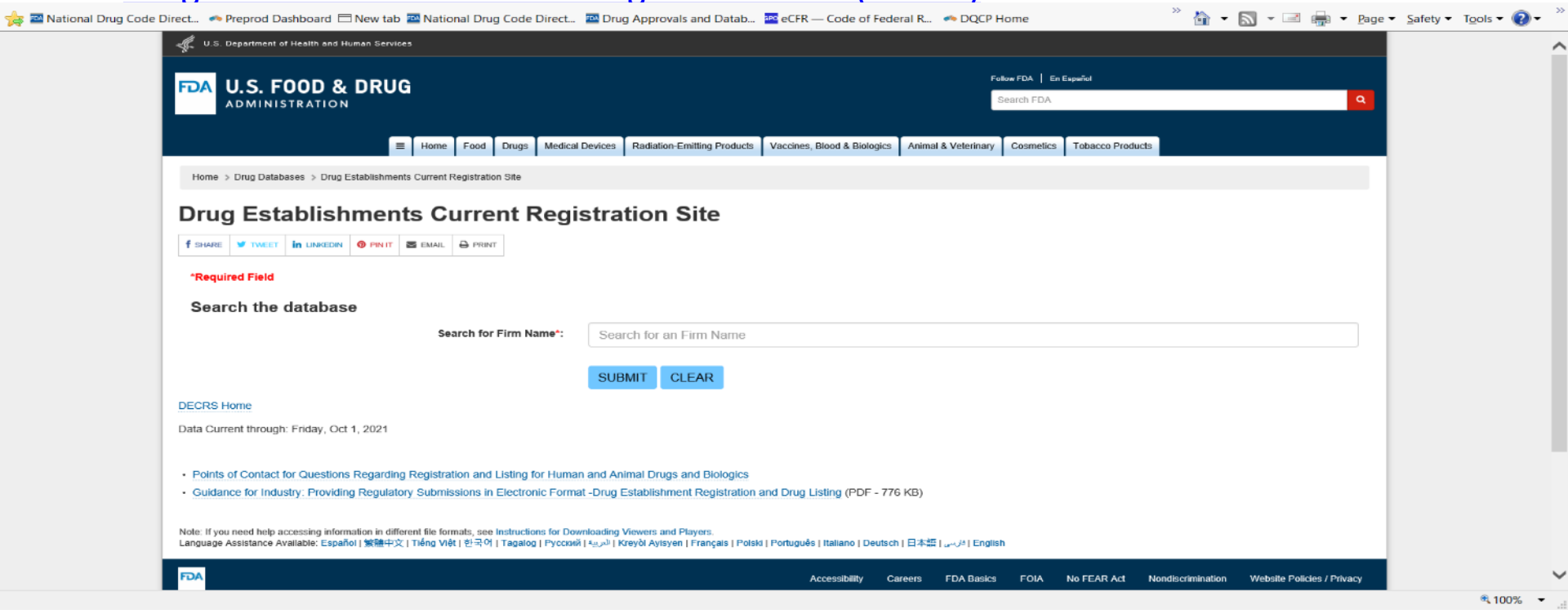
Search for text in the table:

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	42681-7075-1	325 mg/1	TABLET, FILM COATED	ORAL	part343	Whole Foods Market, INC.	42681-7075	Aspirin	ASPIRIN	HUMAN OTC DRUG	08/23/2018	N/A	OTC MONOGRAPH NOT FINAL	100 TABLET, FILM COATED in 1 BOTTLE (42681-7075-1)
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	09/24/2019	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	09/24/2019	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	09/24/2019	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)

