FDA Website: Resources Available to You

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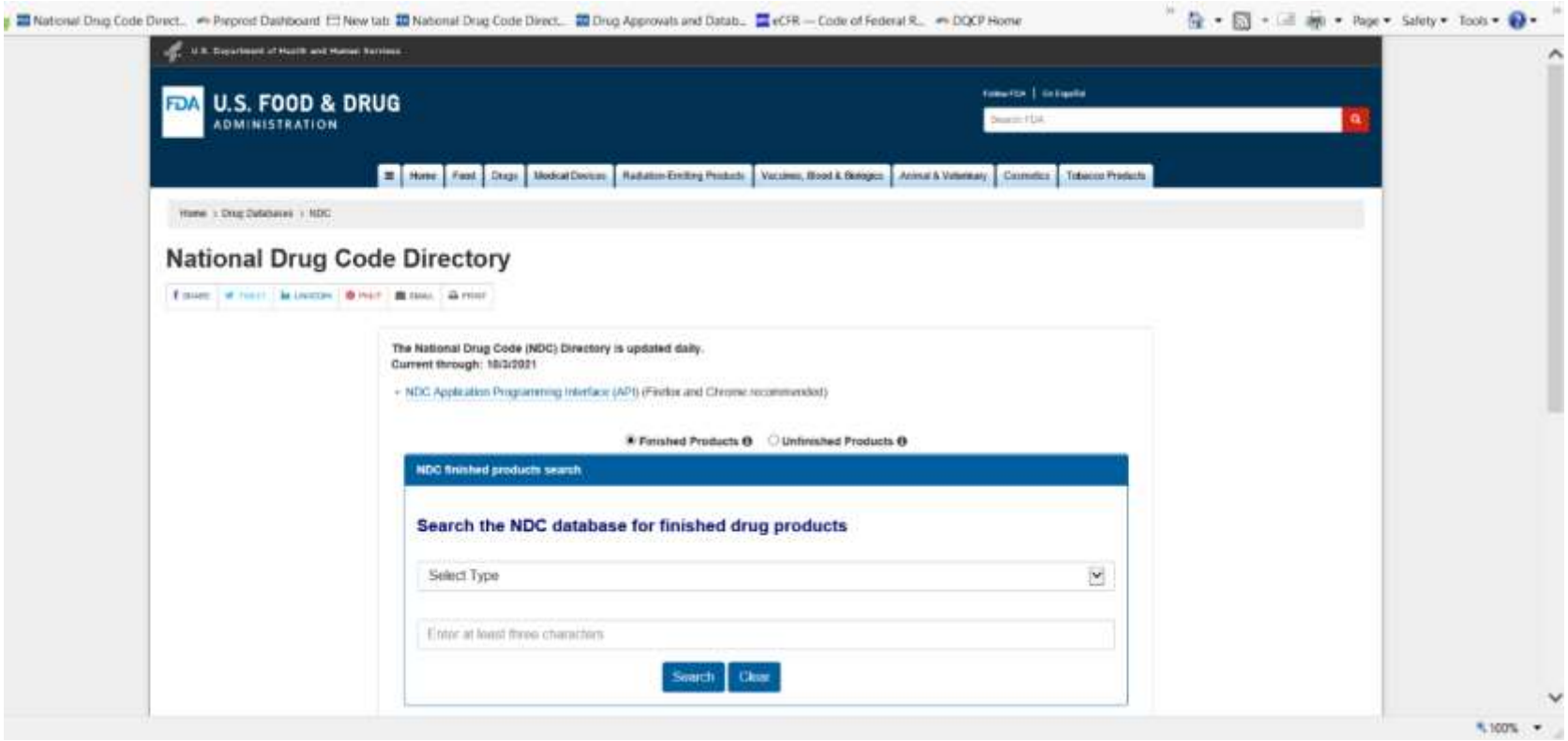
CDER | US FDA

