

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

Manage Existing Product

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

Baseline AMPs

*OBRA '93 Base AMP Quarter <small>(system-generated)</small>	<input type="text" value="Q/YYYY"/>	*OBRA '93 Base AMP <small>(system-generated)</small>	<input type="text" value="0.000000"/>	*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.
*BBA '15 Base AMP Quarter <small>(system-generated)</small>	<input type="text" value="Q/YYYY"/>	*BBA '15 Base AMP <small>(system-generated)</small>	<input type="text" value="0.000000"/>	
OBRA '90 Base AMP	<input type="text" value="0.000000"/>	DRA Base AMP	<input type="text" value="0.000000"/>	ACA Base AMP
				<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.