

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 for a drug. The interface includes a header with 'Portal Help & FAQs' and 'Print'. The main form area contains 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 - Intrused
- 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, there is a table with columns: NDC3, Drug Name, Package Size/Date, Units Per Package Size, Data Termination Date Reported, Drug Termination Date, Reactivation Date, and Audit Trail. The table contains two rows of data for 0.45% Sodium Chloride Injection USP.

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