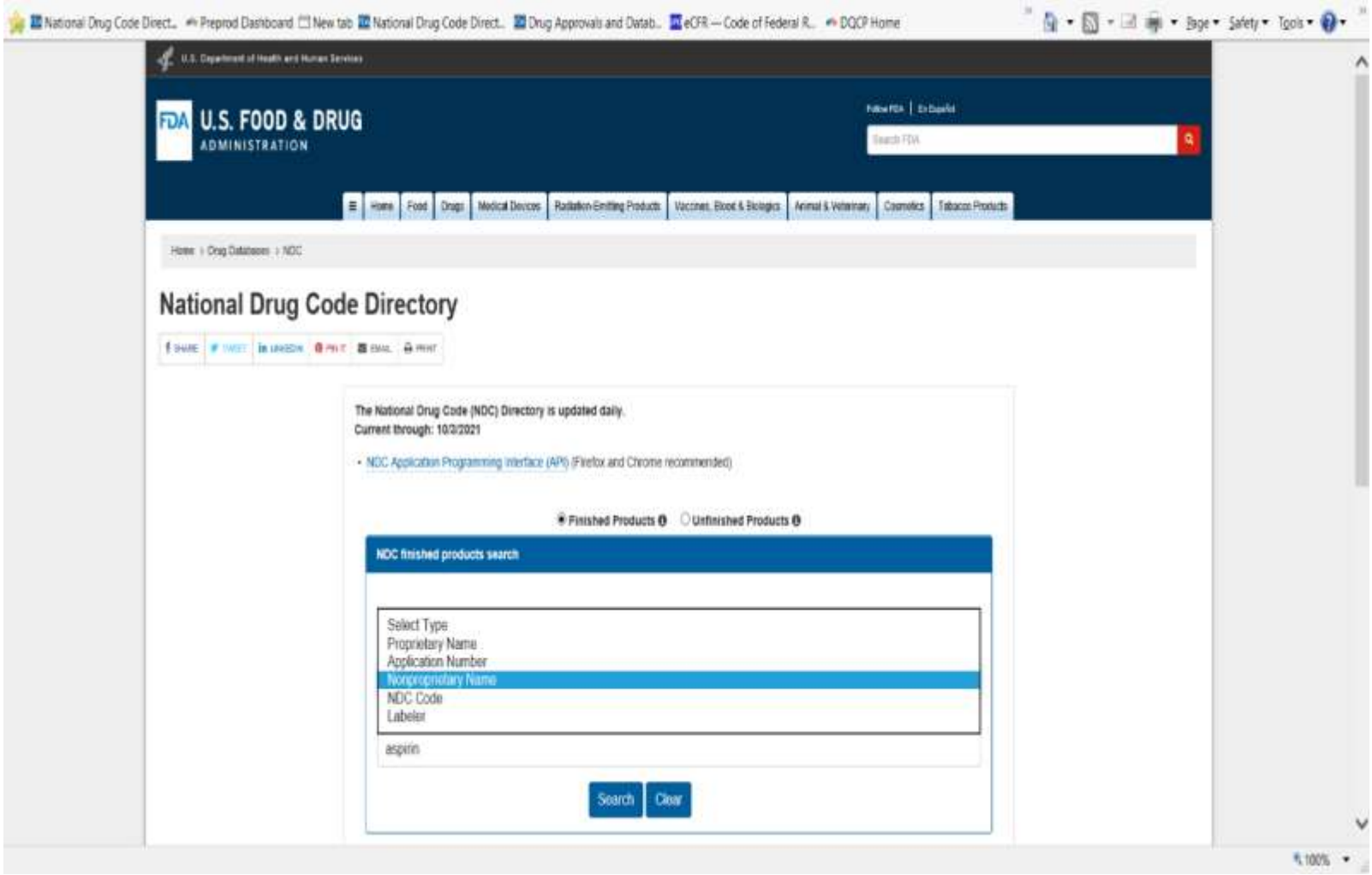
Electronic Drug Registration and Listing
Using CDER Direct – October 13, 2021

