

**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**

*Learning Objectives*



# 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>

U.S. FOOD & DRUG ADMINISTRATION

Home / Drugs / Development & Approval Process / Drugs / Drug Approvals and Databases

## Drug Approvals and Databases

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Drug Approvals and Databases

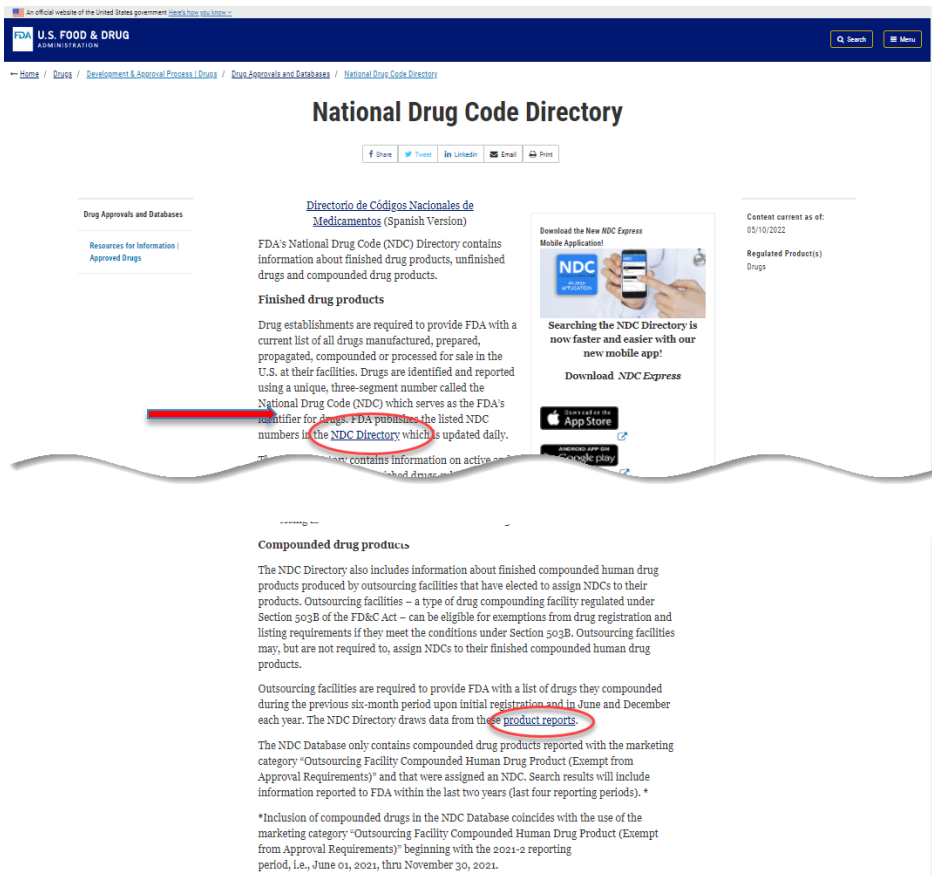
Resources for Information | Approved Drugs

Content current as of: 09/23/2021

- [Acronyms and Abbreviations Search](#)  
More information
- [Approved Risk Evaluation and Mitigation Strategies \(REMS\)](#)
- [Bioresearch Monitoring Information System \(BIMS\) Search](#)  
More information
- [Clinical Investigator Inspection List \(CLIL\) Search](#)  
More information
- [Dissolution Methods Database Search](#)  
More information
- [Drug Establishments Current Registration Site Search](#)  
More information
- [Drug Safety-related Labeling Changes \(SrLC\)](#)  
More information
- [Inactive Ingredient Search for Approved Drug Products Search](#)  
More information
- [Medication Guides Search](#)  
More information
- [National Drug Code Directory Search](#)  
More information
- [Orange Book \(Approved Drug Products with Therapeutic Equivalence Evaluations\) Search](#)  
More information
- [OTC Monographs@FDA](#)
- [Outsourcing Facility Product Report](#)
- [Postmarket Requirements and Commitments Search](#)  
More information
- [Recall's Emergency Plan for AIDS](#)

# Compounded Products

## NDC Directory & Product Reports



U.S. FOOD & DRUG ADMINISTRATION

Home / Drugs / Development & Approval Process / Drugs / Drug Approvals and Databases / National Drug Code Directory

### National Drug Code Directory

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[Directorio de Códigos Nacionales de Medicamentos \(Spanish Version\)](#)

FDA's National Drug Code (NDC) Directory contains information about finished drug products, unfinished drugs and compounded drug products.

