DDR PRODUCT DATA FILE FORMAT
FOR TEXT FILE SUBMISSIONS TO CMS

Source: Drug Manufacturers
Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "P"
Labeler Code	5	2 - 6	NDC 1
Product Code	4	7 - 10	NDC 2
Package Size	2	11 - 12	NDC 3
Drug Category	1	13 - 13	See Data Element Definitions
Unit Type	3	14 - 16	See Data Element Definitions
FDA Approval Date	8	17 - 24	MMDDYYYY
Therapeutic Equivalence Code (TEC)	2	25 - 26	See Data Element Definitions
Market Date	8	27 - 34	MMDDYYYY
Termination Date	8	35 - 42	MMDDYYYY
Drug Type	1	43 - 43	See Data Element Definitions
OBRA'90 Baseline AMP	12	44 - 55	99999.999999
Units Per Package Size (UPPS)	11	56 - 66	9999999.999
FDA Product Name	63	67 - 129	FDA Product Name
Package Size Intro Date (PSID)	8	130-137	MMDDYYYY
Purchased Product Date (PPD)	8	138-145	MMDDYYYY
5i Drug Indicator	1	146-146	See Data Element Definitions
5i Route of Administration	3	147-149	See Data Element Definitions
Covered Outpatient Drug (COD) Status	2	150-151	See Data Element Definitions
FDA Application Number/OTC Monograph Number	7	152-158	See Data Element Definitions
Line Extension Drug Indicator	1	159-159	See Data Element Definitions
*Reactivation Date	*n/a	*n/a	*This field may only be submitted online via DDR.

Form CMS-367c (Exp.) 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.

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			See Data Element Definitions

Drug Product (CMS 367c Form) Data Element Definitions

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). 1character field.

Valid values:

S = Single source
I = Innovator multiple source
N = Non-innovator multiple source

Unit Type: One of the 8 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

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

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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 both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) 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 DDR.) Zero or blank-filled for drugs without Termination Dates. Numeric values; 8-digit field; format: MMDDYYYY.

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

Valid Values:
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; 12-digit field: 5 whole numbers, the decimal point ('.') and 6 decimal places; right-justified; zero-padded for OBRA '90 Baseline AMP values with fewer than 12 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

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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.

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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 No./OTC Monograph No. 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 DDR should submit an initial value of "R" in this field for CMS review and approval. 1-character field.

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 DDR and is **NOT** part of the actual File Format.)