NDC Product File Definitions

NDC Directory – eLIST
Product File Data Elements, Definitions, and Notes

Important Considerations Regarding the NDC Directory

The NDC Directory is updated daily.

- **The NDC Directory contains ONLY information 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 possession 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.
- The NDC Directory does not contain all listed drugs. It does not include animal drugs, blood products, or human drugs that are not in final marketed form, such as active pharmaceutical ingredients, or drugs that are marketed solely as part of a kit or combination product or inner layer of a multi-level packaged product. For more information about how certain kits or multi-level packed drugs are addressed in the new NDC Directory, see the NDC Directory Package File Definitions document.

File Notes

- Package data can be found in the Packages file, linked by the ProductID field.
- Reference code names (translations) are included instead of the codes themselves.

- Fields that have multiple values are identified with an “MV” after their name. Values are concatenated together by a semi-colon “;”.
- If the term NULL appears after an element name, it means there may be records where no value is provided.

Product File Data Elements and their definitions

Product File Data Elements	Type	Definition
ProductID	Text/string	ProductID is a concatenation of the NDCproduct code and SPL documentID. It is included to help prevent duplicate rows from appearing when joining the product and package files together. It has no regulatory value or significance.
ProductNDC www.fda.gov/edrls (/edrls) under Structured Product Labeling Resources	Text/string	The labeler code and product code segments of the National Drug Code number, separated by a hyphen. Asterisks are no longer used or included within the product code segment to indicate certain configurations of the NDC.
ProductTypeName	Text/string	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.
ProprietaryName	Text/string	Also known as the trade name. It is the name of the product chosen by the labeler.
ProprietaryNameSuffix	NULL Text/string	A suffix to the proprietary name, a value here should be appended to the ProprietaryName field to obtain the complete name of the product. This suffix is often used to distinguish characteristics of a product such as extended release (“XR”) or sleep aid (“PM”). Although many companies follow certain naming conventions for suffices, there is no recognized standard.
NonProprietaryName	Text/string. MV	Sometimes called the generic name, this is usually the active ingredient(s) of the product.

Product File Data Elements	Type	Definition
DosageFormName	Text/string	The translation of the DosageForm Code submitted by the firm. The complete list of codes and translations can be found www.fda.gov/edrls (/edrls) under Structured Product Labeling Resources.
RouteName	Text/string. MV	The translation of the Route Code submitted by the firm, indicating route of administration. The complete list of codes and translations can be found at www.fda.gov/edrls (/edrls) under Structured Product Labeling Resources.
StartMarketingDate	Text/string. [Include format]	This is the date that the labeler indicates was the start of its marketing of the drug product.
EndMarketingDate	NULL Text/string. [Include format]	This is the date the product will no longer be available on the market. If a product is no longer being manufactured, in most cases, the FDA recommends firms use the expiration date of the last lot produced as the EndMarketingDate, to reflect the potential for drug product to remain available after manufacturing has ceased. Products that are the subject of ongoing manufacturing will not ordinarily have any EndMarketingDate. Products with a value in the EndMarketingDate will be removed from the NDC Directory when the EndMarketingDate is reached.
MarketingCategoryName	Text/string	Product types are broken down into several potential Marketing Categories, such as NDA/ANDA/BLA, OTC Monograph, or Unapproved Drug. One and only one Marketing Category may be chosen for a product, not all marketing categories are available to all product types. Currently, only final marketed product categories are included. The complete list of codes and translations can be found at www.fda.gov/edrls (/edrls) under Structured Product Labeling Resources.

Product File Data Elements	Type	Definition
ApplicationNumber	NULL Text/string.	This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the Application number will be the CFR citation corresponding to the appropriate Monograph (e.g. “part 341”). For unapproved drugs, this field will be null.
LabelerName	Text/string	Name of Company corresponding to the labeler code segment of the ProductNDC.
SubstanceName	Text/string. MV	This is the active ingredient list. Each ingredient name is the preferred term of the UNII code submitted.
StrengthNumber	Text/string. MV	These are the strength values (to be used with units below) of each active ingredient, listed in the same order as the SubstanceName field above.
StrengthUnit	Text/string. MV	These are the units to be used with the strength values above, listed in the same order as the SubstanceName and SubstanceNumber.
Pharm_Classes	Text/string. MV	These are the reported pharmacological class categories corresponding to the SubstanceNames listed above.
DEASchedule	Text/string	This is the assigned DEA Schedule number as reported by the labeler. Values are CI, CII, CIII, CIV, and CV.

Product File Data Elements	Type	Definition
NDC_Exclude_Flag	Text/String	Values can be ‘E’, ‘U’, ‘I’ or ‘D.’ These indicate the following statuses for a product removed/excluded from the NDC Directory: • ‘E’: Removed for failure to respond to FDA's requests for corrections to deficient or non-compliant submissions. • ‘U’: Excluded because the listing certification expired due to lack of listing certification. • ‘I’: Inactivated by the FDA. • ‘D’: Discontinued by the firm. The PRODUCT.XLS and PRODUCT.TXT files only contain listing records that are not flagged. The PRODUCTS_EXCLUDED.XLS and PRODUCTS_EXCLUDED.TXT files contain all listing records with an NDC_EXCLUDE_FLAG of ‘E’, ‘U’, ‘I’ and ‘D.’
Listing_Record_Certified_Through	Text/String	This is the date when the listing record will expire if not updated or certified by the firm.