

DRUG PRODUCT DATA
Web File Structure and Definitions

Field	Size	Position	Remarks
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
DESI Indicator	1	52 - 52	See data element definitions
Drug Type Indicator	1	53 - 53	See data element definitions
Termination Date	8	54 - 61	MMDDYYYY
Unit Type	3	62 - 64	See data element definitions
Units Per Pkg Size	10	65 - 74	9999999V999
FDA Approval Date	8	75 - 82	MMDDYYYY
Market Date	8	83 - 90	MMDDYYYY
FDA Thera. Equiv. Code	2	91 - 92	See data element definitions
FDA Product Name	63	93 - 155	FDA Product Name
Clotting Factor Indicator	1	156 - 156	Y or N
Pediatric Indicator	1	157 - 157	Y or N
Package Size Intro. Date	8	158 - 165	MMDDYYYY
Purchased Product Date	8	166 - 173	MMDDYYYY
Filler	2	174 - 175	Zero

PRODUCT DATA 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

DESI Indicator: Drug Efficacy Study Implementation code.

2 = Safe and effective

3 = Drug under review (no NOOH issued)

4 = LTE/IRS drug for some indications

5 = LTE/IRS drug for all indications

6 = LTE/IRS drug withdrawn from market

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Termination Date: Date drug was withdrawn from market or the drug's last lot expiration date.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

Purchase 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...).