How to Use The National Drug Code Directory

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Learning Objectives

- What is the NDC Directory and how often is it updated?
- What is included and what is not included
- Important considerations about the NDC Directory
- Proprietary information in NDC Directory
- How to access and search the NDC Directory
- Challenge questions

The National Drug Code (NDC) Directory

- A publication of FDA that includes listing information submitted by companies as part of the listing requirements under section 510 of the FD&C Act, 21 USC 360.
- The NDC – a unique 3 segment code – universal product identifier for drugs
- The NDC Directory is maintained by Drug Registration and Listing Staff
- Data in the NDC Directory is updated daily on weekdays

What is included in the NDC Directory

The NDC Directory includes information on final marketed drugs submitted to FDA in Structured Product Labeling (SPL) format

It includes:

- Prescription and nonprescription drugs
- Approved and unapproved drugs
- Repackaged and relabeled drugs

Data Files for Unfinished Drugs

Unfinished file (not part of the NDC Directory, but resides on its homepage) contains product listing data for all unfinished drugs:

- Active Pharmaceutical Ingredients (API)
- Drugs for further processing
- Bulks for human drug compounding

What is not included in the NDC Directory

The NDC Directory does not contain all listed drugs:

- It does not include animal drugs or blood products
- It does not include 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
- It does not include drugs with the “Manufactured Under Contract” marketing categories

Important Considerations

- Assignment of an NDC number does not in any way denote FDA approval of the product. Any representation that creates an impression of official approval because of possession of an NDC number is misleading and violates federal law

- Inclusion in the NDC Directory or assignment of an NDC number does not mean that a product is a drug as defined by the FD&C Act.

- 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.

Important Considerations

- The NDC Directory contains product listing data that have reached the marketing start date and have not reached the marketing end date
- Inclusion in the NDC Directory does not mean a product is covered or eligible for reimbursement by Medicare, Medicaid or other payors.
- Assignment of NDC number to non-drug products is prohibited
- An NDC number cannot be reused

Exclusion Flags

- Several exclusion codes found next to the proprietary name in the search results:
- Show status of products which have been removed/excluded from the Directory
  - "U" -- Records marked with (U): This information was removed from publication, because the record is uncertified**.**
  - "E" – Records marked with (E) Means this information was removed from publication, because FDA has found inaccuracy in the data submitted by the firm.
    - ***Data will be released for publication once complete and accurate information is submitted to FDA***

Proprietary Information

Data marked as confidential by the labeler will not be found in the NDC Directory:

- Manufacturing facility
- Inactive ingredient data

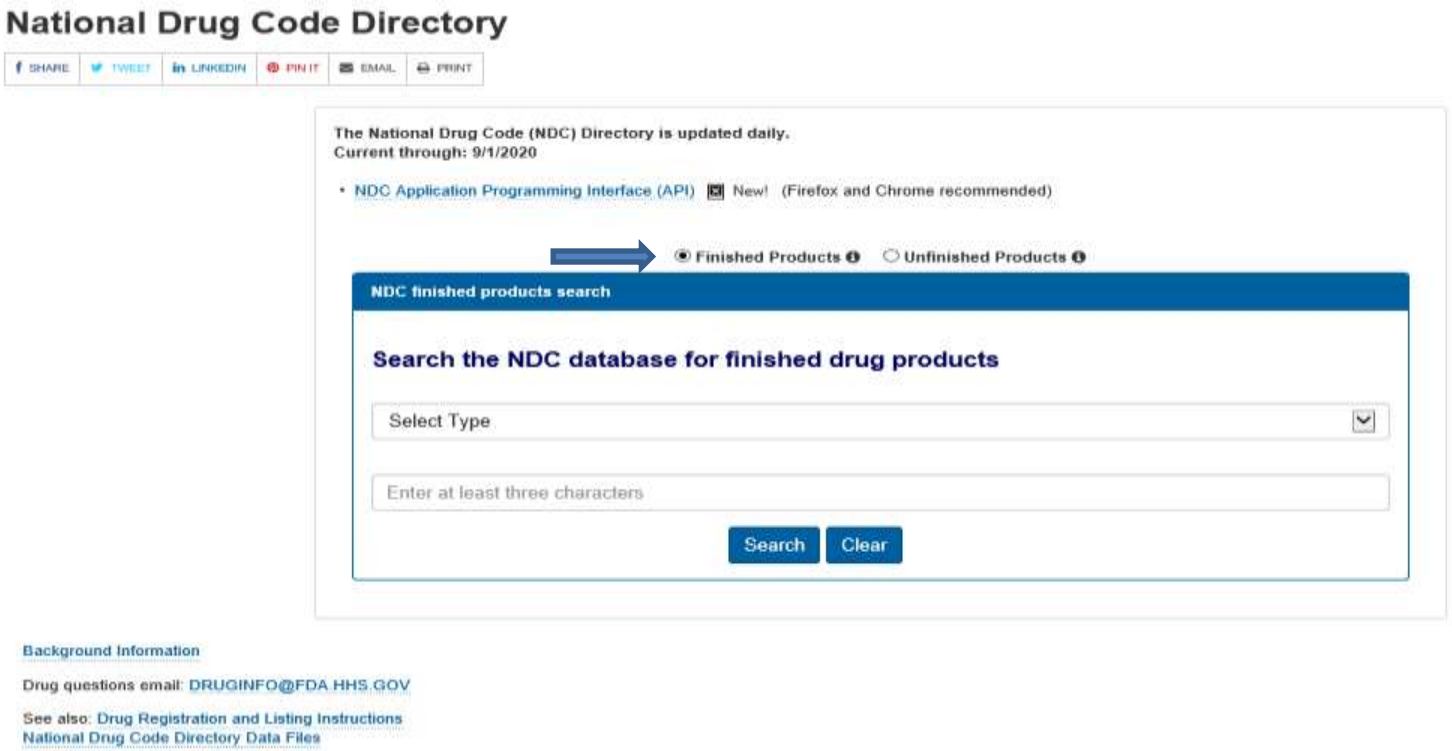
The NDC Directory Files

Downloadable Files

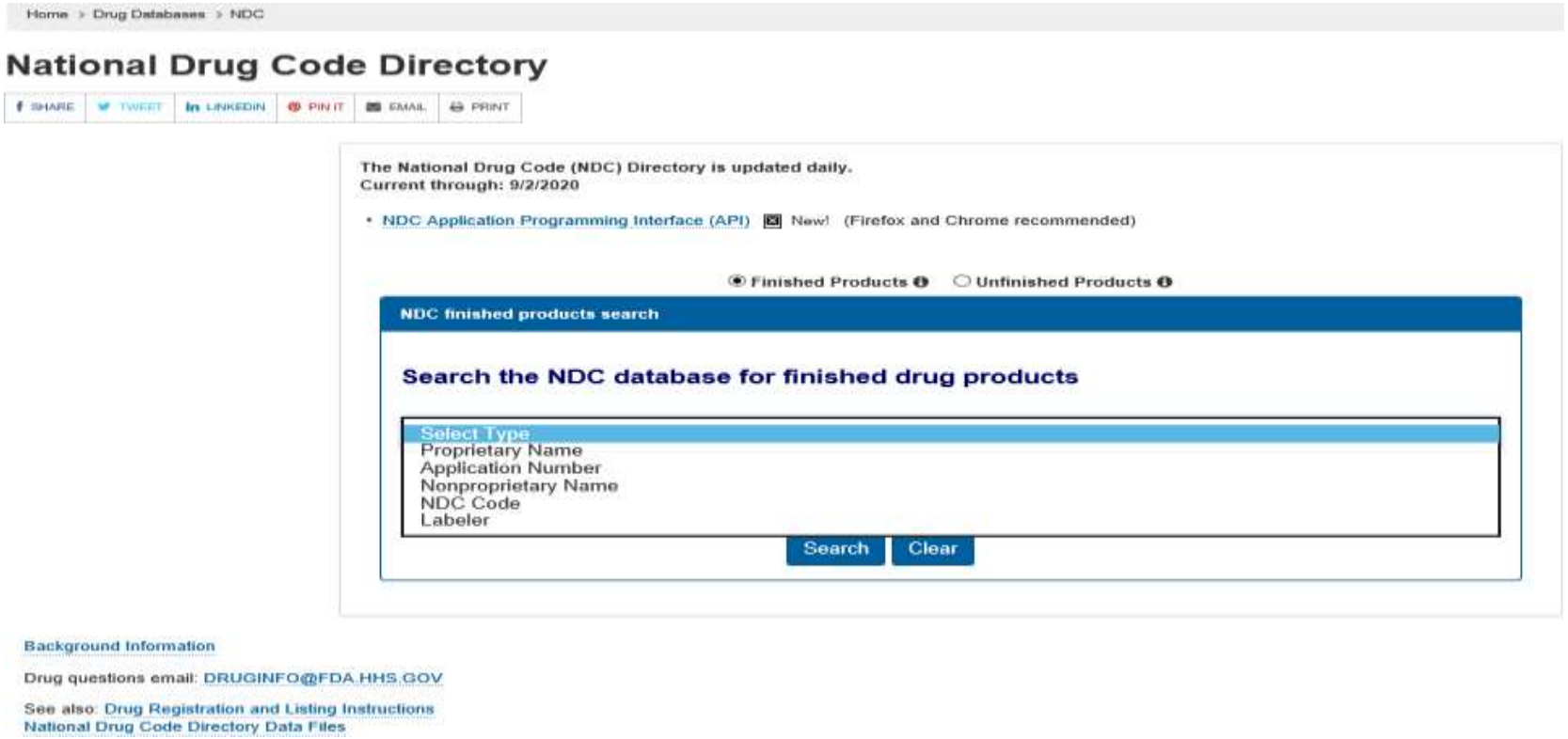
- Two files available- products file and packages file
- Two file formats- spreadsheet version and CSV format

Searching in the NDC Directory

https://www.accessdata.fda.gov/scripts/cder/ndc/



Searching in the NDC Directory



Searching in the NDC Directory

Searching in the NDC Directory

- Searching for unfinished products

Adding or Updating Entries in the NDC Directory

- To add a new entry or to update an incorrect entry
  - Labelers must submit a new or updated drug listing SPL
- Accuracy of the listing data is the responsibility of the company submitting the information to FDA
- Data accuracy and integrity is monitored through the Drug Registration and Listing Compliance Program

Challenge Questions

Challenge Question #1---------- True or False

You can search for medicated feed in the NDC Directory.

Challenge Questions

Challenge Question #2

All of these are options for searching under the unfinished file except:

A. The NDC Code

B. Labeler name

C. Nonproprietary name

D. Application number

Questions?

Contact us: EDRLS@fda.hhs.gov