

**MEDICAID DRUG REBATE PROGRAM
MDP PRODUCT DATA
FILE SUBMISSION TO CMS
Form CMS-367c**

FILE FORMAT

Effective: July 1, 2021

Source: Drug Manufacturers

Target: CMS

Ordinal Position	Field Name (.TXT) Header Row (.CSV)	Size	Position	Remarks
1	Record ID	1	1 - 1	Constant of "P"
2	Labeler Code	5	2 - 6	NDC 1
3	Product Code	4	7 - 10	NDC 2
4	Package Size	2	11 - 12	NDC 3
5	Drug Category	1	13 - 13	See Data Definitions
6	Unit Type	3	14 - 16	See Data Definitions
7	FDA Approval Date	8	17 - 24	MMDDYYYY
8	Therapeutic Equivalence Code	2	25 - 26	See Data Definitions
9	Market Date	8	27 - 34	MMDDYYYY
10	Termination Date	8	35 - 42	MMDDYYYY
11	Drug Type	1	43 - 43	See Data Definitions
12	OBRA '90 Baseline AMP	15	44 - 58	99999999.999999
13	Units Per Package Size	11	59 - 69	9999999.999
14	FDA Product Name	63	70 - 132	FDA Product Name
15	Package Size Intro Date	8	133 - 140	MMDDYYYY
16	Purchased Product Date	8	141 - 148	MMDDYYYY
17	5i Drug Indicator	1	149 - 149	See Data Definitions
18	5i Route of Administration	3	150 - 152	See Data Definitions
19	Covered Outpatient Drug Status	2	153 - 154	See Data Definitions
20	FDA Application Number/ OTC Monograph Number	7	155 - 161	See Data Definitions
21	Line Extension Drug Indicator	1	162 - 162	See Data Definitions
	Reactivation Date	n/a	n/a	See Data Definitions

Form CMS-367c (Exp. 06/30/2026) is used by manufacturers to report a new drug to CMS either electronically or via file transfer, or when the manufacturer has to report a change to the product data of an existing drug electronically or via file transfer. When needed, the use of Form CMS-367c by manufacturers is considered mandatory under the authority of Section 1927 of the Social Security Act and the National Drug Rebate Agreement. Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 43.5 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

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DATA DEFINITIONS

Effective: July 1, 2021

Record ID: Constant of “P”. The P Record ID indicates that the information reported for this NDC represents product data.

Labeler Code: First segment of the National Drug Code (NDC) that identifies the labeler. Numeric values; 5-digit field; right-justified; zero-padded.

Product Code: Second segment of the NDC. Alpha-numeric values; 4-digit field; right-justified; zero-padded.

Package Size: Third segment of the NDC. Alpha-numeric values; 2-digit field; right-justified; zero-padded.

Drug Category: Indicates whether the drug is single source (S), innovator multiple source (I), or non-innovator multiple source (N). 1-character field.

Valid Values:

S = Single source

I = Innovator multiple source

N = Non-innovator multiple source

Unit Type: One of the 10 unit types by which a drug may be dispensed. 3-character field; left-justified; blank-filled for Unit Type values with fewer than 3 characters.

Valid Values:

AHF = Injectable Anti-Hemophilic Factor

CAP = Capsule

EA = EACH

GM = Gram

ML = Milliliter

SUP = Suppository

TAB = Tablet

TDP = Transdermal Patch

MCI = Millicurie

UCI = Microcurie

FDA Approval Date: NDA (including Authorized Generic), ANDA, or BLA approval date. For covered outpatient drugs (CODs) for which the FDA does not require approval, use

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9/30/1990 or, if the drug was first marketed after 9/30/1990, the actual date first marketed. Numeric values; 8-digit field; format: MMDDYYYY.

Therapeutic Equivalence Code (TEC): FDA-assigned Therapeutic Equivalence Codes as found in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*. Alpha-numeric values; 2-digit field.

Valid Values:

AA = Products in Conventional Dosage Forms Not Presenting Bioequivalence Problems
AB = Products Meeting Necessary Bioequivalence Requirements assigned an FDA TEC of AB, or AB1 through AB9
AN = Solutions and Powders for Aerosolization
AO = Injectable Oil Solutions
AP = Injectable Aqueous Solutions and, in Certain Instances, Intravenous Non-Aqueous
AT = Topical Products
BC = Extended-Release Dosage Forms (Capsules, Injectables, and Tablets)
BD = Active Ingredients and Dosage Form With Documented Bioequivalence Problems
BE = Delayed-Release Oral Dosage Forms
BN = Products in Aerosol-Nebulizer Drug Delivery Systems
BP = Active Ingredients and Dosage Forms with Potential Bioequivalence Problems
BR = Suppositories or Enemas That Deliver Drugs for Systemic Absorption
BS = Products Having Drug Standard Deficiencies
BT = Topical Products with Bioequivalence Issues
BX = Drug Products for Which the Data Are Insufficient To Determine Therapeutic Equivalence
NR = Not Rated

Market Date: For S, I and N drugs marketed under an FDA-approved application (e.g. ANDA, BLA, NDA, NDA Authorized Generic), the earliest date the drug was first marketed under the application number by any labeler. For drugs marketed without an FDA-approved application (e.g., OTC monograph, unapproved drug), the earliest date the drug was first marketed by any labeler. For all drugs (i.e., those marketed with or without an FDA-approved application) that were purchased or otherwise acquired from another labeler, the Market Date should be equal to the Market Date of the original product. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in the Medicaid Drug Programs (MDP) system, since dates earlier than the start of the Medicaid Drug Rebate Program have no bearing on the program. Numeric values; 8-digit field; format: MMDDYYYY.

