

**DRUG PRODUCT DATA**  
**Web File Structure and Definitions**  
**November 2014**

<b>Field</b>	<b>Size</b>	<b>Position</b>	<b>Remarks</b>
Labeler Name	39	1 - 39	Company associated with NDC 1
Labeler Code	5	40 - 44	NDC 1
Product Code	4	45 - 48	NDC 2
Package Size Code	2	49 - 50	NDC 3
Drug Category	1	51 - 51	See data element definitions
Drug Type Indicator	1	52 - 52	See data element definitions
Termination Date	8	53 - 60	MMDDYYYY
Unit Type	3	61 - 63	See data element definitions
Units Per Pkg Size	10	64 - 73	9999999V999
FDA Approval Date	8	74 - 81	MMDDYYYY
Market Date	8	82 - 89	MMDDYYYY
FDA Ther. Equiv. Code	2	90 - 91	See data element definitions
FDA Product Name	63	92 - 154	FDA Product Name
Clotting Factor Indicator	1	155 - 155	Y or N
Pediatric Indicator	1	156 - 156	Y or N
Package Size Intro. Date	8	157 - 164	MMDDYYYY
Purchased Product Date	8	165 - 172	MMDDYYYY
COD Status	2	173 - 174	See data element definitions
FDA Appl. No./OTC Mono. No.	7	175 - 181	See data element definitions
Reactivation Date	8	182 - 189	MMDDYYYY
Filler	2	190 - 191	Zero

## DRUG PRODUCT DATA FIELD DEFINITIONS

**Labeler Name:**

Corporate name of entity identified by the labeler code

**Labeler Code:**

First segment of National Drug Code that identifies the labeler

**Product Code:**

Second segment of National Drug Code

**Package Size Code:**

Third segment of National Drug Code

**Drug Category:**

N = Non-innovator multiple source

S = Single source

I = Innovator multiple source

**Drug Type Indicator:**

Identifies a drug as prescription (Rx) or Over-the-Counter (OTC)

Valid values: 1 = Rx

2 = OTC

**Termination Date:**

Date drug was withdrawn from market or the drug's last lot expiration date

**Unit Type:**

One of the 8 unit types by which the 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:**

Total number of units in the smallest dispensable amount for the 11-digit NDC

**FDA Approval Date:**

NDC or monograph approval date

**Market Date:**

For S and I drugs, the date the drug was first marketed by the original manufacturer (i.e., NDA holder). For N drugs, the date the drug was first marketed under the manufacturer's rebate agreement. 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 this aspect of the program.

**FDA Product Name:**

Drug 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.