Center of Excellence
503B Product Reporting
Compounded Products Update
NDC Directory

Office: CDER/OC/OCQC

September 7, 2022

Learning Objectives

- Regulation
  - 503B Registration
  - 503B Product Reporting
- NDC Directory Search
- Summary
- Related Resources

FD&C Act

Upon Registration per 503B the Outsourcing Facility must:

- Submit an initial product reporting of all products compounded during the previous six-month period
- Submit product reports twice a year thereafter, in June and December

Compounded Products Online

- FDA received requests to:
  - Create a new marketing category
  - Include compounded drug NDCs in the NDC Directory
- FDA created marketing category:

  "Outsourcing Facility Compounded Human Drug Product
  (Exempt from Approval Requirements)"
- FDA published a new feature in the NDC Directory Search

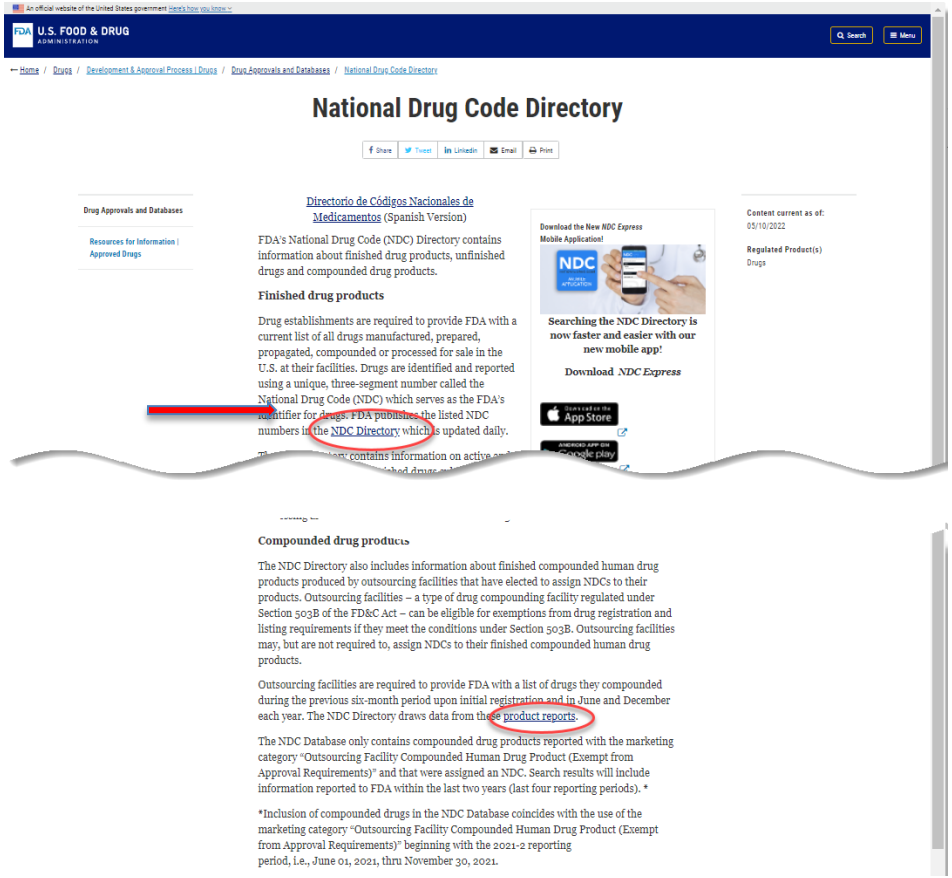
  Search tool now includes "Compounded Products"
  (Outsourcing Facility Compounded Human Drug Products)

Compounded Products Online

- **National Drug Code Directory & Outsourcing Facility Product Report**
  https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