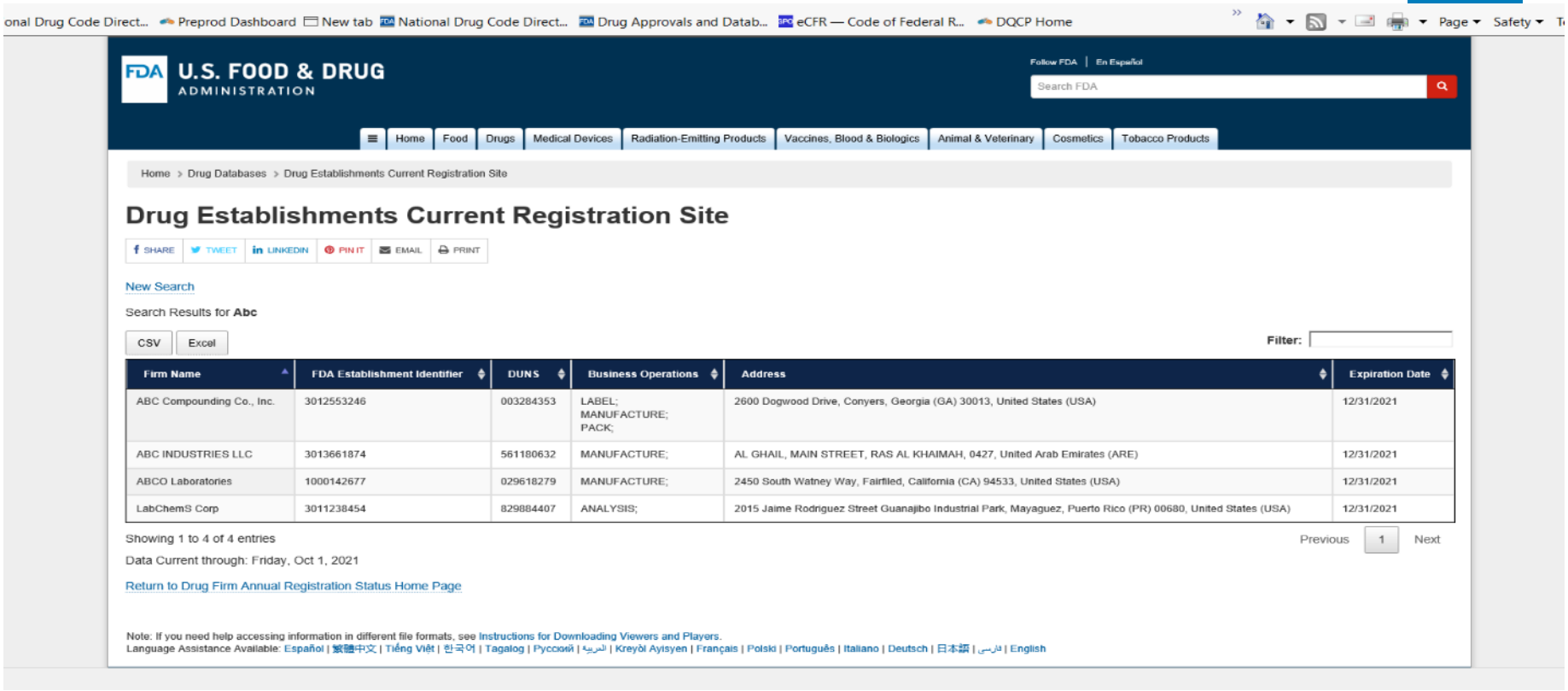
100%

DECRS

- Drug Establishments Current Registration Site (DECRS)



DECRS Continued



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?[2]	Other Action, if Any, Based on Last Inspection[4,3]	Intends to Compounds Sterile Drugs From Bulk Drug Substances[6]