Termination Date: The date a drug is withdrawn from the market or the drug's last lot expiration date. (Note: Initial termination date submissions may be provided via file transfer; however, subsequent changes to this field may only be submitted online via MDP.) Zero or blank-filled for drugs without Termination Dates. Numeric values; 8-digit field; format: MMDDYYYY.

Drug Type: Identifies a drug as prescription (Rx) or over-the-counter (OTC). Numeric values; 1-digit field.

Valid Values:

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1 = Rx
2 = OTC

OBRA'90 Baseline AMP: The AMP per unit for the period that establishes the OBRA'90 Baseline AMP for single source or innovator multiple source drugs. There will be one weighted Baseline AMP for the product, which applies to all package sizes. Compute to 7 decimal places and round to 6 decimal places. Zero or blank-filled if the NDC does not have an OBRA '90 Baseline AMP, and for all Non-Innovator Multiple Source drugs. Numeric values; 15-digit field: 8 whole numbers, the decimal point (‘.’) and 6 decimal places; right-justified; zero-padded for OBRA '90 Baseline AMP values with fewer than 15 digits.

Units Per Package Size (UPPS): The total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values; 11-digit field: 7 whole numbers, the decimal point (‘.’) and 3 decimal places; right-justified; zero-padded for UPPS values with fewer than 11 digits.

FDA Product Name: Drug name as it appears on FDA SPL listing. Alpha-numeric values; 63-character field; left-justified; blank-filled for FDA Product Names fewer than 63 characters.

Package Size Intro Date (PSID): The date the package size is first available on the market. Numeric values; 8-digit field; format: MMDDYYYY.

Purchased Product Date (PPD): The date the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc.). Zero or blank-filled for drugs without Purchased Product Dates. Numeric values; 8-digit field; format: MMDDYYYY.

5i Drug Indicator: Identifies whether a product is a 5i Drug. 1-character field.

Valid Values:

Y = Yes
N = No

5i Route of Administration: Identifies the method by which the 5i drug is administered to a patient. If a product is not a 5i drug, a value of "000" (Not Applicable) should be reported. Numeric values; 3-digit field.

Valid Values:

000 = Not Applicable
001 = Implanted
002 = Infused
003 = Inhaled
004 = Injected
005 = Instilled

Covered Outpatient Drug (COD) Status: A category that identifies how a product meets the statutory definition of a covered outpatient drug in accordance with sections 1927(k)(2) to 1927(k)(4) of the Social Security Act. Numeric values; 2-digit field.

Valid Values:

- 01 = Abbreviated New Drug Application (ANDA)
- 02 = Biological License Application (BLA)
- 03 = New Drug Application (NDA)
- 04 = NDA Authorized Generic
- 05 = DESI 5* – LTE/IRS drug for all indications
- 06 = DESI 6* – LTE/IRS drug withdrawn from market
- 07 = Prescription Pre-Natal Vitamin or Fluoride
- 08 = Prescription Dietary Supplement/Vitamin/Mineral (Other than Prescription Pre-Natal Vitamin or Fluoride)
- 09 = OTC Monograph Tentative
- 10 = OTC Monograph Final
- 11 = Unapproved Drug – Drug Shortage
- 12 = Unapproved Drug – Per 1927(k)(2)(A)(ii)
- 13 = Unapproved Drug – Per 1927(k)(2)(A)(iii)

*NDCs with a COD Status of DESI 5/6 are not eligible for coverage or rebates under the Medicaid Drug Rebate Program.

FDA Application Number/OTC Monograph Number: For drugs with a COD status of ANDA, BLA, NDA, or NDA Authorized Generic, this is the application number (assigned by the FDA for approval to market a drug or biological in the United States) under which the NDC is currently marketed. Numeric values; 7-digit field; padded with leading zeros as needed.

For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA’s regulatory citation for the OTC. Alpha-numeric values; 7-digit field. For drugs with a COD Status of OTC Monograph Final, the first four characters are a constant of “PART”; the last three characters are the numeric values for the appropriate regulatory citation for the product (e.g., “225”). For drugs with a COD Status of OTC Monograph Tentative, the first four characters are a constant of “PART”; the last three characters are the numeric values for the appropriate regulatory citation for the product, or three zeros if a Monograph Number is not available.

For drugs with a COD Status other than ANDA, BLA, NDA, NDA Authorized Generic, OTC Monograph Final, or OTC Monograph Tentative, the FDA Application Number/OTC Monograph Number field should be zero-filled.

Line Extension Drug Indicator: Identifies whether a product is a line extension drug as defined in Section 1927 (c)(2)(C) of the Social Security Act, including whether the drug is excluded from the statutory definition of a line extension on the basis of being an abuse-deterrent formulation (ADF). Labelers seeking an ADF exclusion at the time a drug is initially reported in MDP should submit an initial value of “R” in this field for CMS review and approval. 1-character field.

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Valid Values:

Y = Yes

N = No (i.e., neither LE nor ADF)

R = Request for ADF Exclusion

E = Excluded (Due to ADF)*

*NOTE: This value may only be assigned by CMS and cannot be reported by a labeler.

Reactivation Date: The date on which a terminated product is re-introduced to the market. (Note: This field may only be submitted online via MDP and is **NOT** part of the actual File Format.)

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