Compounded Products

NDC Directory & Product Reports

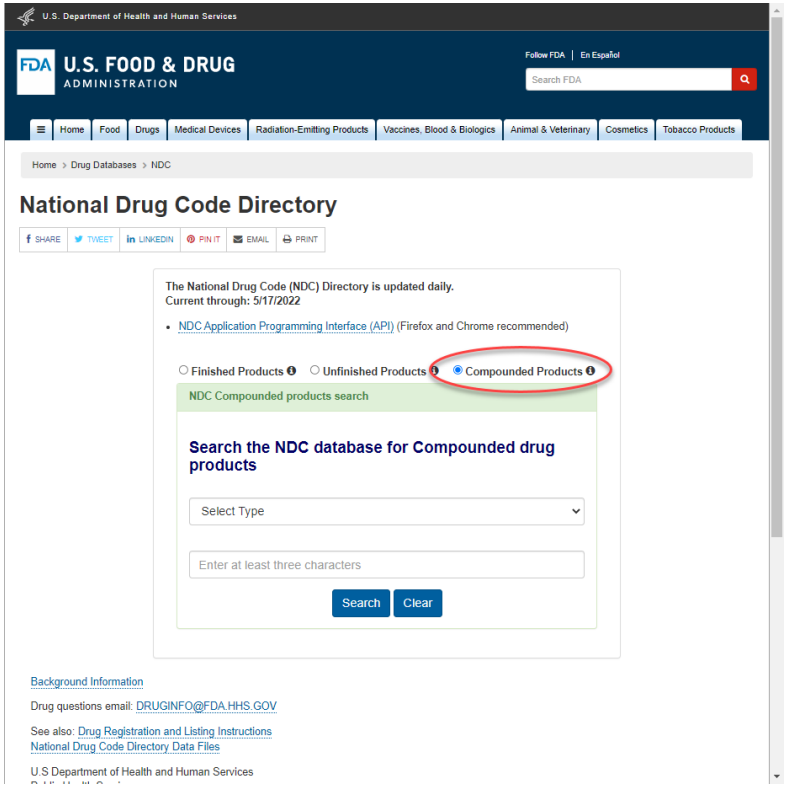


NDC Directory Search

- Daily Updates
- Select radio button for:

  “Compounded Products”
- Notice green header

  NDC Compounded products search
- Select Type
  - Nonproprietary name
  - NDC Code
  - Establishment information



NDC Directory Search: Example

EXAMPLE: search for product name the contains letters “fen”

- Select radio button for:

  “Compounded Products”

- Notice green header

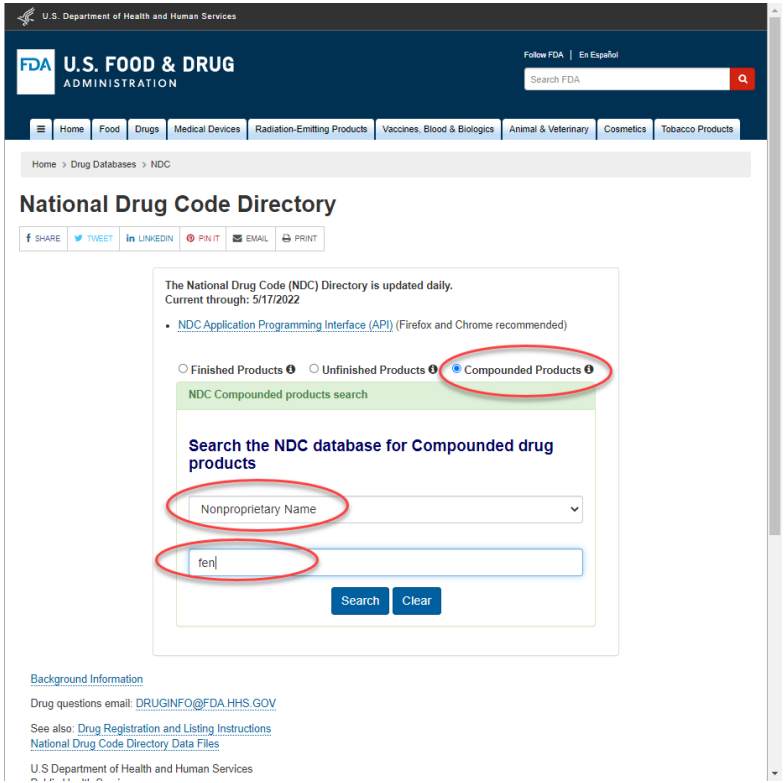
  NDC Compounded products search

- Select Type from list:

  “Nonproprietary Name”