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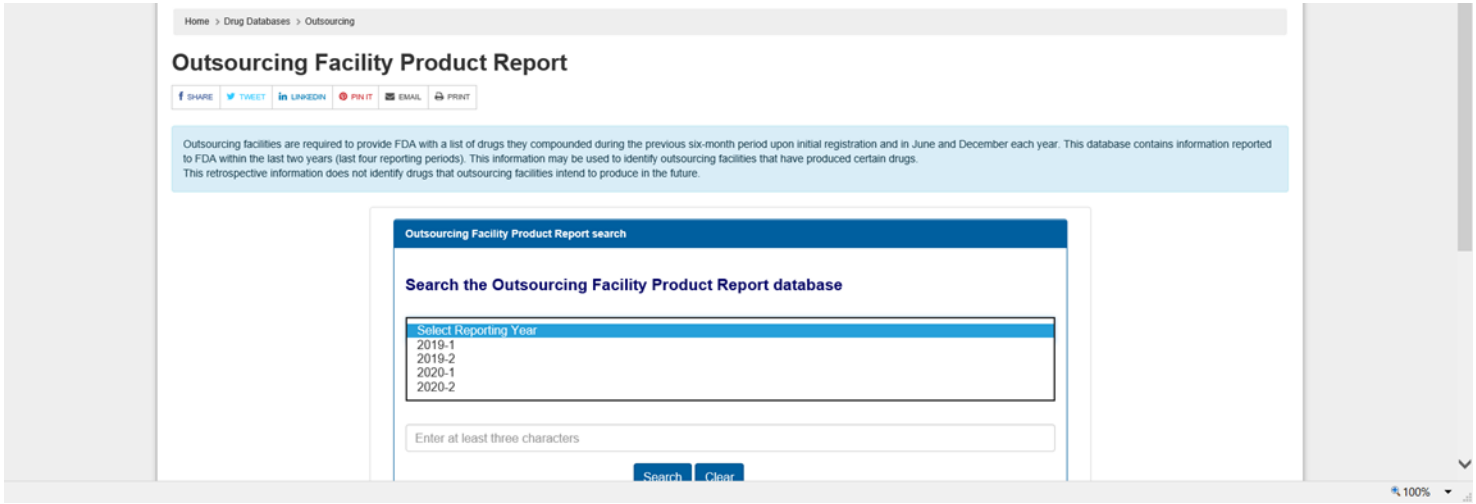
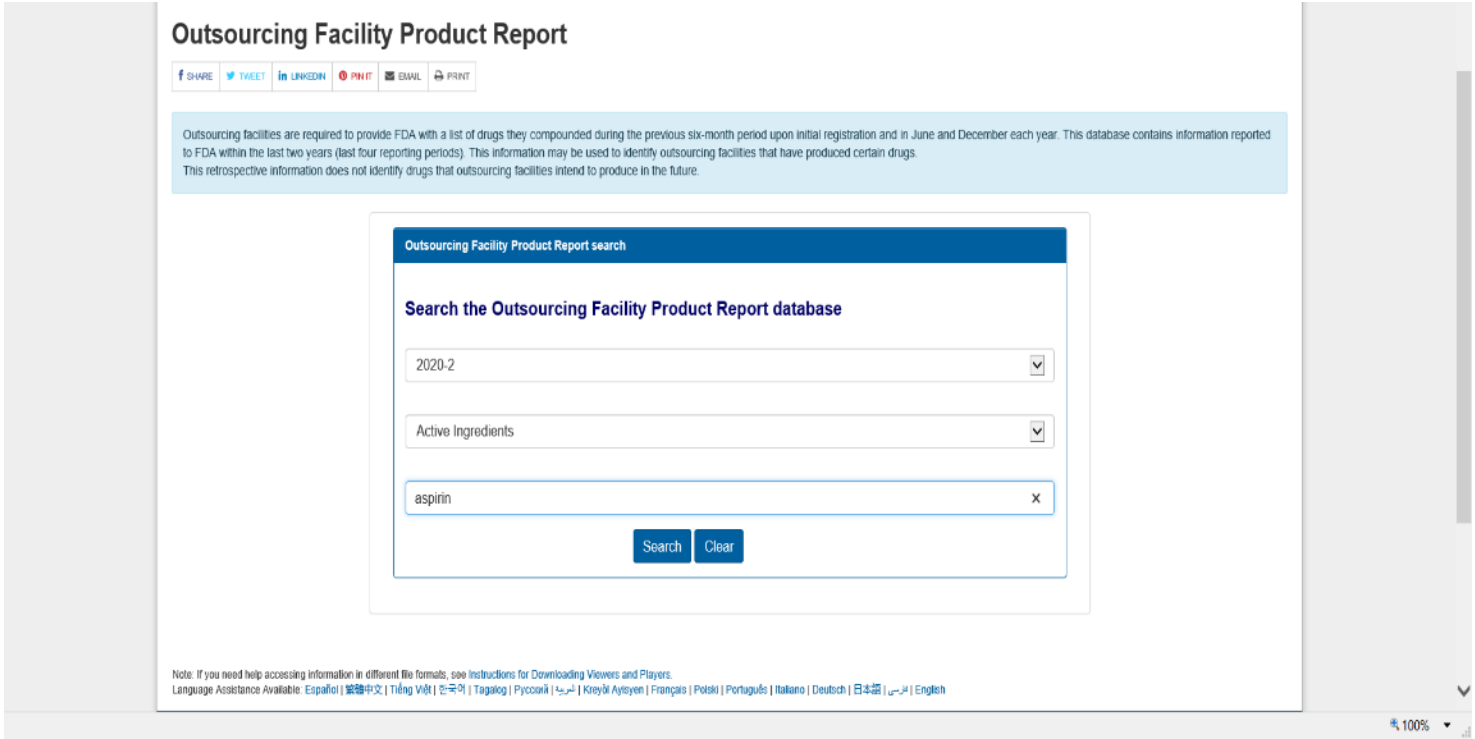
Information for Outsourcing Facilities