A Walkthrough of the FDA Website

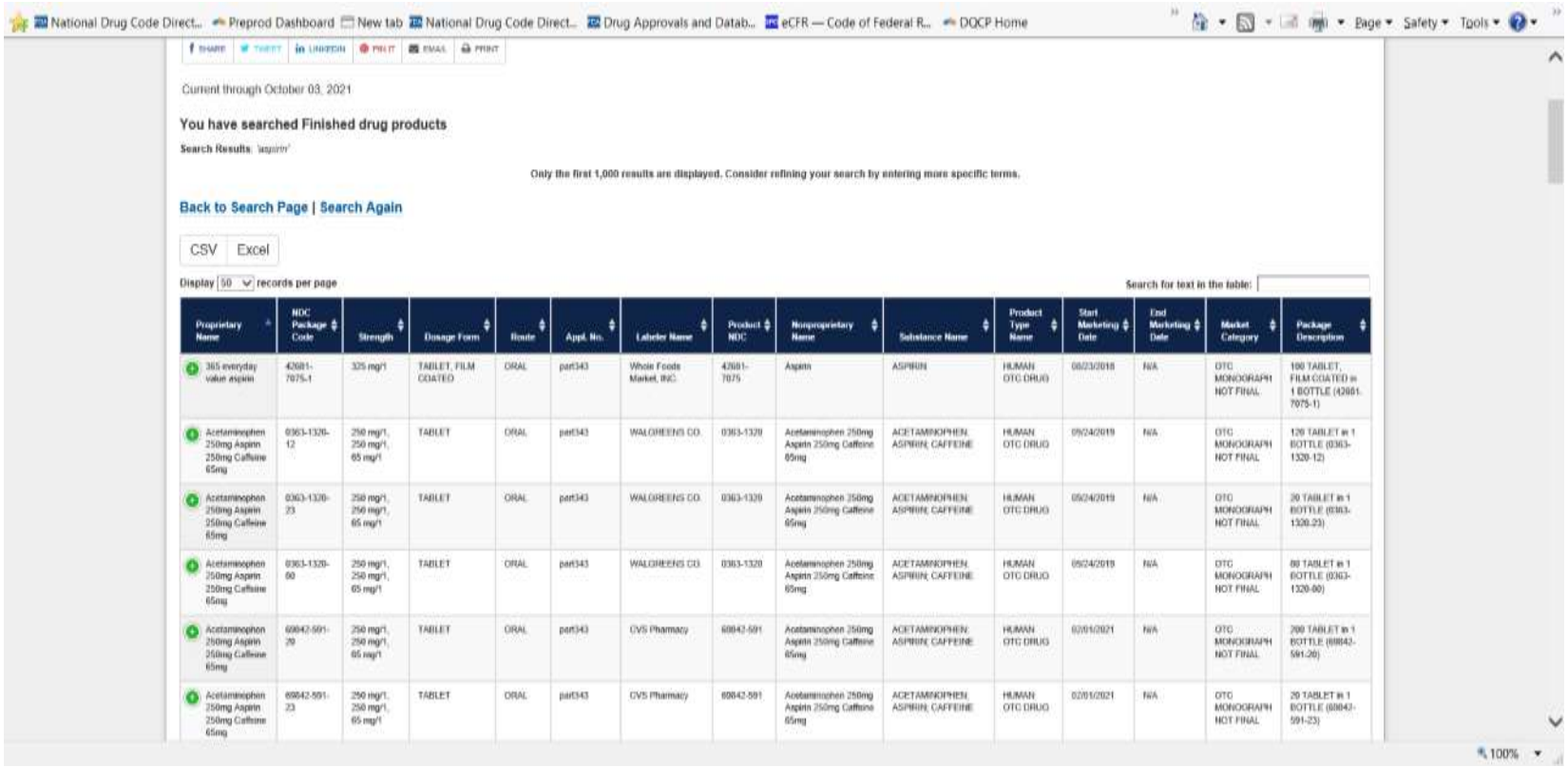
- The National Drug Code (NDC)Directory
  - Inclusion in the NDC Directory does not indicate that FDA has verified the information provided. The content of each NDC Directory entry is the responsibility of the labeler submitting the SPL file.
  - The NDC Directory does not contain all listed drugs. It 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