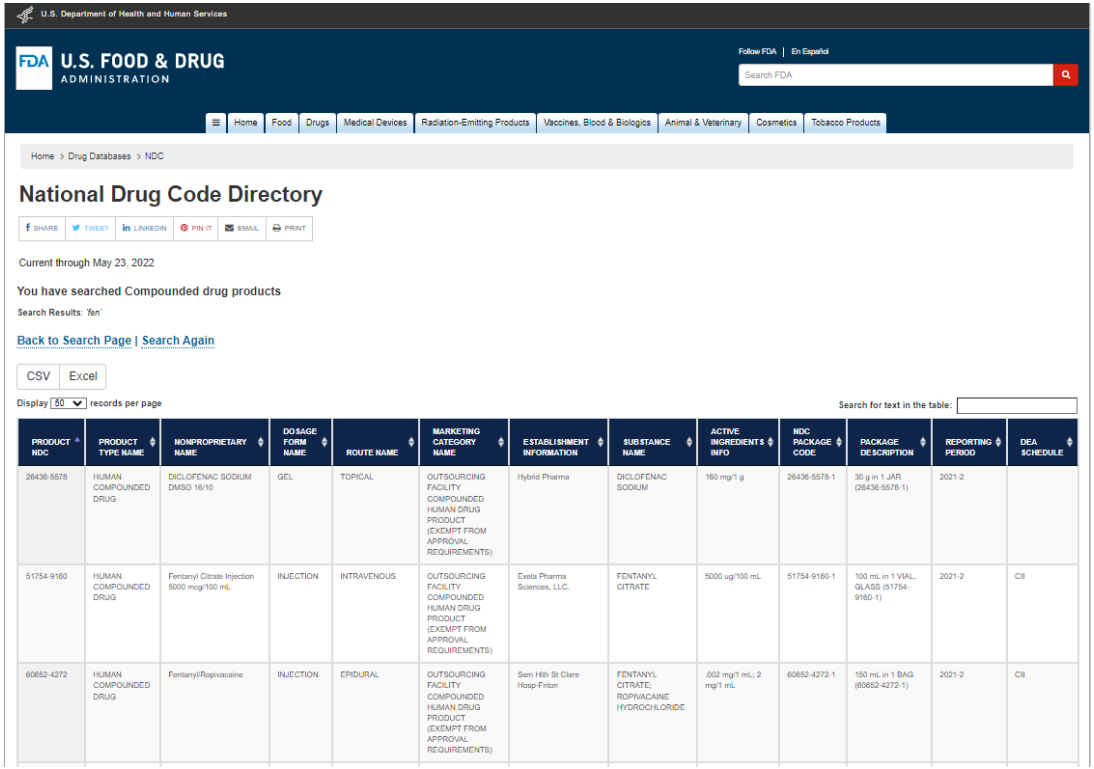
- Enter at least three characters

  “fen”



NDC Directory Search: Result

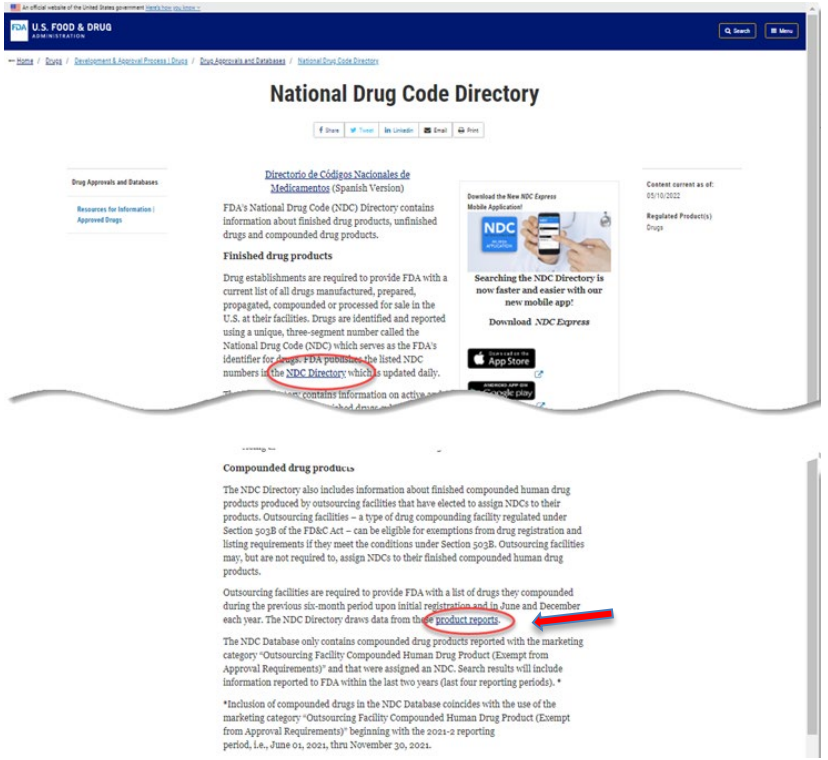
- PRODUCT NDC
- PRODUCT TYPE NAME
- NONPROPRIETARY NAME
- DOSAGE FORM NAME
- ROUTE (OF ADMIN.) NAME
- MARKETING CATEGORY NAME
- ESTABLISHMENT INFORMATION
- SUBSTANCE NAME
- ACTIVE INGREDIENTS INFORMATION
- NDC PACKAGE CODE
- PACKAGE DESCRIPTION
- REPORTING PERIOD
- DEA SCHEDULE