- Information for Outsourcing Facilities – link to reporting



Example


Outsourcing Facility Product Report
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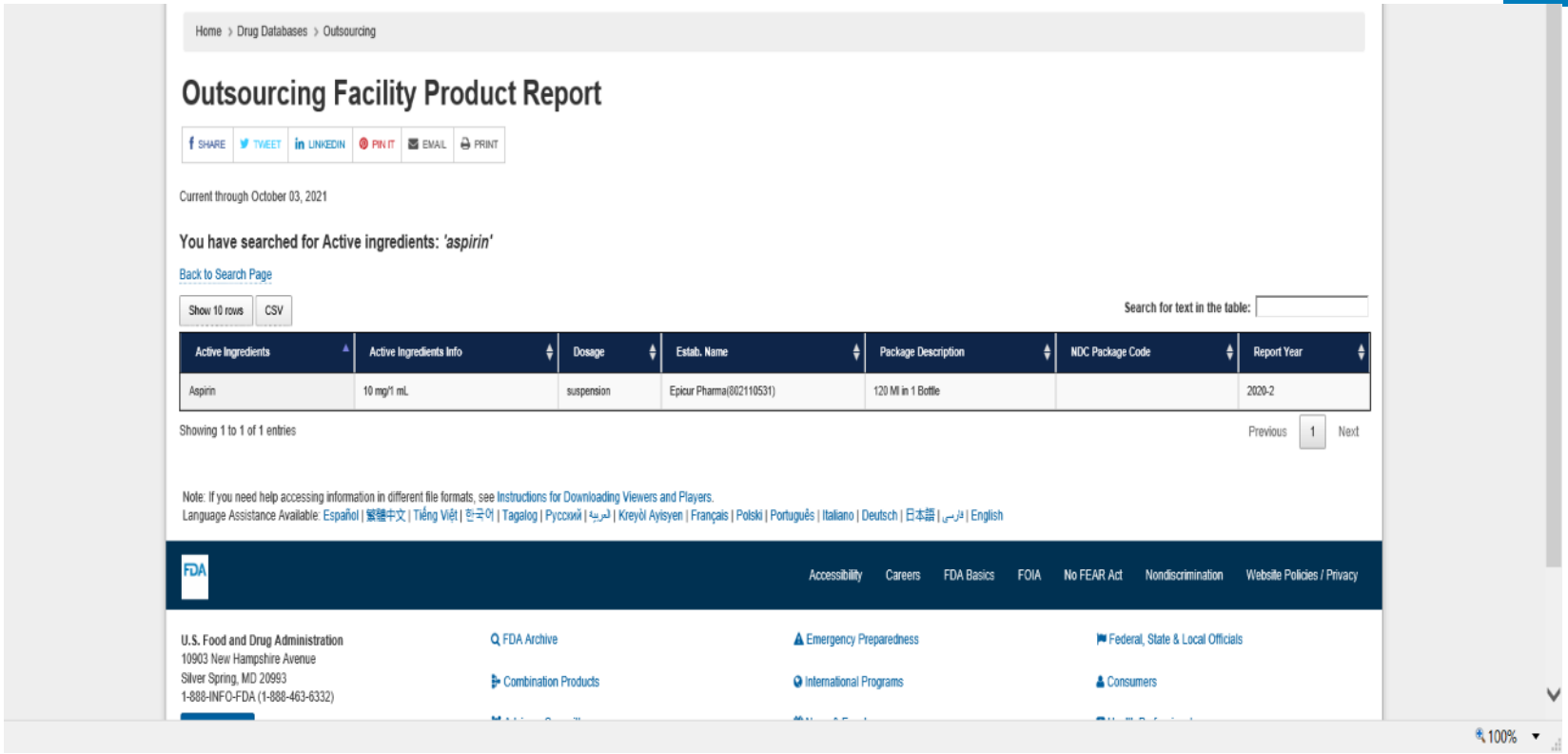
PRINT
Outsourcing facilities are required to provide FDA with a list of drugs they compounded during the previous six-month period upon initial registration and in June and December each year. This database contains information reported to FDA within the last two years (last four reporting periods). 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.
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
100%

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 Ml in 1 Bottle		2020-2

Showing 1 to 1 of 1 entries

Previous 1 Next

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

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1-888-INFO-FDA (1-888-463-6332)

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Combination Products | International Programs | Consumers

