

Drug Name and National Drug Code (NDC) Reference Data Instructions Calendar Year 2019

Introduction

The Drug Name and National Drug Code (NDC) Reference Data is a reference tool for applicable manufacturers and applicable group purchasing organizations (GPOs), hereafter collectively referred to as reporting entities, to validate Drug Name and NDC information before reporting payments to the Open Payments system. This reference data includes drug name and NDC information of all the drugs listed in the Federal Drug Administration (FDA) NDC Directory from calendar year 2013 to December 31st, 2018, including those delisted or removed from the FDA directory. Reporting entities may use the calendar year 2019 version of the reference data to pre-validate the drug information for payments made during Program Year 2018 or prior program years.

How to use the Drug Name and NDC Reference Data

The Drug Name and NDC Reference Data is intended to be used as a reference when creating payment records for submission to the Open Payments system. It can be used to fill in missing information for a specific drug associated with a payment, or to validate drug information that the reporting entity has already collected.

The reference data is **not** a complete list of drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution under the Open Payments program, nor are all of the data elements for the listed drugs exhaustive. This reference data contains only information that the FDA was able to collect from calendar year 2013 up until December 31st, 2018, including the information that was ultimately removed from the NDC Directory.

According to the Final Rule, reporting entities may report up to five covered / non-covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. For drugs and biologicals, reporting entities must report the name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. (See 42 C.F.R. § 403.904.)

Excluded Information

The drugs in the following categories will not be part of this list and must still be reported in the payment record if they fall under the definition of a covered product.

- Any new drugs registered on the FDA website after December 31st, 2018 will not be included in the reference data.
- 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.
- Drugs that do not have a marketed name.

Contents of the Drug Name and NDC Reference Data

1. The Drug Name and NDC Reference Data file:

The Drug Name and NDC Reference Data is delivered in one pipe-delimited .csv file. The file contains the following drug information:

- **NDCPackageCode** (Column A): The labeler code, product code, and package code segments of the National Drug Code number, separated by hyphens per FDA website.
 - In the Open Payments application, this element corresponds to the “National Drug Code (NDC) of Associated Covered Drug or Biological” field for PY2013 – PY2015 submissions or the “Associated Drug or Biological NDC” field for PY2016 onward submissions.
- **ProprietaryName** (Column B): Also known as the trade name. It is the name of the drug product chosen by the labeler.
 - In the Open Payments application, this element corresponds to the “Name of Associated Covered Drug or Biological” field for PY2013 – PY2015 submissions or the “Marketed Name of Drug, Device, Biological, or Medical Supply” field for PY2016 onward submissions. It is applicable when the reporting payment is related to drug.

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- **ProprietaryNameSuffix** (Column C): 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.
 - Not used in the Open Payments application. This information is provided for reference only, and does not correspond to any Open Payments payment submission elements.
- **NonProprietaryName** (Column D): Sometimes called the generic name, this is usually the active ingredient(s) of the product.
 - Not used in the Open Payments application. This information is provided for reference only, and does not correspond to any Open Payments payment submission elements.
- **LabelerName** (Column E): Name of Company corresponding to the labeler code segment of the Product NDC.
 - Not used in the Open Payments application. This information is provided for reference only, and does not correspond to any Open Payments payment submission elements.

Note: During the submission, NDCs are required for all drugs and biologicals that have NDCs. If the reported drug or biological does not have an NDC this field may be left blank. To see more details about data submission, refer to the Open Payments User Guide for Reporting Entities available on the Resources page of the Open Payments website (<https://www.cms.gov/OpenPayments/About/Resources.html>).

2. Considerations for using the CSV Files:

Microsoft Excel removes leading zeroes from data fields in CSV files. Certain fields in these data sets may have leading zeroes. These zeroes will be missing when viewing the information within Microsoft Excel. To avoid this, it is recommended to set format of the fields containing leading zeroes to “Text” instead of “Number” before importing the data file.

Additionally, the latest versions of Microsoft Excel cannot display data sets with more than 1,048,576 rows, and this CSV file may exceed that limit. Displaying the data in its entirety may require the use of spreadsheet programs capable of handling very large numbers of records. If

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the version of the Microsoft Excel is 2003 or lower, consider downloading the data file and use import feature of Excel.

If a Drug Is Not Found in the Reference Data

Drugs that do not appear in the Drug Name and NDC Reference Data may still be submitted with a payment record. Information of new drugs listed in the FDA NDC Directory after December 31st, 2018 may be found in the NDC Directory at <https://www.fda.gov/drugs/informationondrugs/ucm142438.htm>.

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