OF Product Report: NDC

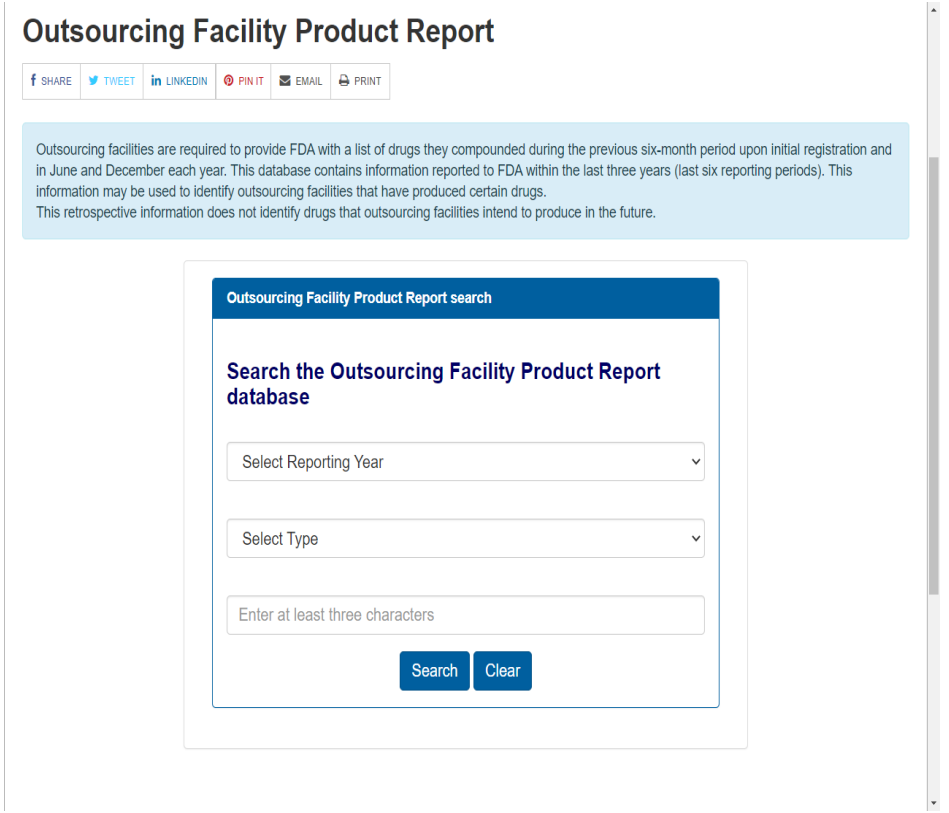
- The complete list is in the “product reports”
- Will include three years

  (last six reporting periods)
- The OF product report will include products with the new marketing category which became available on reporting period 2021-2.