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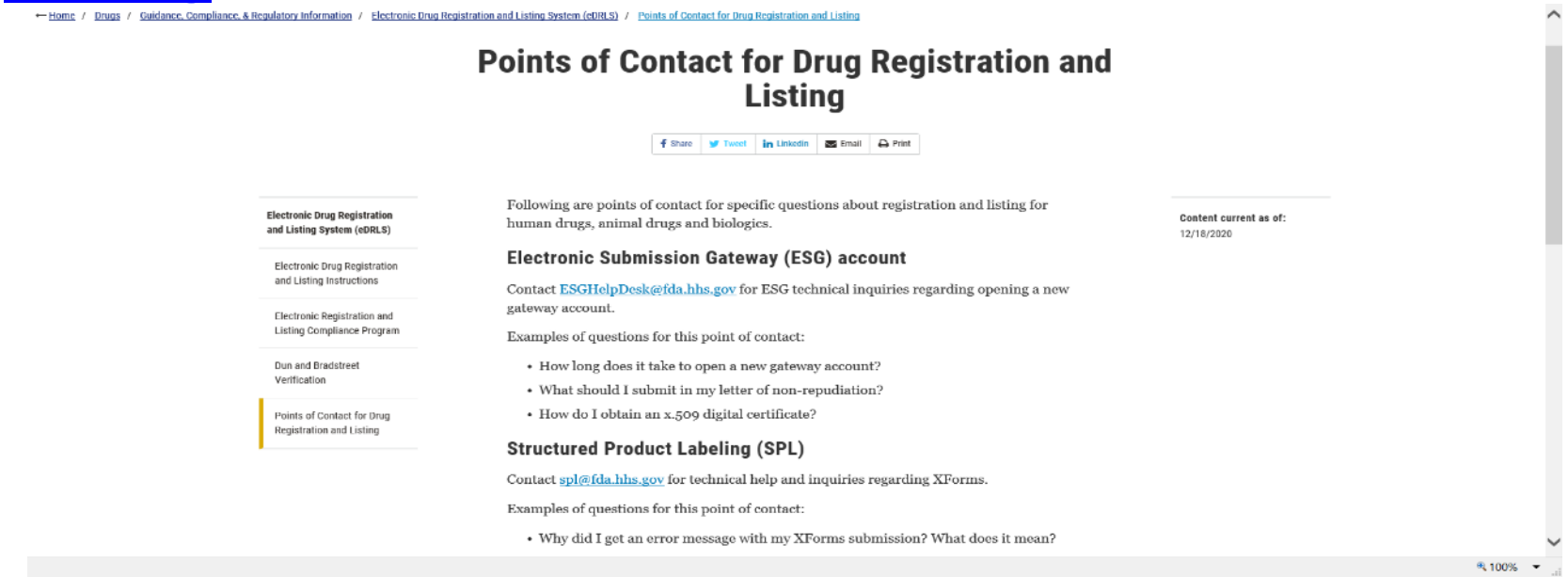
Points of Contact

- [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.

Content current as of:
12/18/2020

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?

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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

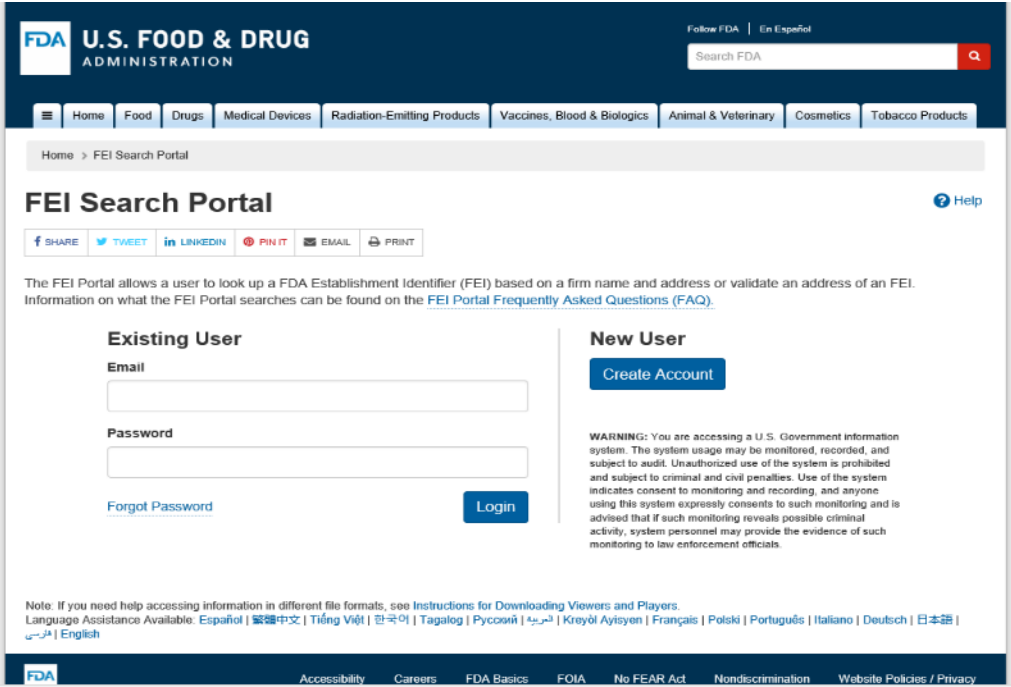
- Structured Product Labeling Resources
  - SPL Guidance Documents
  - SPL Terminology
  - SPL Implementation Guide and Validation Procedures
  - SPL Schema and Stylesheet information
  - GDUFA SPL Step-by-Step Instructions & Technical Specifications
  - Questions regarding SPL submissions should be 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

