

## Instructions to Labelers for CMS-367a, CMS-367b and CMS-367c

The following data fields are required for the relevant collections:

### DATA FIELDS – CMS-367a

**Labeler Code:** First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right justified and zero-filled for 4-digit labeler codes.

**Product Code:** Second segment of National Drug Code. Numeric values only, 4-digit field, right justified, zero-filled.

**Package Size Code:** Third segment of National Drug Code. Numeric values only, 2-digit field, right justified, zero-filled.

**Period Covered:** Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY.

Valid values for Q:

1 = January 1 - March 31

2 = April 1 - June 30

3 = July 1 - September 30

4 = October 1 - December 31

Valid values for YYYY: 4-digit calendar year.

**Average Manufacturer's Price (AMP):** The AMP per unit for the period covered. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place (‘.’) and 6 decimal places; right-justified, zero-filled.

**Best Price:** Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal (‘.’) and 6 decimal places; right-justified, zero-filled. Zero-fill for Non-innovator Multiple Source drugs.

**Nominal Price (NP):** Sales that meet the statutory definition of NP. Total dollar figure per NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers. If no sales for an NDC, labelers must zero-fill.

DATA FIELDS – CMS-367b

**Labeler Code:** First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right justified and zero-filled for 4-digit labeler codes.

**Product Code:** Second segment of National Drug Code. Numeric values only, 4-digit field, right justified, zero-filled.

**Package Size Code:** Third segment of National Drug Code. Numeric values only, 2-digit field, right justified, zero-filled.

**Month:** Calendar month covered by data submission. Numeric 2-digit field, MM.

Valid values for MM:

01 = January	07 = July
02 = February	08 = August
03 = March	09 = September
04 = April	10 = October
05 = May	11 = November
06 = June	12 = December

**Year:** Calendar year covered by data submission. Numeric 4-digit field, YYYY. Valid values for YYYY: 4-digit calendar year.

**Average Manufacturer's Price (AMP):** The AMP per unit for the period covered. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.

DATA FIELDS – CMS-367c

**Labeler Code:** First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

**Product Code:** Second segment of National Drug Code. Numeric values only, 4-digit field, right justified, zero-filled.

**Package Size Code:** Third segment of National Drug Code. Numeric values only, 2-digit field, right-justified, zero-filled.

**Drug Category:** Alpha-numeric values, 1 character.

Valid values:

S = Single source

I = Innovator multiple source

N = Non-innovator multiple source

**Unit Type:** One of the 8 unit types by which the drug is dispensed. Alpha-numeric values, 3-character field, left-justified.

Valid values:

AHF = Injectable Anti-Hemophilic Factor

CAP = Capsule

SUP = Suppository

GM = Gram

ML = Milliliter

TAB = Tablet

TDP = Transdermal Patch

EA = EACH

**FDA Approval Date:** NDA or monograph approval date. Numeric values, 8-digit field, (MMDDYYYY).

**TEC:** FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2 character field.

Valid values:

AA BC BS

AB BD BT

AN BE BX

AO BN NR - Not rated

AP BP A1 thru A9 = AB value

AT BR

**Market Date:** If marketed prior to 10-01-90, first day of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed. Numeric values, 8-digit field, (MMDDYYYY).

**Termination Date:** The date a drug is withdrawn from market or the drug's last lot expiration date. Numeric values, 8-digit field, (MMDDYYYY).

**DESI Indicator:** Drug Efficacy Study Implementation code. Numeric value, 1 digit.

Valid values:

2 = Safe and effective

3 = Drug under review (no NOOH issued)

4 = LTE/IRS drug for SOME indicators

5 = LTE/IRS drug for ALL indicators

6 = LTE/IRS drug withdrawn from market

**Drug Type Indicator:** Identifies a drug as prescription or over-the-counter (OTC).

1 = Rx

2 = OTC

**Baseline AMP:** The AMP per unit for the period that establishes the Baseline AMP for innovator drugs. There will be one weighted baseline AMP for the product, which will be the same for all package sizes. Numeric values, 12-digit field: 5 whole numbers, the decimal (‘.’) and 6 decimal places; right-justified, zero-filled. Compute to 7 decimal places and round to 6 decimal places.

