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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92065406
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Attachments	Drug Approvals and Databases National Drug Code Directory.pdf(506507 bytes)

National Drug Code Directory

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The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

The information submitted as part of the listing process, the NDC number, and the NDC Directory are used in the implementation and enforcement of the Act.

NDC Directory

- **Search National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm)**
  Searchable database
- **NDC Database File - Text Version (Zip Format) (https://www.accessdata.fda.gov/cder/ndctext.zip)**
  Last updated:10/27/2017
- **NDC Database File - Excel Version (Zip Format) (https://www.accessdata.fda.gov/cder/ndcxls.zip)**
  Last updated:10/27/2017
- **NDC Product File Definitions (https://www.fda.gov/Drugs/InformationOnDrugs/ucm254527.htm)**
  Product File Data Elements, Definitions, and Notes
- **NDC Package File Definitions (https://www.fda.gov/Drugs/InformationOnDrugs/ucm254528.htm)**
  Package File Data Elements, Definitions, and Notes

The following file contains product listing data submitted for all unfinished drugs, including the marketing categories of Active Pharmaceutical Ingredient (API), Drug for Further Processing, Bulk for Human Drug Compounding, and Bulk for Animal Drug Compounding. FDA does not review and approve unfinished products. Therefore, **all products in this file are considered unapproved**.

Data Files for Unfinished Drugs

- **NDC Unfinished Drugs Database File (Zip Format) (https://www.accessdata.fda.gov/cder/ndc_unfinished.zip)**
  Last updated:10/27/2017

Current regulations require a registered establishment to update its drug listing data in June and December of each year, or, at the discretion of the establishment, when a change occurs (see 21 C.F.R. § 207.57(c)); therefore, FDA may not yet have been notified of recent changes before updating the NDC Directory. FDA makes every effort to prevent errors and discrepancies in the NDC Directory data. Users who detect any errors are requested to contact:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance, Immediate Office
Drug Registration and Listing Team
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
Email: **eDRLS@fda.hhs.gov (mailto:eDRLS@fda.hhs.gov)**

New Version

For four decades, the NDC Directory has been published by FDA, derived from information submitted to the agency as part of drug listing requirements under section 510 of the FD&C Act, 21 USC 360.

Section 510(p) of the FD&C Act (21 USC 360(p)) now requires registration and listing information for human drugs to be submitted electronically, unless a waiver is granted. In keeping with this provision, in June of 2009, the FDA stopped accepting hardcopy/paper submissions of drug registration and listing information using Forms 2656, 2657, and 2658, and began accepting only electronic submissions. The format for these submissions employs Extensible Markup Language (XML) and uses the Structured Product Labeling (SPL) standard to organize the data within the file. This data is processed and stored within an FDA internal software system known as eLIST and eDRLS.

The data from the older paper-based Drug Registration and Listing System (DRLS) was not migrated to these electronic systems.. Although FDA began accepting new listing submissions only in electronic form in June 2009, since that date, FDA continued to publish the NDC Directory based on information in DRLS, which has been maintained in parallel until 2011 using data submitted to eLIST. eLIST and eDRLS, however, continue to grow over time as companies list new products and update existing records. The FDA believes that sufficient time has passed since the establishment of eLIST and eDRLS for it to now serve as the data source for the NDC Directory.

On June 1, 2011, the NDC Directory switched its data source from the older DRLS system to eLIST and later to eDRLS. **Starting June 1, 2011, only drugs for which electronic listings (SPL) have been submitted to FDA are included in the NDC Directory**. Drugs for which listing information was last submitted to FDA on paper forms, prior to June 2009, are included on a separate file and will not be updated after June 2012.

The FDA is taking this opportunity to overhaul the NDC Directory as well, simplifying its structure, while adding new records (such as OTC products) and new data elements. The new features of the NDC Directory, along with some very important usage notes, are provided in the following sections.

Important Considerations Regarding the NDC Directory

- The NDC Directory is updated daily.
- **The new NDC Directory contains ONLY information on final marketed drugs submitted to FDA in SPL electronic listing files by labelers**. (A labeler may be either a manufacturer, including a repackager or relabeler, or, for drugs subject to private labeling arrangements, the entity under whose own label or trade name the product will be distributed.) Inclusion of information 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 official approval because of possession of an NDC number is misleading and constitutes misbranding. (21 CFR 207.37 (a)(2))
- Neither inclusion in the NDC Directory nor assignment of an NDC number is a determination that a product is a drug as defined by the FD&C Act, nor does either denote that a product is covered or eligible for reimbursement by Medicare, Medicaid or other payers. **Assignment of NDC number to non-drug products is extremely prohibited**.
- The NDC Directory does not contain all listed drugs. The new version includes the final marketed drugs which listing information were submitted electronically. It does not include animal drugs, blood products, or human drugs that are not in final marketed form, such as Active Pharmaceutical Ingredients(APIs), drugs for further processing, drugs manufactured exclusively for a private label distributor, 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. For more information about how certain kits or multi-level packaged drugs are addressed in the new NDC Directory,

see the NDC Directory Package File definitions document. For the FDA Online Label Repository page and additional resources go to: **FDA Online Label Repository (http://labels.fda.gov/)**