#### Finished drug products

Drug establishments are required to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded or processed for sale in the U.S. at their facilities. Drugs are identified and reported using a unique, three-segment number called the National Drug Code (NDC) which serves as the FDA's identifier for drugs. FDA publishes the listed NDC numbers in the NDC Directory which is updated daily.

The NDC Directory contains information on active and discontinued drugs.

#### Compounded drug products

The NDC Directory also includes information about finished compounded human drug products produced by outsourcing facilities that have elected to assign NDCs to their products. Outsourcing facilities – a type of drug compounding facility regulated under Section 503B of the FD&C Act – can be eligible for exemptions from drug registration and listing requirements if they meet the conditions under Section 503B. Outsourcing facilities may, but are not required to, assign NDCs to their finished compounded human drug products.

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. The NDC Directory draws data from these product reports.

The NDC Database only contains compounded drug products reported with the marketing category "Outsourcing Facility Compounded Human Drug Product (Exempt from Approval Requirements)" and that were assigned an NDC. Search results will include information reported to FDA within the last two years (last four reporting periods). \*

\*Inclusion of compounded drugs in the NDC Database coincides with the use of the marketing category "Outsourcing Facility Compounded Human Drug Product (Exempt from Approval Requirements)" beginning with the 2021-2 reporting period, i.e., June 01, 2021, thru November 30, 2021.

Download the New NDC Express Mobile Application!

Searching the NDC Directory is now faster and easier with our new mobile app!

Download NDC Express

Available on the App Store

GET IT ON Google play

Content current as of: 05/10/2022

Regulated Product(s) Drugs

# 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

The screenshot shows the FDA's National Drug Code Directory search page. At the top, there is a navigation bar with the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". Below this is a search bar and a menu with categories like Home, Food, Drugs, Medical Devices, etc. The main heading is "National Drug Code Directory". Below the heading are social media sharing options (SHARE, TWEET, LINKEDIN, PIN IT, EMAIL, PRINT). A notice states: "The National Drug Code (NDC) Directory is updated daily. Current through: 5/17/2022". Below the notice are three radio buttons: "Finished Products", "Unfinished Products", and "Compounded Products". The "Compounded Products" radio button is selected and circled in red. Below the radio buttons is a green header that says "NDC Compounded products search". Underneath is a search form with the text "Search the NDC database for Compounded drug products". The form includes a "Select Type" dropdown menu, a text input field with the placeholder "Enter at least three characters", and "Search" and "Clear" buttons.

# 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”

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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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

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The National Drug Code (NDC) Directory is updated daily.  
Current through: 5/17/2022

- [NDC Application Programming Interface \(API\)](#) (Firefox and Chrome recommended)

Finished Products  Unfinished Products  **Compounded Products**

**NDC Compounded products search**

**Search the NDC database for Compounded drug products**

Nonproprietary Name

fen

Search Clear

[Background Information](#)

Drug questions email: [DRUGINFO@FDA.HHS.GOV](mailto:DRUGINFO@FDA.HHS.GOV)

See also: [Drug Registration and Listing Instructions](#)  
[National Drug Code Directory Data Files](#)

U.S. Department of Health and Human Services



# 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

U.S. Department of Health and Human Services

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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

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Current through May 23, 2022

You have searched Compounded drug products

Search Results: 'fen'

[Back to Search Page](#) | [Search Again](#)

