

Online Quarterly Pricing Data Entry Screen (CMS-367a)

Pricing For: 4/2015

AMP:

Best Price:

Initial Drug Available for LE: X - Not an LE drug

Initial Drug:

Initial Drug is only reported at the NDC-9 level for Line Extension drugs and should reflect the initial drug that has the highest additional rebate ratio across all possible initial drugs for each Line Extension drug.

**** You have reached the first record.****

CMS-367a (Exp. 03/31/2019) OMB No. 0938-0578 Disclosure: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 34.8 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

File Transfer Quarterly Pricing Layout (CMS-367a)

| Field | Size | Position | Remarks |
|-------------------------------|------|----------|------------------------|
| Record ID | 1 | 1 - 1 | Constant of "Q" |
| Labeler Code | 5 | 2 - 6 | NDC #1 |
| Product Code | 4 | 7 - 10 | NDC #2 |
| Package Size | 2 | 11 - 12 | NDC #3 |
| Period Covered | 5 | 13 - 17 | QYYYY (Qtr/Yr) |
| Average Mfr Price | 12 | 18 - 29 | 99999.999999 |
| Best Price | 12 | 30 - 41 | 99999.999999 |
| Nominal Price | 9 | 42 - 50 | 999999999 |
| Customary Prompt Pay Disc. | 9 | 51 - 59 | 999999999 |
| Initial Drug Available for LE | 1 | 60-60 | Y, N, X or Z |
| Initial Drug | 9 | 61-69 | 9 digits alpha-numeric |

Online Monthly Pricing Data Entry Screen (CMS-367b)

Pricing For: 2/2016

Si Threshold: X - Not a Si drug

AMP: AMP Units: SUP

**** You have reached the first record.****

CMS-367b (Exp. 03/31/2019) OMB No. 0938-0578 Disclosure: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 44.8 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

File Transfer Monthly Pricing Layout (CMS-367b)

| Field | Size | Position | Remarks |
|-------------------|------|----------|-----------------|
| Record ID | 1 | 1 - 1 | Constant of "M" |
| Labeler Code | 5 | 2 - 6 | NDC #1 |
| Product Code | 4 | 7 - 10 | NDC #2 |
| Package Size | 2 | 11 - 12 | NDC #3 |
| Month | 2 | 13 - 14 | MM |
| Year | 4 | 15 - 18 | YYYY |
| Average Mfr Price | 12 | 19 - 30 | 99999.999999 |
| AMP Units | 14 | 31 - 44 | 99999999999.99 |
| 5i Threshold | 1 | 45 - 45 | Y, N, X, or Z |

Online Product Data Entry Screen – Screenshot #1 with Narrow Exception Indicator added (CMS-367c)

The screenshot displays the Online Product Data Entry Screen with the following fields and values:

- NDC1: 00264, NDC2: 7802
- Line Extension Drug Indicator: No
- COO Status: 03 - New Drug Application (NDA)
- FDA Application No./OTC Monograph No.: 0019630
- Drug Category: N - Non-Innovator Multiple Source
- Initial Drug Indicator: [Empty]
- Clotting Factor: N
- Pediatric Indication Only: N
- TEC: AP - Injectable Aqueous Solutions And, In Certain Instances, Intravenous Non-Aqueous
- DESI Indicator: 1 - Safe and Effective or Non-DESI Drug
- Unit Type: MILLILITER
- Drug Type: RX - Prescription
- SI Drug Indicator: Yes, SI Route of Administration: 002 - Inhaled
- FDA Approval Date: 9/30/1990
- Market Date: 9/30/1990, BaseAMP Quarter: [Empty]
- Coverage Effective Date: 1/1/1991
- Purchased Product Date: [Empty]
- Late Submission Cert Date: [Empty]
- Baseline AMPs: OBRA '93: 0.000000, OBRA '90: 0.000000, DRA: 0.000000, ACA: 0.000000

At the bottom, a table lists drug details:

| NDC3 | Drug Name | Package Size/Date | Units Per Package Size | Data Termination Date Reported | Drug Termination Date | Reactivation Date | AmB Trail |
|------|-------------------------------------|-------------------|------------------------|--------------------------------|-----------------------|-------------------|----------------------|
| 00 | 0.45% SODIUM CHLORIDE INJECTION USP | 9/30/1990 | 1000.000 | | Terminates | Reactivates | View |
| 10 | 0.45% SODIUM CHLORIDE INJECTION USP | 9/30/1990 | 500.000 | | Terminates | Reactivates | View |

Product does not have all of its required monthly and quarterly pricing data submitted

Note that the "Narrow Exception Indicator" will only appear in DDR if it has first been checked in MDR by CMS. This is not a field that manufacturers will have access to edit.

Online Product Data Entry Screen – Screenshot #2 with burden hours updated (CMS-367c)

| NDC3 | Drug Name | Package Size Intro Date | Units Per Package Size | Date Termination Date Reported | Drug Termination Date | Reactivation Date | Audit Trail |
|-----------|-----------------------------|-------------------------|------------------------|--------------------------------|-----------------------|-------------------|-------------|
| Select 01 | No ACA I Base AMP submitted | 1/01/2014 | 10.000 | | Terminate | | View |
| Select 02 | No ACA I Base AMP submitted | 1/01/2014 | 20.000 | | Terminate | | View |

Product does not have all of its required monthly and quarterly pricing data submitted

**** You have reached the first record.****

CMS-367c (Exp. 03/31/2019) OMB No. 0938-0578 Disclosure: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 53.5 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

File Transfer Product Layout (CMS-367c)

| 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 Code | 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 |
| FDA Thera. Eq. Code | 2 | 25 - 26 | See Data Element Definitions |
| Market Date | 8 | 27 - 34 | MMDDYYYY |
| Termination Date | 8 | 35 - 42 | MMDDYYYY |
| Drug Type Indicator | 1 | 43 - 43 | See Data Element Definitions |
| OBRA'90 Baseline AMP | 12 | 44 - 55 | 99999.999999 |
| Units Per Pkg Size | 11 | 56 - 66 | 9999999.999 |
| FDA Product Name | 63 | 67 - 129 | FDA Product Name |
| DRA Baseline AMP | 12 | 130 - 141 | 99999.999999 |
| Package Size Intro Date | 8 | 142 - 149 | MMDDYYYY |
| Purchased Product Date | 8 | 150 - 157 | MMDDYYYY |
| 5i Drug Indicator | 1 | 158 - 158 | See Data Element Definitions |
| 5i Route of Administration | 3 | 159 - 161 | See Data Element Definitions |
| ACA Baseline AMP | 12 | 162 - 173 | 99999.999999 |

| | | | |
|-------------------------------|---|-----------|------------------------------|
| COD Status | 2 | 174 - 175 | See Data Element Definitions |
| FDA Appl. No./OTC Mono. No. | 7 | 176 - 182 | See Data Element Definitions |
| Line Extension Drug Indicator | 1 | 183 - 183 | See Data Element Definitions |