- Each listed drug product is assigned a unique 10-digit, 3-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug for a particular firm. Different formulations or different strengths of the same formulation should be assigned different product codes. This means even if the same formulations of a drug product ultimately deliver different strengths of the active ingredient to the recipient, they should be assigned different product codes. Also, drug products that share the same formulation but have different product characteristics that clearly distinguish one drug product version from another can not share the same product code under the same labeler code. The third segment, the package code, identifies package sizes and types. Different package codes only differentiate between different quantitative and qualitative attributes of the product packaging. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.
- The previous version of the NDC Directory only included listed human prescription drugs and insulin products and excluded many products, including Over The Counter (OTC) products. The new edition of the NDC Directory includes electronically listed human prescription and OTC drugs that have been manufactured, prepared, propagated, compounded, or processed by registered establishments for commercial distribution.

New Features

Simplified File Structure: The download files have been condensed into two files: a Products file and a Packages file. These two files can be linked using the PRODUCTNDC data element. Two file formats are offered as well: a spreadsheet version and a traditional tab delimited CSV format.

New Data Elements:

ProductTypeName: This field indicates the type of product, such as Human Prescription Drug or Human OTC Drug. This data element corresponds to the “Document Type” of the SPL submission for the listing. The complete list of codes and translations can be found at **Electronic Drug Registration and Listing Instructions (http://www.fda.gov/edrls)** under Structured Product Labeling Resources.

MarketingCategoryName: This field is based on the SPL data element of the same name, indicating the marketing category identified by the labeler. Possible values include: NDA, ANDA, BLA, and OTC Monograph (Final and Not Final), and thus provide the labeler’s representation about whether the product is marketed under an approved application. The complete list of codes and translations can be found at **Electronic Drug Registration and Listing Instructions (http://www.fda.gov/edrls)** under Structured Product Labeling Resources.

Pharm_Classes: Pharmacologic Class. This value(s) replaces the old Drug Class data element, which was discontinued from the NDC directory several years ago. The complete list of codes and translations can be found at **Electronic Drug Registration and Listing Instructions (http://www.fda.gov/edrls)** under Structured Product Labeling Resources. Expanded range of human drug products included: The previous version of the NDC Directory excluded many products, including Over the Counter products. This version includes final marketed human drug products that have been submitted into the eLIST system, whether prescription or OTC, approved, monograph, or otherwise unapproved. The NDC Directory excludes certain product types, such as Active Pharmaceutical Ingredients (APIs), drugs for further processing, drugs manufactured exclusively for a private label distributor, animal drugs, and blood related products.

DEA Schedule: This field indicates the Drug Enforcement Administration (DEA) schedule applicable to the drug as reported by the labeler. The definition of controlled substance schedules can be found on DEA's website: **Office of Diversion Control (http://www.deadiversion.usdoj.gov/schedules/index.html)**.

Requests for more specific information should be submitted in writing and directed to FDA's Freedom of Information Staff. For more information on how to make a FOIA request, visit FDA's Freedom of Information site: **How to Make a FOIA Request (/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm)**

What happened to the data in the old NDC Directory? A final edition of the DRLS based NDC Directory will be published on June 1, 2012. Some NDCs that cannot be found in the newer eLIST and eDRLS version of the Directory may potentially be found in this **older version of the NDC Directory (/Drugs/InformationOnDrugs/ucm257245.htm)**. It is important to note that this database is not comprehensive. If a record is not found in the older NDC Directory, it may still be on file in hard copy with the FDA, but may not have been entered into DRLS or the listing information submitted was not complete and accurate and was never corrected by the firm.

How often is the NDC Directory updated? **The NDC Directory is not updated in real time**. Initially, the NDC Directory, like the prior version, was updated approximately twice a month. FDA then moved to a weekly update of the new Directory in June of 2012. The FDA has increased the frequency of updates to daily (weekdays), starting February 1, 2013. Drug information from SPL entries submitted after the last date on which the new NDC Directory was updated will not appear until the next compilation date. The NDC Directory will indicate the date on which it was last updated.

How can NDC Directory entries be added, corrected or updated?

To add a new entry, or to correct erroneous or incomplete product data in the NDC Directory, a labeler should submit a new SPL to update the information. See the **eDRLS website (http://www.fda.gov/edrls)** for instructions on submitting SPL.

Contact Us:

- For questions about drug products in the NDC Directory **edrls@fda.hhs.gov (mailto:edrls@fda.hhs.gov)**
- For questions about biologic products in the NDC Directory **cberspl@fda.hhs.gov (mailto:cberspl@fda.hhs.gov)**
- For questions regarding technical issues related to the submission of SPL files **spl@fda.hhs.gov (mailto:spl@fda.hhs.gov)**
- **Points of Contact for Questions Regarding Registration and Listing for Human and Animal Drugs and Biologics (/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm254946.htm)**

More in Drug Approvals and Databases (/Drugs/InformationOnDrugs/default.htm)

Approved Drugs (/Drugs/InformationOnDrugs/ApprovedDrugs/default.htm)