**Units Per Package Size:** Total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values, 11-digit field: 7 whole numbers, the decimal (‘.’) and 3 decimal places; right-justified, zero-filled.

**FDA Product Name:** Drug name as it appears on FDA listing form. Alpha-numeric values, 63 characters, left-justified.

**DRA Baseline AMP:** For active innovator drugs with a Market Date less than 10/1/2006, the Baseline AMP excluding CPP discounts. If no CPP discounts were given in the quarter that established Baseline AMP, the labeler restates the current Baseline AMP in this field. There will be one weighted DRA Baseline AMP for the product, which will be the same for all package sizes. Numeric values, 12-digit field: 5 whole numbers, the decimal (‘.’) and 6 decimal places; right-justified, zero-filled. Compute to 7 decimal places and round to 6 decimal places.

Labelers will have two data reporting options within DDR: first, they may key their data online on an NDC basis; second, they may transfer a saved file to DDR. Labelers that key their data online will have an interactive “pop-up” help function when the DDR has detected a data error. Labelers that opt to transfer their data via a file to DDR will have a report emailed to them the next business day that will outline the errors detected and alerts for potential errors or data issues. The following File Transfer Edit Report includes the current errors and alerts and the instructions to the labeler to correct each data issue:

	<b>New Message</b>	<b>Type</b>	<b>Reason For Occurrence</b>
1	Missing or non-existent labeler code for product record	Error	NDC1 on the product record is blank or does not exist in the database.
2	Missing or non-existent labeler code for pricing record	Error	NDC1 on the price record is blank or does not exist in the database.
3	Missing or incorrect product code	Error	NDC2 is blank or incorrect format or value.
4	Missing or incorrect package size	Error	NDC3 is blank or incorrect format or value.
5	Deleted product - rejected by CMS	Error	Product or package size has been deleted by CMS.
6	Drug category is blank	Error	Drug category field may not be blank.
7	Drug category is not S, I, or N	Error	Drug category field must be S, I, or N.
8	Missing or invalid TEC	Error	TEC is blank or not a valid code.
9	Missing drug type	Error	Drug type is blank.
10	Drug type is not 1 or 2	Error	Drug type must be 1 or 2.
11	Base AMP required for OBRA '90 drugs	Error	Base AMP is blank or contains zero and drug category is S or I and the market date is earlier than 10/01/1993.
12	Base AMP change is rejected	Error	Pricing changes after 12 quarters are not allowed.
13	Base AMP is less than 6 decimal places and/or is not numeric	Error	Base AMP must be both numeric and 6 decimal places.
14	DRA base AMP required	Error	DRA base AMP is blank or zero and the drug category is S or I and the market date is greater than 09/30/1993 and less than 10/01/2006.
15	Term date is invalid and/or earlier than the market date	Alert	Term Date must be later than the market date ...
16	Missing or invalid unit type	Error	Unit type is blank or not a valid value.
17	Missing or invalid UPPS	Error	UPPS is blank or not numeric.
18	UPPS is less than 3 decimal places and/or is not numeric	Error	UPPS must be both numeric and 3 decimal places.
19	Future FDA approval date not allowed	Error	FDA approval date must be equal to current quarter or earlier.
20	Missing or invalid market date	Error	Market date is invalid or blank.
21	Market date not allowed	Error	Market date cannot be greater than current quarter plus one.