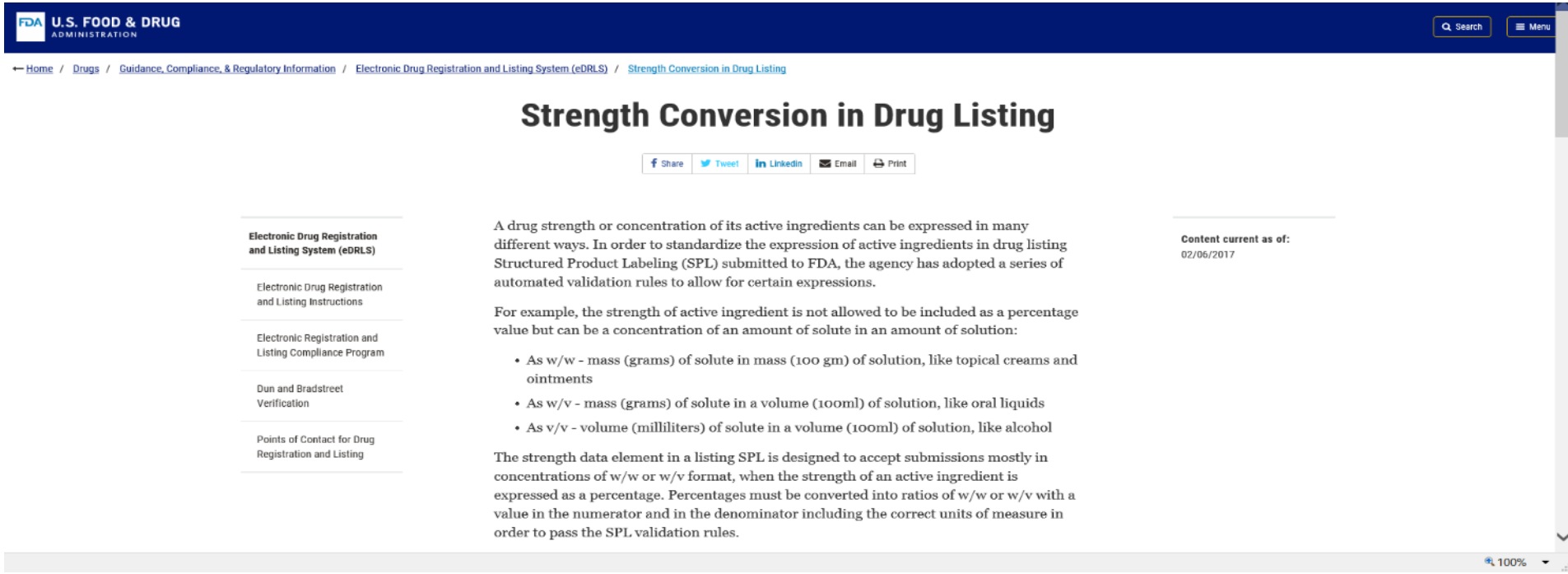
FEI Search Portal

- [FEI Search Portal]



Strength Conversion

- Strength Conversion in Drug Listing



U.S. FOOD & DRUG ADMINISTRATION

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Home / Drugs / Guidance, Compliance, & Regulatory Information / Electronic Drug Registration and Listing System (eDRLS) / 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

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Resources

- The National Drug Code (NDC)Directory
  - 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
- 503B Facilities
  - https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities
- Information for Outsourcing Facilities – 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
- 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


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