U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drugs

NDC Package File Definitions

NDC Directory - eLIST
Package File Data Elements, Definitions, and Notes

Important Considerations Regarding the NDC Directory

- NDC Directory is currently updated every Monday.

- **The 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 207.39)

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- 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. 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.

File notes:

- **Only the OUTERMOST packages and dispensable inner layer packages, reported by firms as part of their product listing submission to the FDA, are included in the NDC Directory.** This applies to co-packaged products listed as kits and multi-level packaged products.

  The inner level of a multi level packaging or components of a kit will be included in the package description of the product to show the relationship between all layers and parts as reported by the listing firm.

  If a product contained within a kit is approved/ authorized to be marketed separately, then a separate SPL file must be submitted.

  If the inner level of a multi level packaging is a marketable/ dispensable layer, the NDCPackageCode assigned to it should be reported as a separate package code on the same listing SPL.

  The relation between different levels of a multi level packaged product or components of a kit is still provided in the package description section. For any additional information, users can go to the FDA Online Label Repository page: http://labels.fda.gov/[1]

ProductNDC *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.

NDCPackageCode *Text/string*
The labeler code, product code, and package code segments of the National Drug Code number, separated by hyphens. Asterisks are no longer used or included within the product and package code segments to indicate certain configurations of the NDC.

PackageDescription *Text/string*
A description of the size and type of packaging in sentence form. Multilevel packages will have the descriptions concatenated together. For example: *4 BOTTLES in 1 CARTON/100 TABLETS in 1 BOTTLE.*

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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Links on this page:

1. http://labels.fda.gov