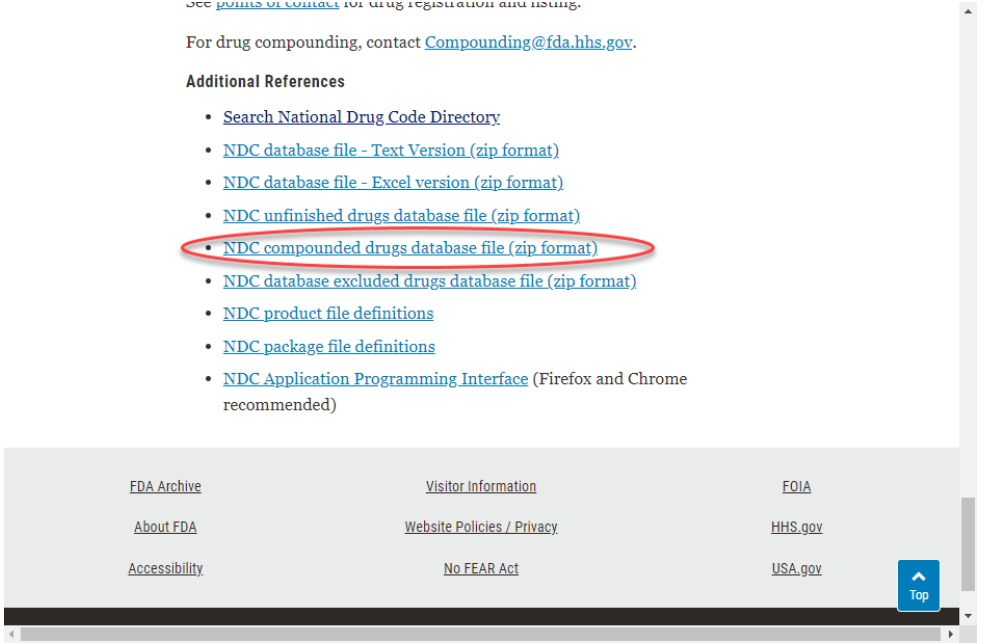
OF Product Report: NDC cont..

- Complete outsourcing facility reports
- Must select a reporting year period
- Select type of search:
  Active Ingredients or
  Establishment Name
- Enter at least three characters
- Results
  - Active Ingredients
  - Active Ingredients Information
  - Dosage Form
  - Establishment Name
  - Package Description
  - NDC Package Code
  - Report Year Period



NDC compounded drugs file

- The complete list of compounded human drugs with an NDC as a file is available for download.
- File can be unzipped and read as an excel file.
- The file contains the following data elements:
  - PRODUCT NDC
  - PRODUCT TYPE NAME
  - PROPRIETARY NAME
  - PROPRIETARY NAME SUFFIX
  - NONPROPRIETARY NAME
  - DOSAGE FORM NAME
  - ROUTE [OF ADMINISTRATION] NAME
  - MARKETING CATEGORY NAME
  - LABELER NAME
  - SUBSTANCE NAME
  - ACTIVE INGREDIENTS INFO
  - DEA SCHEDULE
  - NDC PACKAGE CODE
  - PACKAGE DESCRIPTION
  - REPORTING PERIOD



NDC Directory

Important Considerations

The NDC Directory contains compounded human drug products made by outsourcing facilities

- Assigned NDC within the last two years (last four reporting periods)
- Reported using the marketing category “Outsourcing Facility Compounded Human Drug Product (Exempt from Approval Requirements)”

- Publishing of the NDC does not constitute drug listing per FFDCA Section 510 and 21CFR207
- Assignment of an NDC number does not in any way denote FDA approval of the product
- Inclusion in the NDC Directory does not indicate that FDA has verified the information provided

Helpful Resources

- **The Drug Quality and Security Act: Human Drug Compounding Outsourcing Facility:** https://www.fda.gov/drugs/human-drug-compounding/text-compounding-quality-act

- **Guidance for Industry: Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Final Guidance):** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-drug-product-reporting-human-drug-compounding-outsourcing-facilities-under-section-503b

Helpful Resources

- **Drug Approvals and Databases:** https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

- **Electronic Drug Registration and Listing Instructions:** https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions

- **Human Drug Compounding Website:** https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

Helpful Resources

- **National Drug Code Directory:**
  https://www.fda.gov/drugs/informationondrugs/ucm142438.htm

- **NDC Directory Search:**
  https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm

- **Outsourcing Facility Product Report Search:**
  https://www.accessdata.fda.gov/scripts/cder/outsourcingfacility/index.cfm

- **NDC compounded drugs database file (zip format):**
  https://www.accessdata.fda.gov/cder/compounders_ndc_directory.zip

Challenge Question

Which of the following are TRUE statements related to Outsourcing Facilities and Product Reporting?

A. If available, the NDC for any source drug or bulk active ingredient must be reported to FDA.

B. Assignment of an NDC number to a final product is not required.

C. Only one search location is available for compounded human drugs with NDCs.

D. If a firm registers in April 2021, they are not required to submit an initial product reporting as long as they submit one by end of June 2021.

Contact Us!

- **eDRLS Helpdesk:** edrls@fda.hhs.gov
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