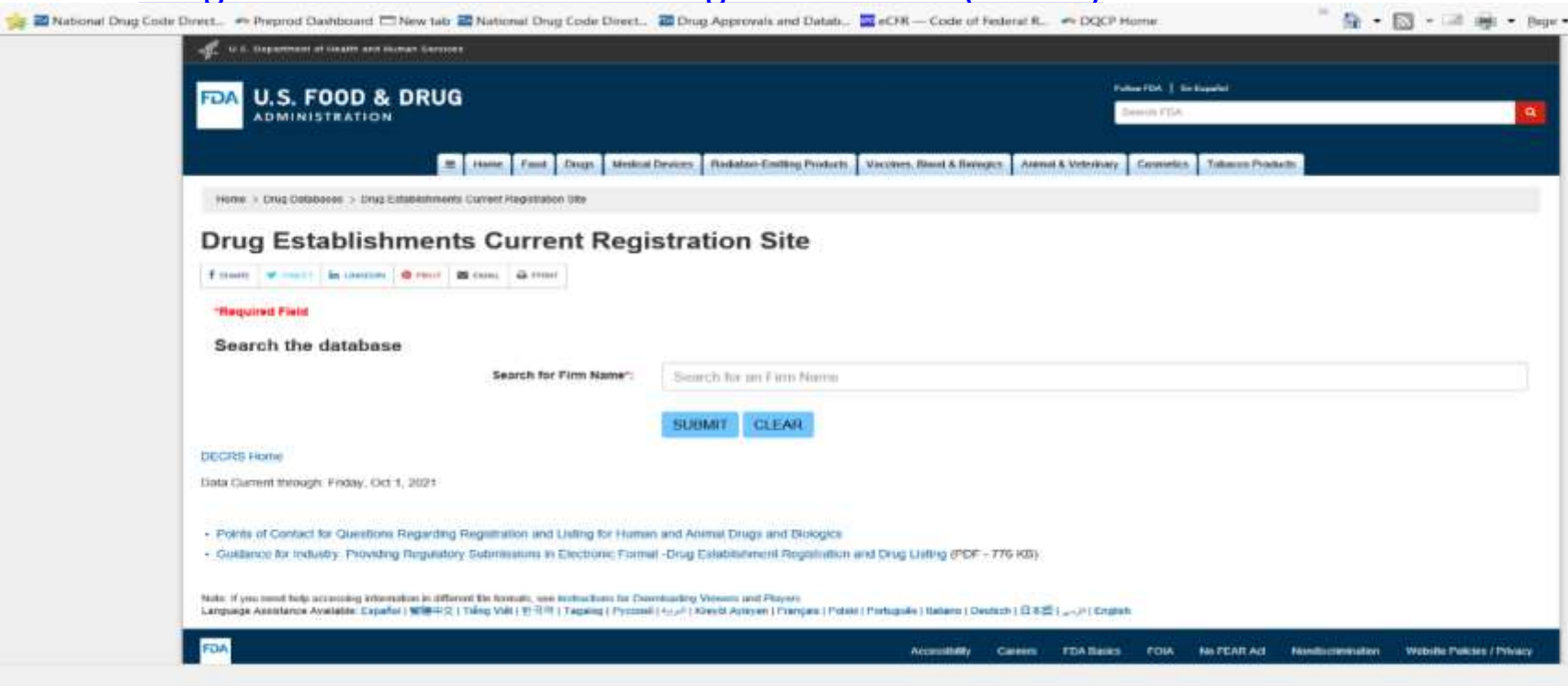

National Drug Code Direct...
Preprod Dashboard
New tab
National Drug Code Direct...
Drug Approvals and Datab...
eCFR — Code of Federal R...
DQCP Home
Page
Safety
Tools
U.S. Department of Health and Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION
Follow FDA | En Español
Search FDA
Home
Food
Drugs
Medical Devices
Radiation-Emitting Products
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Tobacco Products
Home › Drug Databases › NDC
National Drug Code Directory
SHARE
TWEET
LINKEDIN
PIN IT
EMAIL
PRINT
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

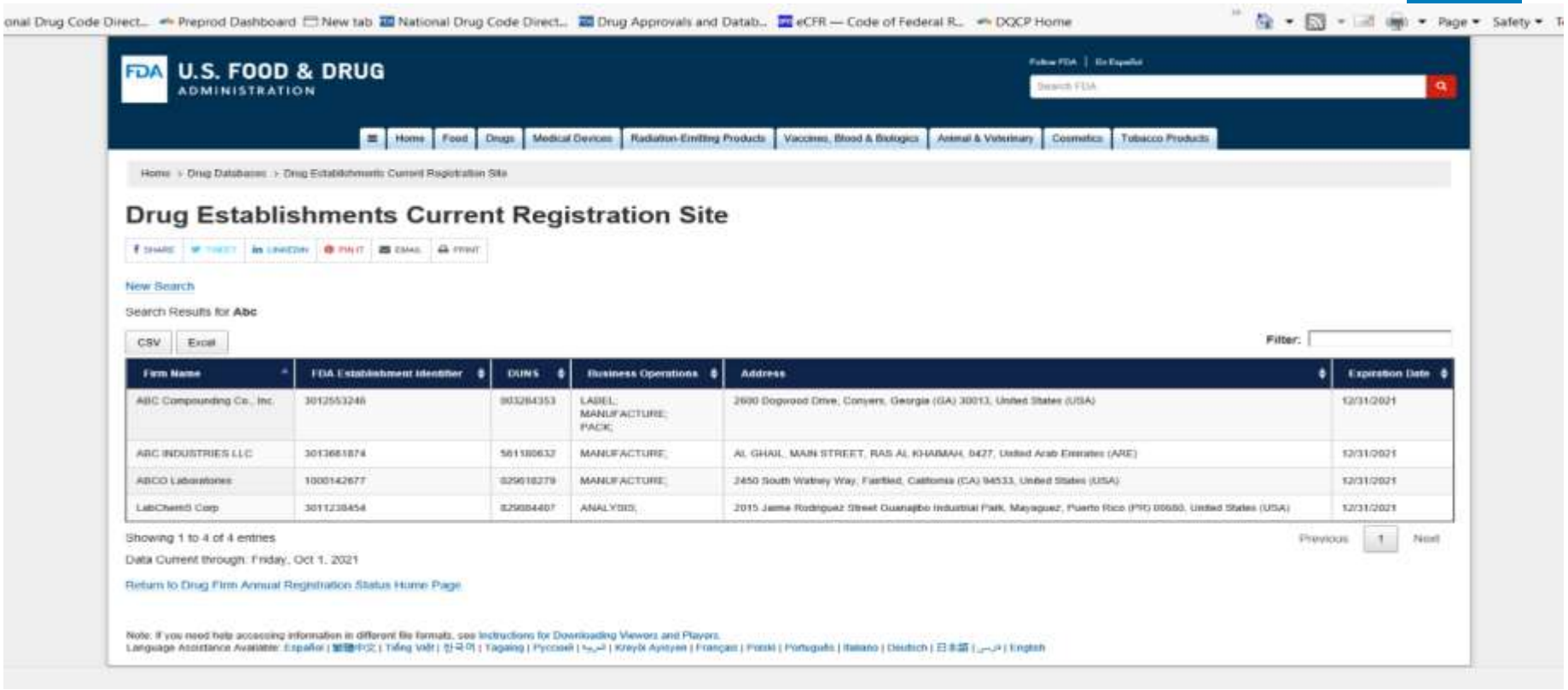


DECRS

- Drug Establishments Current Registration Site (DECRS)



