

How to use the Drug Establishment Current Registration Site (DECRS)

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Learning Objectives

- What is the Drugs Establishment Current Registration Site?
- How can you access and search the database?
- What can and cannot be searched in DECRS?
- How often is the database updated and when does new registration information appear?
- Who should scan the data found in DECRS?
- What if you find inaccurate information in the database?
- Challenge questions

What is DECRS and what is included in the database



A database which includes a list of all currently registered drug establishments (facilities) which manufacture, prepare, propagate, compound or process drugs that are commercially distributed in the U.S. or are offered for import into the U.S. See section 510 of the FD&C Act, 21 USC 360.

What types of firms are included in DECRS?

- Manufacturers
- Repackagers
- Relabelers
- Contract manufacturing organizations (manufacture, pack, label)
- Analytical labs



What is Not Included in DECRS?

What firms are not included in DECRS?

- Firms with expired registration
- Firms which have deregistered their establishments
- Firms which are dropped from the registration submission

What is Not Included in DECERS



- This database does not contain establishments registered as human drug compounding outsourcing facilities under section 503B.
 - For a list of current 503B registrants, see [outsourcing facilities](#).
 - An outsourcing facility may also appear in the DECERS 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.
 - See [wholesale distributor and third party logistics providers reporting](#) for more information.



The DECERS Webpage

- When is it updated?
 - The data is updated daily on weekdays
- How long after registration does data show up in the directory
 - The registration data will appear within 1-2 business days of successful registration
- Includes a search page and a downloadable file

How to search in the DECRS



<https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>

Home > Drug Databases > Drug Establishments Current Registration Site

Drug Establishments Current Registration Site

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***Required Field**

Search the database

Search for Firm Name*:

SUBMIT

CLEAR

[DECRS Home](#)

Data Current through: Wednesday, Sep 2, 2020

- [Points of Contact for Questions Regarding Registration and Listing for Human and Animal Drugs and Biologics](#)
- [Guidance for Industry: Providing Regulatory Submissions in Electronic Format -Drug Establishment Registration and Drug Listing](#) (PDF - 776 KB)

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

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The Search Results in DECRS



Results of a search will include:

- The firm name
- FDA Establishment Identifier (FEI)
- DUNS number
- Business operations
- Address of the registered firm
- Expiration date of the registration



The DECRS Data

- Search result is downloadable (CSV or Excel)
- There's also a downloadable file available
- <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site>
 - This is the complete file and includes more information such as
 - Establishment's contact information
 - Registrant's contact information
 - U.S. agent details

How the Data is Used

- Some uses of the data in DECRS:
 - To verify the registration status of a firm
 - Research
 - U.S. agents monitoring unauthorized use

Inaccurate Data

- A manufacturer is registered by another entity without authorization
- Registration data of a company is known to be inaccurate
 - Email us at edrls@fda.hhs.gov
- A U.S. agent is included on a registration submission without authorization
 - Contact the firm. You can cc edrls@fda.hhs.gov.

Challenge Questions

- Challenge Question #1
- Which statement is incorrect:
 - A. DECRS includes a list of all currently registered drug establishments
 - B. Search result in DECRS is downloadable
 - C. The data is updated once a week on Mondays
 - D. Analytical labs are included in the database

Challenge Questions



- Challenge Question #2
- How long after registration does the data show up in the directory?
 - A. 2 hours after submission of the registration SPL
 - B. 24 hours after submission of the registration SPL
 - C. 1- 2 business days after successful submission of the registration SPL
 - D. Data can take up to 10 business days

Thank You!

Questions?

Contact us: EDRLS@fda.hhs.gov