Drug Name and National Drug Code (NDC) Reference Data Instructions Calendar Year 2026

Introduction

The Drug Name and National Drug Code (NDC) Reference Data is a reference tool for Applicable Manufacturers (AMs) 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. The Calendar Year 2025 reference data includes drug name and NDC information of all the drugs listed in the U.S. Food and Drug Administration (FDA) NDC Directory from January 1, 2013, to December 31, 2025, including those delisted or removed from the FDA directory. Reporting entities may use the Calendar Year 2026 version of the reference data to pre-validate the drug information for payments made during Program Year 2025 or prior program years.

How to use the Drug Name and NDC Reference Data

The Drug Name and NDC Reference Data are 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 payment or to validate drug information that the reporting entity has already collected. Beginning in Program Year 2021, information relating to drug or biological name and National Drug Code (NDC) must match the CMS-approved dataset in order for the record to be submitted in the Open Payments system. Records that contain a "drug or biological name" or "drug or biological name and NDC combination" that does not match the CMS-approved dataset will not be able to be submitted.

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 through December 31, 2025, 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 NDC(s), if any. (See 42 C.F.R. § 403.904.) The name of the drug or biological and NDC (if any) must be successfully validated against the CMS-approved dataset when submitting records in the Open Payments system.

Excluded Information

The drugs in the following categories are not included in the Drug Name and NDC Reference Data list and will fail validation for the name of the drug and relevant NDC(s), if any. However, reporting entities must still report payments that are associated with drugs in these categories. To report these payments, reporting entities must select "No" for the Related Product Indicator on the Associated Related Products Page.

- Any new drugs registered on the FDA website after December 31, 2025, 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 are 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 NDC 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 the drug.

- **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.

NDCs are required to be included 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. The combination of drug or biological name and any NDC(s) entered must match the CMS-approved dataset. 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/Resources).

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 the 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 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 will fail validation against the CMS-approved dataset in the Open Payments system. Records containing drugs that do not appear in the Drug Name and NDC Reference Data will not be able to be submitted in the Open Payments system. Information for new drugs listed in the FDA NDC Directory after December 31, 2025, may be found in the NDC Directory at https://www.fda.gov/drugs/informationondrugs/ucm142438.htm.

Disclosure

- **Disclaimer**: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

- **Activities/persons addressed by this document**: Guidance to be used as a reference when creating payment records for submission to the Open Payments system.

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- **Summary of Document**: The instructions document provides details about the use of the Drug Name and NDC Reference Data. (CSV).

- **Citation to statutory provision/regulation applicable to this document**:
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  - **Rule citation**: 42 C.F.R. §403.900-14