DECRS


onal Drug Code Direct... Preprod Dashboard New tab National Drug Code Direct... Drug Approvals and Datab... eCFR — Code of Federal R... DQCP Home
Page Safety
FDA U.S. FOOD & DRUG ADMINISTRATION
Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products
Home › Drug Databases › Drug Establishments Current Registration Site
Drug Establishments Current Registration Site
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 | 803284353 | LABEL; MANUFACTURE; PACK; | 2600 Dogwood Drive, Conyers, Georgia (GA) 30013, United States (USA) | 12/31/2021
ABC INDUSTRIES LLC | 3013681874 | 561180632 | MANUFACTURE; | AL GHAIL, MAIN STREET, RAS AL KHAIMAH, 0427, United Arab Emirates (ARE) | 12/31/2021
ABCO Laboratories | 1000142677 | 829618279 | MANUFACTURE; | 2450 South Watney Way, Fairfield, California (CA) 94533, United States (USA) | 12/31/2021
LabChem5 Corp | 3011238454 | 825884407 | 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 1 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?[2]	Other Action, if Any, Based on Last Inspection[2,3]	Intends to Compounds Sterile Drugs From Bulk Drug Substances[4]

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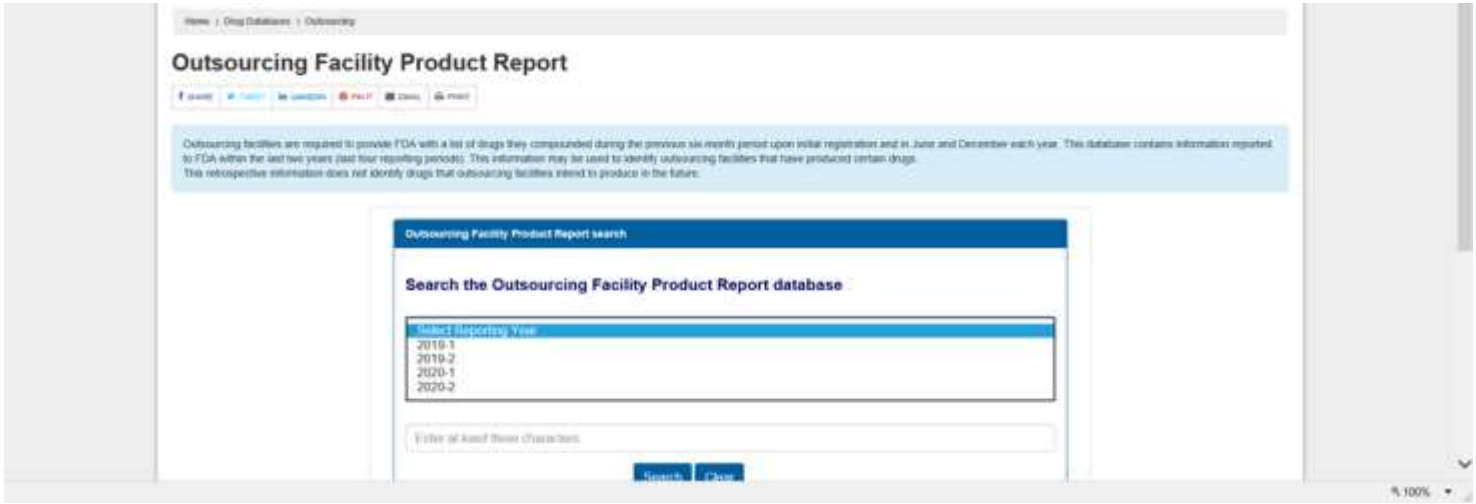
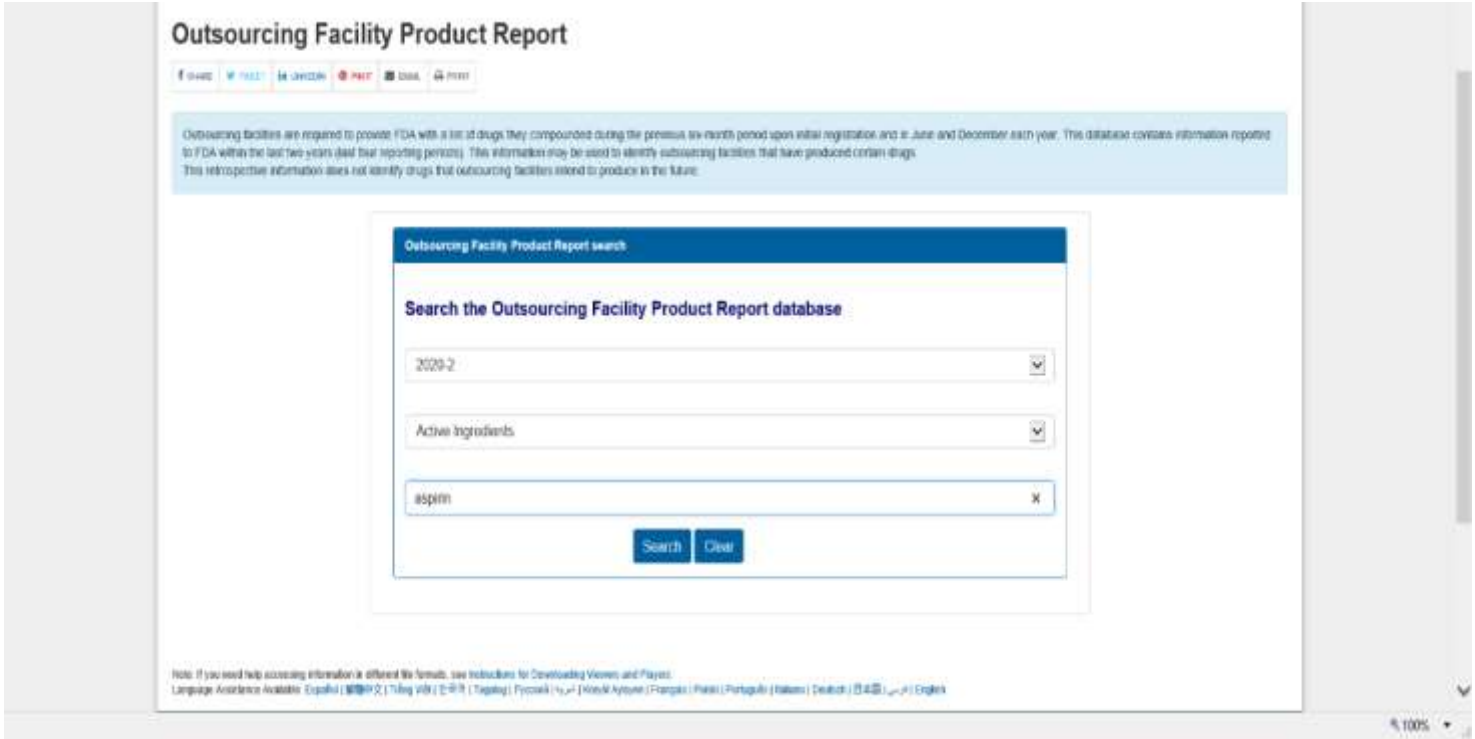
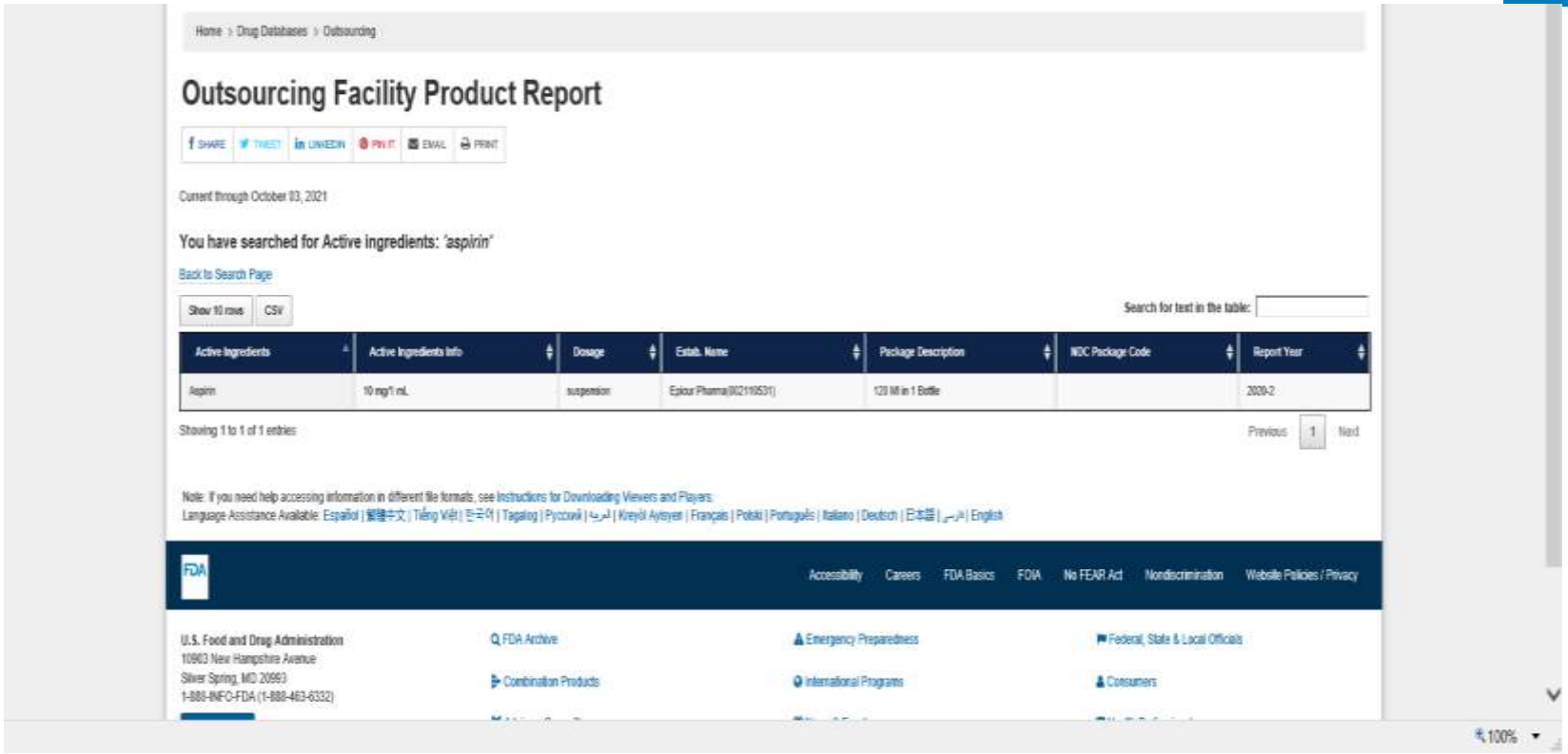
Information for Outsourcing Facilities

