

2013 (old version)	2014 (new version)	Type of Change	Reason for Change	Burden Change
Data Fields - CMS-367a	Quarterly Pricing Data Fields - CMS-367a	Rev	To clarify which data fields are being described on the 367a	No
Data Fields - CMS-367b	Monthly Pricing Data Fields - CMS-367b	Rev	To clarify which data fields are being described on the 367b	No
Blank	5i Threshold	Rev	In accordance with the Affordable Care Act, the 5i Threshold data definition and valid values are being added.	1 hour per labeler per month
Data Fields - CMS-367c	Drug Product Data Fields - CMS-367c	Rev	To clarify which data fields are being described on the 367c	No
DESI Indicator	COD Status and FDA Application Number/OTC Monograph Number	Rev	The data definition and valid values for the DESI Indicator are being replaced with the data definition and valid values for the new Covered Outpatient Drug Status field and the associated FDA Application Number/OTC Monograph Number field.	One-time burden of 5 hours per labeler
Blank	5i Drug Indicator and 5i Route of Administration	Rev	In accordance with the Affordable Care Act, the data definitions and valid values for the 5i Drug Indicator and 5i Route of Administration fields are being added.	One-time burden of 2.5 hours per labeler

Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesignation.

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Blank	ACA Baseline AMP	Rev	In accordance with the Affordable Care Act, the data definition and valid values for the voluntary ACA Baseline AMP are being added.	Negligible because not every labeler will report it, nor will it be reported for every drug
Blank	Reactivation Date	Rev	To ensure more accurate product data reporting and allow labelers to report a date on which a terminated NDC is reintroduced to the market, the data definition for the voluntary Reactivation Date field is being added for purposes of online reporting.	Negligible because not every labeler will report it, nor will it be reported for every drug
Edits & Alerts	Edits & Alerts	Rev	Various systems-generated edit and alert messages are being revised and/or added to reflect current business rules. Labelers may receive these messages in response to file transfer data submissions.	No

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