	<b>New Message</b>	<b>Type</b>	<b>Reason For Occurrence</b>
22	Market date change rejected	Error	Market date changes are not allowed after 12 quarters.
23	Market date less than FDA approval date	Error	Market date must be equal to or greater than the FDA approval date.
24	Missing FDA drug name	Error	FDA drug name is blank.
25	Missing or invalid DESI	Error	DESI is blank or not equal to 2, 3, 4, 5 or 6.
26	NDC2 does not exist	Error	Pricing rejected. NDC2 not found.
27	Missing year and/or quarter	Error	Period (QCCYY) is blank.
28	Quarter must be 1, 2, 3, or 4	Error	Quarter is not equal to 1, 2, 3 or 4.
29	Invalid year	Error	Year reported is not numeric or is greater than current year.
30	Year earlier than start of rebate program	Error	Year on the price record cannot be earlier than 1991.
31	Future period pricing not allowed	Error	Pricing quarter cannot be greater than current quarter.
32	Best price must contain 6 decimal places	Error	Best price is less than 6 decimal places.
33	Best price must be present, numeric and greater than zero	Error	Best price is blank, non-numeric, or zero.
34	AMP must contain 6 decimal places	Error	AMP is less than 6 decimal places.
35	AMP must be present, numeric, and greater than zero	Error	AMP is blank, non-numeric, or zero.
36	NDC3 does not exist	Error	Pricing rejected. NDC3 not found.
37	Package size is terminated	Error	Pricing record cannot be used to change AMP and/or Best Price because package size was terminated for the quarter specified. Only active package sizes can be used to change pricing.
38	Pricing change rejected	Error	Pricing changes not allowed after 12 quarters.
39	AMP change not approved by CMS	Error	Only best price change approved by CMS.
40	Best price change not approved by CMS	Error	Only AMP change approved by CMS.
41	Pricing change submitted after expiration date	Error	Labeler submitted changes after specified date.
42	Pricing submission equals current price	Error	Submitted pricing data equaled the pricing data already in the database.
43	Drug category change not allowed	Alert	Drug category has a different value than the current value. Cannot change from S/I to N or vice versa without CMS approval.
44	Warning: Unit type changed	Alert	Unit type change often requires UPPS and pricing changes. Review and adjust as needed
45	Base AMP must be zero-filled if market date greater than 9/30/1993 and for N drugs	Alert	Database uses AMP submitted for base AMP quarter. Base AMP not required for N drugs.
46	Market date changes are not allowed	Alert	Market date cannot be changed after 12 quarters without prior CMS approval.

	<b>New Message</b>	<b>Type</b>	<b>Reason For Occurrence</b>
47	DESI change not allowed	Alert	DESI cannot be changed from a value of 2, 3, or 4 to a value of 5 or 6 or vice-versa.
48	FDA approval date may not be after market date	Alert	Previous FDA approval date remains in database.
49	Multiple package size OBRA '90 base AMP error	Alert	OBRA '90 base AMP was not weighted as required. CMS used highest submitted base AMP which will result in highest possible AMP. Review/correct.
50	Multiple package size DRA '05 base AMP error	Alert	DRA '05 base AMP was not weighted as required. CMS used highest submitted base AMP which will result in highest possible AMP. Review/correct.
51	Multiple package size AMP error	Alert	AMP was not weighted as required. CMS used highest submitted base AMP which will result in highest possible AMP. Review/correct.
52	Multiple package size FDA approval date error	Alert	Initial FDA approval date does not change when new package size is added.
53	Multiple package size market date error	Alert	Initial market date does not change when new package size is added.
54	Drug category change made	Alert	Drug category changed from S to I or vice-versa.
55	Terminated drug pricing submitted	Alert	Pricing does not change during four quarters after termination.
56	Terminated package size latest active best price used	Alert	Pricing does not change during four quarters after termination.
57	Best price change not made	Alert	Best price change contains non-numeric characters or spaces.
58	WARNING: Best price greater than AMP	Alert	Best price cannot be greater than AMP. CMS changed best price to equal AMP. Review/correct
59	Multiple package size – Best price error	Alert	Best price must be lowest price regardless of package size and the same value across all package sizes. CMS used lowest submitted best price which will result in highest possible URA. Review/correct.
60	Pricing data exists after termination date	Alert	Labeler submitted pricing data greater than new termination date. Review for accuracy.