







Online Product Data Entry Screen in DDR (CMS-367c)

Manage Existing Product

| | | | | |
|---|---|---|---|---|
| NDC1  (required) | NDC2  (required) | <input type="text"/> | <input type="text"/> | <input type="button" value="SELECT"/> |
| COD Status  (required) | Drug Category (required) | <input type="text" value="Select"/> | <input type="text" value="Select"/> | <input type="button" value="SELECT"/> |
| FDA Application No./OTC Monograph No. (required) | DESI Indicator (system-generated) | <input type="text"/> | <input type="text"/> | Clotting Factor (system-generated) |
| 5i Drug Indicator (required) | 5i Route of Administration (required) | <input type="text" value="Select"/> | <input type="text"/> | <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Drug Type (required) | Line Extension Drug Indicator (required) | <input type="text"/> | <input type="text" value="Select"/> | Exclusively Pediatric (system-generated) |
| FDA TEC (required) | FDA Approval Date (required) | <input type="text"/> | <input type="text" value="MM/DD/YYYY"/>  | <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Purchased Product Date | Coverage Effective Date (system-generated) | <input type="text" value="MM/DD/YYYY"/>  | <input type="text"/> | Market Date (required) |
| | | | | <input type="text" value="MM/DD/YYYY"/>  |
| | | | | Unit Type (required) |
| | | | | <input type="text" value="Select"/> |

Baseline AMPs

| | | |
|---|---------------------------------------|---|
| *OBRA '93 Base AMP Quarter (system-generated) | *OBRA '93 Base AMP (system-generated) | *This Base AMP was system-generated using Quarterly AMP data and is not available for manual entry. Please see the Labeler Data Guide for more details about the different Base AMP fields. |
| <input type="text" value="Q/YYYY"/> | <input type="text" value="0.000000"/> | |
| *BBA '15 Base AMP Quarter (system-generated) | *BBA '15 Base AMP (system-generated) | |
| <input type="text" value="Q/YYYY"/> | <input type="text" value="0.000000"/> | |
| OBRA '90 Base AMP | DRA Base AMP | ACA Base AMP |
| <input type="text" value="0.000000"/> | <input type="text" value="0.000000"/> | <input type="text" value="0.000000"/> |

Form CMS-367c (02/28/2023) is used by manufacturers to report a new drug to CMS either electronically or via file transfer, or when the manufacturer has to report a change to the product data of an existing drug electronically or via file transfer. When needed, the use of Form CMS-367c by manufacturers is considered mandatory under the authority of Section 1927 of the Social Security Act and the National Drug Rebate Agreement. Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. 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 43.5 hours per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.