- Information for Outsourcing Facilities – link to reporting



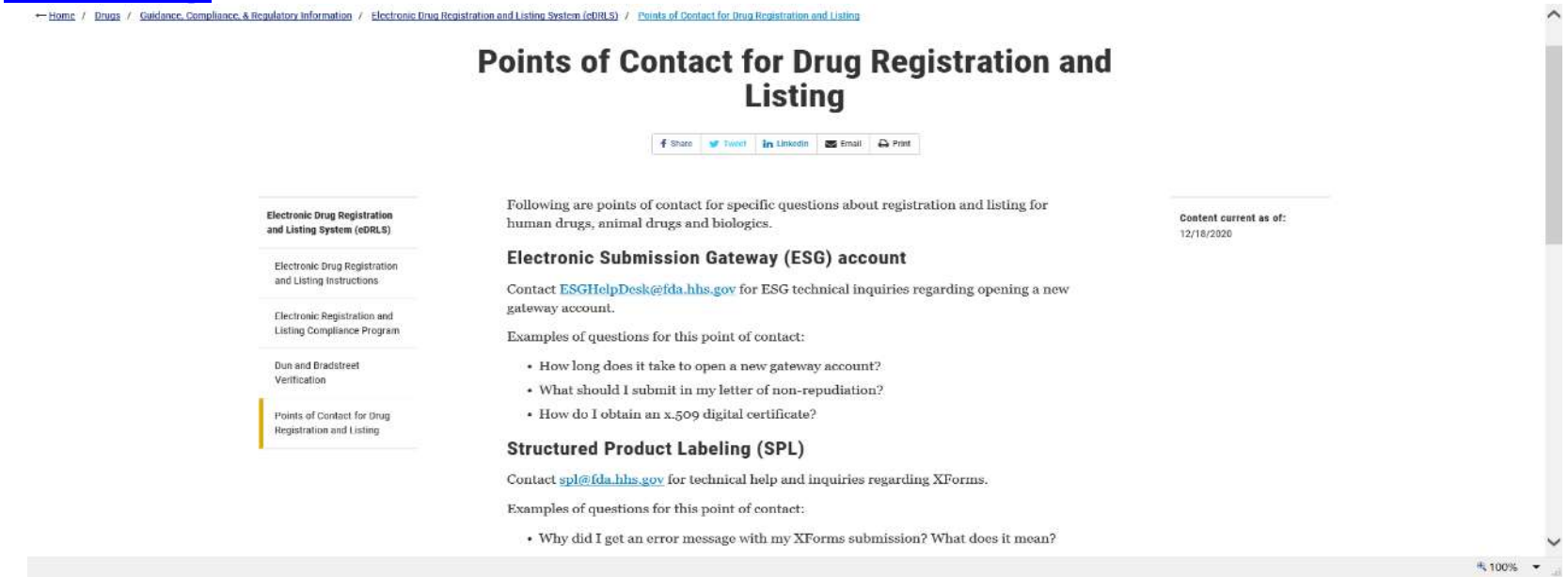

Outsourcing Facility Product Report
Outsourcing Facility Product Report search
Search the Outsourcing Facility Product Report database
2020-2
Active Ingredients
aspirin
Search
Clear

Outsourcing Facility Product Report



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 contd.

- **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 contd.