CSV Excel

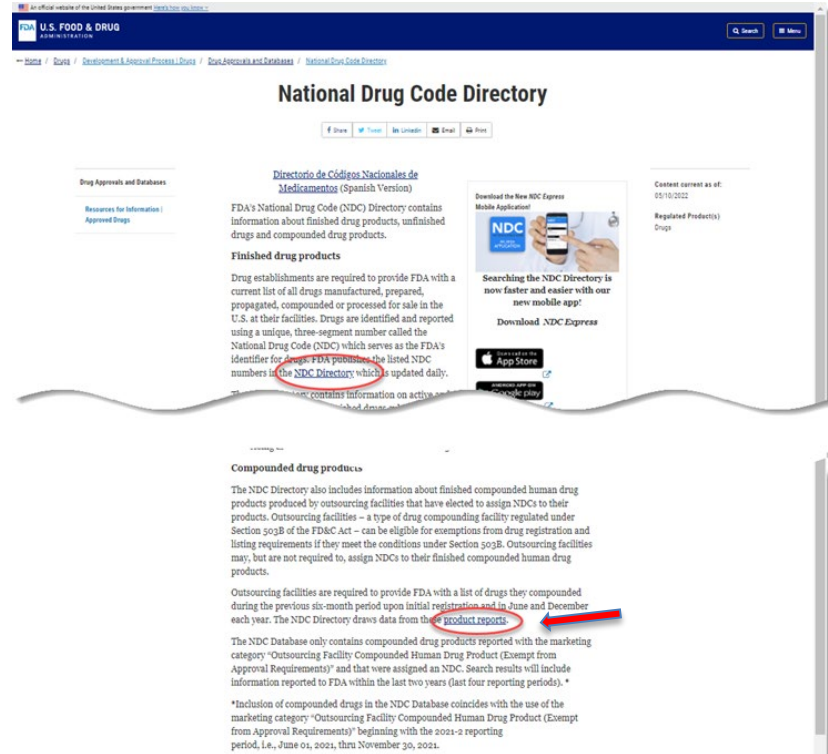
Display 30 records per page

Search for text in the table:

PRODUCT NDC	PRODUCT TYPE NAME	NONPROPRIETARY NAME	DOSAGE FORM NAME	ROUTE NAME	MARKETING CATEGORY NAME	ESTABLISHMENT INFORMATION	SUBSTANCE NAME	ACTIVE INGREDIENTS INFO	NDC PACKAGE CODE	PACKAGE DESCRIPTION	REPORTING PERIOD	DEA SCHEDULE
26436-5578	HUMAN COMPOUNDED DRUG	DICLOFENAC SODIUM DMSO 16/10	GEL	TOPICAL	OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (EXEMPT FROM APPROVAL REQUIREMENTS)	Hybrid Pharma	DICLOFENAC SODIUM	100 mg/1 g	26436-5578-1	30 g in 1 JAR (26436-5578-1)	2021-2	
51754-9160	HUMAN COMPOUNDED DRUG	Fentanyl Citrate Injection 5000 mcg/100 mL	INJECTION	INTRAVENOUS	OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (EXEMPT FROM APPROVAL REQUIREMENTS)	Exelis Pharma Sciences, LLC	FENTANYL CITRATE	5000 ug/100 mL	51754-9160-1	100 mL in 1 VIAL GLASS (51754-9160-1)	2021-2	III
60652-4272	HUMAN COMPOUNDED DRUG	Fentanyl/Ropivacaine	INJECTION	EPIDURAL	OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (EXEMPT FROM APPROVAL REQUIREMENTS)	Born 18th St Clare Hosp Frisco	FENTANYL CITRATE, ROPIVACAIN HYDROCHLORIDE	.002 mg/1 mL, 2 mg/1 mL	60652-4272-1	100 mL in 1 BAG (60652-4272-1)	2021-2	III

# 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

## Outsourcing Facility Product Report

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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 three years (last six 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**

Select Reporting Year

Select Type

Enter at least three characters

# 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

See [points of contact](#) for drug registration and listing.

For drug compounding, contact [Compounding@fda.hhs.gov](mailto:Compounding@fda.hhs.gov).

#### Additional References

- [Search National Drug Code Directory](#)
- [NDC database file - Text Version \(zip format\)](#)
- [NDC database file - Excel version \(zip format\)](#)
- [NDC unfinished drugs database file \(zip format\)](#)
- [NDC compounded drugs database file \(zip format\)](#)
- [NDC database excluded drugs database file \(zip format\)](#)
- [NDC product file definitions](#)
- [NDC package file definitions](#)
- [NDC Application Programming Interface](#) (Firefox and Chrome recommended)

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Top

# 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 FFDC 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/outourcingfacility/index.cfm>
- **NDC compounded drugs database file (zip format):**  
[https://www.accessdata.fda.gov/cder/compounders\\_ndc\\_directory.zip](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](mailto:edrls@fda.hhs.gov)
- CDER Direct Helpdesk: [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov)
- Compounding Helpdesk: [Compounding@fda.hhs.gov](mailto:Compounding@fda.hhs.gov)



