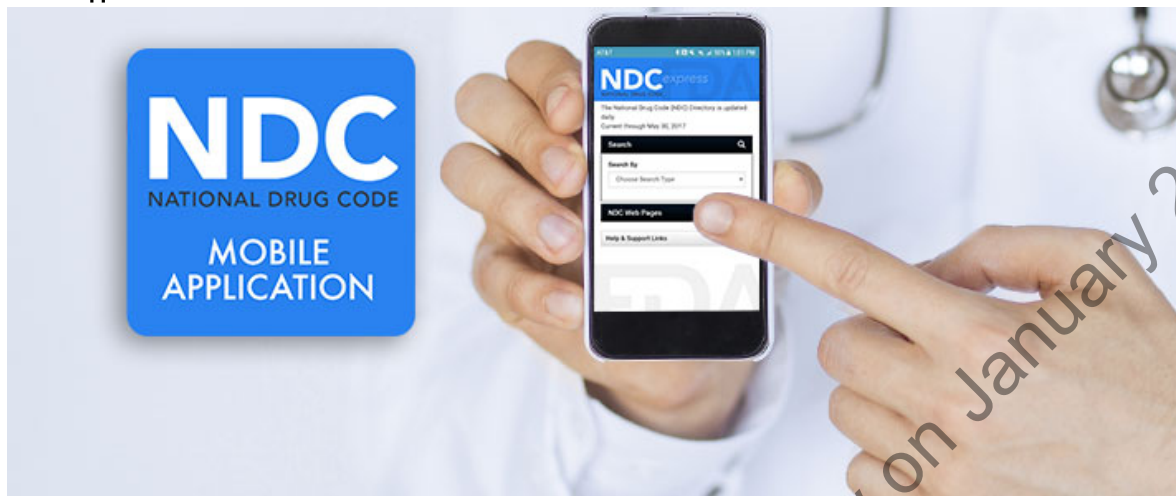


National Drug Code Directory

Download the New *NDC Express*
Mobile Application!



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

Download *NDC Express*



(<https://itunes.apple.com/us/app/ndc-express/id1230454293?ls=1&mt=8>) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)



(<https://play.google.com/store/apps/details?id=gov.fda.ndc>) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

[Directorio de Códigos Nacionales de Medicamentos \(/drugs/drug-approvals-and-databases/directorio-de-codigos-nacionales-de-medicamentos\)](#) (Spanish Version)

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](#) (<https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm>) which is updated daily.

The NDC Directory contains information on active and certified finished and unfinished drugs submitted to FDA in structured product labeling (SPL) electronic listing files by labelers. A labeler may be a manufacturer, including a repackager or relabeler, or the entity named on the product label.

The NDC Directory contains product listing data submitted for all finished drugs including prescription and over-the-counter drugs, approved and unapproved drugs and repackaged and relabeled drugs.

The NDC unfinished drugs database (https://www.accessdata.fda.gov/cder/ndc_unfinished.zip) contains product listing data submitted for all unfinished drugs, including active pharmaceutical ingredients, drugs for further processing and bulk drug substances for compounding.

Important considerations about the 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.
- Assignment of an NDC number does not in any way denote FDA approval of the product. Any representation that creates an impression of FDA approval because a product has an NDC number is misleading and violates federal law.
- Inclusion in the NDC Directory or assignment of an NDC number does not mean a product is a drug as defined by federal law.
- Inclusion in the NDC Directory does not mean a product is covered or eligible for reimbursement by Medicare, Medicaid or other payers. Assignment of NDC number to non-drug products is prohibited.
- 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.
- The NDC Directory contains product listing data that have reached the marketing start date and have not reached marketing end date.

Adding, correcting or updating the NDC Directory

Submit a new or updated product listing through SPL to add, correct or update product listing information in the NDC Directory. FDA does not submit or alter registration or listing data. Accuracy of the listing data is the responsibility of the company submitting the information to FDA. The agency monitors data accuracy and integrity through its compliance program

(<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm531142.htm>).

See the DRLS instructions (<https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions>) for more information.

Questions

See points of contact

(<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm254946.htm>)

for drug registration and listing.

Additional References

- Search National Drug Code Directory (<https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm>)
- NDC database file - Text Version (zip format) (<https://www.accessdata.fda.gov/cder/ndctext.zip>)
- NDC database file - Excel version (zip format) (<https://www.accessdata.fda.gov/cder/ndcxls.zip>)
- NDC unfinished drugs database file (zip format) (https://www.accessdata.fda.gov/cder/ndc_unfinished.zip)
- NDC database excluded drugs database file (zip format) (https://www.accessdata.fda.gov/cder/ndc_excluded.zip)

- [NDC product file definitions \(https://www.fda.gov/Drugs/InformationOnDrugs/ucm254527.htm\)](https://www.fda.gov/Drugs/InformationOnDrugs/ucm254527.htm).
- [NDC package file definitions \(https://www.fda.gov/Drugs/InformationOnDrugs/ucm254528.htm\)](https://www.fda.gov/Drugs/InformationOnDrugs/ucm254528.htm).
- [NDC Application Programming Interface \(https://open.fda.gov/apis/drug/ndc/\)](https://open.fda.gov/apis/drug/ndc/). (Firefox and Chrome recommended)

Last viewed by the First Circuit Library on January 28, 2022