- **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

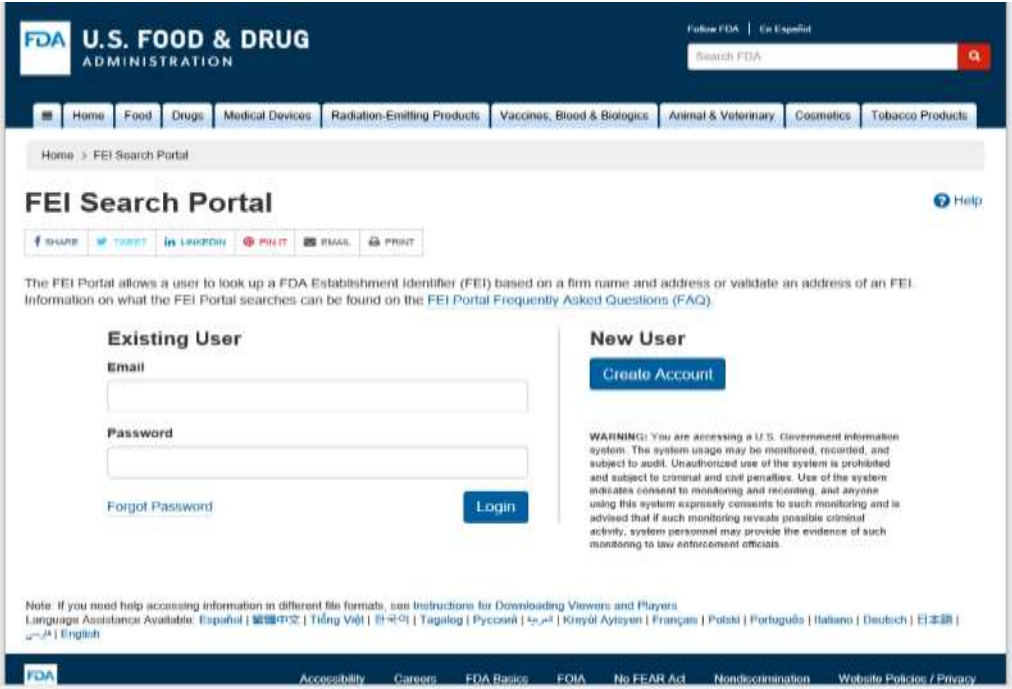
- Structured Product Labeling Resources
  - SPL Guidance Documents
  - SPL Terminology
  - SPL Implementation Guide and Validation Procedures
  - SPL Schema and Stylesheet information
  - GDUFA SPL Step-by-Step Instructions & Technical Specifications
  - Questions regarding SPL submissions should be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

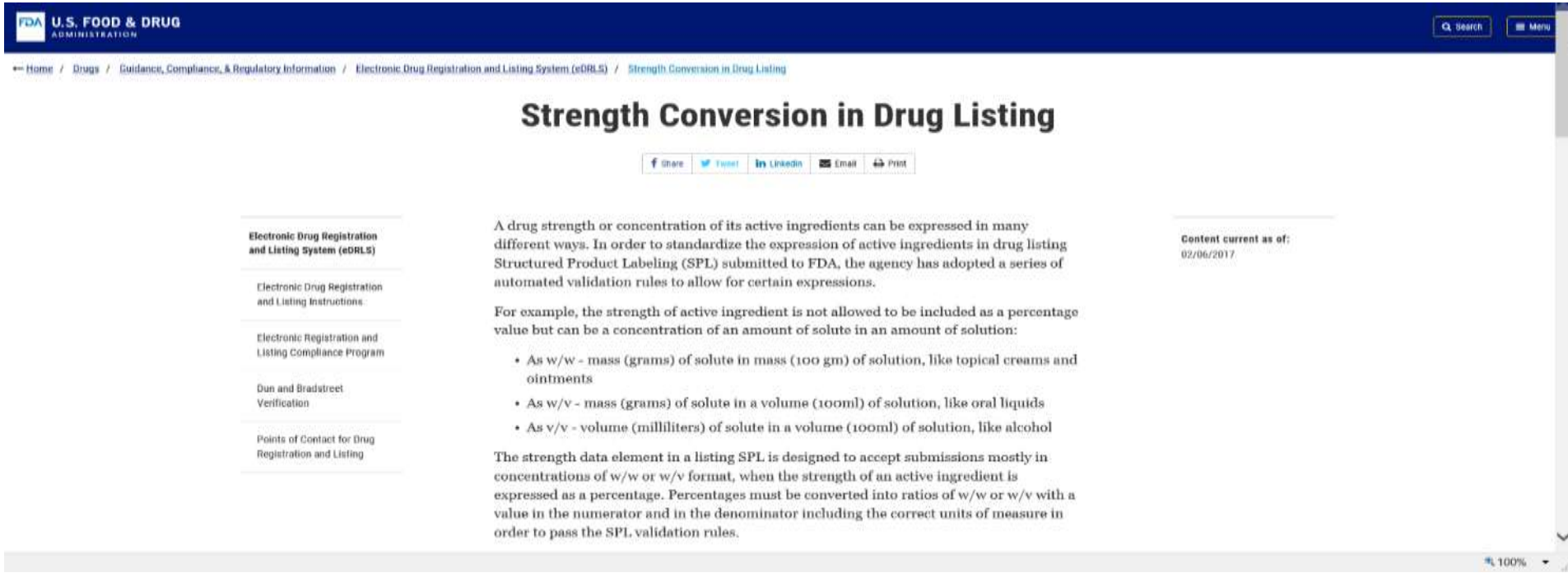
FEI Search Portal

- [FEI Search Portal]



Strength Conversion

- Strength Conversion in Drug Listing



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

- 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

- 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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