DRUG PRODUCT DATA FIELD DEFINITIONS

Labeler Name:
The corporate name of the entity identified by the labeler code.

Labeler Code:
The first segment of the National Drug Code that identifies the labeler.

Product Code:
The second segment of the National Drug Code that identifies the product.

Package Size Code:
The third segment of the National Drug Code that identifies the package size.

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

Valid Values:
N = Non-innovator multiple source
S = Single source
I = Innovator multiple source

Drug Type Indicator:
This field identifies a drug as prescription (Rx) or Over-the-Counter (OTC).

Valid values:
1 = Rx
2 = OTC

Termination Date:
The date on which the drug was withdrawn from market or the drug's last lot expiration date.

Unit Type:
One of the 8 unit types by which a drug can be dispensed.

Valid Values:
AHF = Injectable Anti-Hemophilic Factor
CAP = Capsule
SUP = Suppository
GM = Gram
ML = Milliliter
TAB = Tablet
TDP = Transdermal patch
EA = EACH

Units Per Package Size:
The total number of units in the smallest dispensable amount for the 11-digit NDC.

FDA Approval Date:

The NDC or monograph approval date.

Market Date:
For S, I, and N drugs marketed under an FDA-approved application (e.g. BLA, NDA, ANDA), 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), if a drug was 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 Drug Rebate Program have no bearing on the program. Numeric values, 8-digit field, format: MMDDYYYY.

FDA Product Name:
The drug's name as approved by the FDA.

Clotting Factor Indicator:
In accordance with section 1927(c)(1)(B)(iii) of the Social Security Act, an indicator which identifies a Single Source or Innovator Multiple Source drug as a clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act.

Valid values: Y = Yes
N = No

Pediatric Indicator:
In accordance with section 1927(c)(1)(B)(iii) of the Social Security Act, an indicator which identifies a Single Source or Innovator Multiple Source drug approved by the FDA exclusively for pediatric indications for patients in the FDA-defined pediatric age group (i.e., birth to 16 years).

Valid values: Y = Yes
N = No

Package Size Intro. Date:
The date the package size is first available on the market. If the product was purchased from another company, the Package Size Introduction Date should equal the date the package size is first available on the market under the labeler code of the company currently holding legal title to the NDC.

Purchased Product Date:
The date on which 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…).

Covered Outpatient Drug (COD) Status:

A category that identifies whether or not 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.

Valid Values:
" " (Spaces) = The Labeler has not reported this field to the Medicaid Drug Rebate Program.
"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 seven-digit application number that is assigned by the FDA for approval to market a generic drug or new drug in the United States
- For drugs with a COD status of OTC Monograph Tentative or Final, this is the FDA's regulatory citation for the OTC
- 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 3 zeroes 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 will be zero-filled

  For drugs where a COD Status has never been reported to CMS, the FDA Application Number/OTC Monograph Number field will be padded with spaces.

Reactivation Date:
The date on which a terminated product is re-introduced to the market.