

## CROSSWALK DOCUMENT FOR CMS 10110

CHANGE	RATIONALE						
Deleted 1 data element to Addendum A to remove the 11 digit NDC information	Three additional data elements were added to split the NDC number into three components, NDC1, NDC2, and NDC3						
<p>Added 3 data elements to Addendum A to identify the labeler, product, and package size, respectively.</p> <table border="1" data-bbox="188 554 807 611"> <tr> <td data-bbox="188 554 402 611"><b>NDC1</b></td> <td data-bbox="402 554 631 611"><b>NDC2</b></td> <td data-bbox="631 554 807 611"><b>NDC3</b></td> </tr> </table>	<b>NDC1</b>	<b>NDC2</b>	<b>NDC3</b>	Entering each NDC component in a separate field allows CMS to better identify information about each product.			
<b>NDC1</b>	<b>NDC2</b>	<b>NDC3</b>					
<p>Added 1 data element to Addendum A to identify an Alternate ID for the drug product</p> <table border="1" data-bbox="188 793 402 850"> <tr> <td data-bbox="188 793 402 850"><b>Alt ID</b></td> </tr> </table>	<b>Alt ID</b>	To provide identification for a product when an NDC is not available.					
<b>Alt ID</b>							
<p>Added 6 data elements to Addendum A to identify the FDA approval for the drug product.</p> <table border="1" data-bbox="188 1031 807 1520"> <tr> <td data-bbox="188 1031 402 1293"><b>FDA Application Supplement Number</b></td> <td data-bbox="402 1031 602 1293"><b>Additional FDA Application Number #1</b></td> <td data-bbox="602 1031 807 1293"><b>Additional FDA Application Supplement Number #1</b></td> </tr> <tr> <td data-bbox="188 1293 402 1520"><b>Additional FDA Application Number #2</b></td> <td data-bbox="402 1293 602 1520"><b>Additional FDA Application Supplement Number #2</b></td> <td data-bbox="602 1293 807 1520"><b>Description of FDA Approval Type</b></td> </tr> </table>	<b>FDA Application Supplement Number</b>	<b>Additional FDA Application Number #1</b>	<b>Additional FDA Application Supplement Number #1</b>	<b>Additional FDA Application Number #2</b>	<b>Additional FDA Application Supplement Number #2</b>	<b>Description of FDA Approval Type</b>	To appropriately determine payment amounts under Section 1847A of the Social Security Act, CMS must identify and associate the FDA approval number of a product with the applicable ASP data. The FDA approval number at the drug product level is not available to CMS from an existing source. Therefore, CMS must collect these data directly from manufacturers. Additional columns have been added in the case that the product has more than one FDA Application number. We are also adding a column to obtain a description on the FDA approval type.
<b>FDA Application Supplement Number</b>	<b>Additional FDA Application Number #1</b>	<b>Additional FDA Application Supplement Number #1</b>					
<b>Additional FDA Application Number #2</b>	<b>Additional FDA Application Supplement Number #2</b>	<b>Description of FDA Approval Type</b>					
Added Macro to validate data entered in spreadsheet	This will help verify that data are complete and submitted to CMS in the correct format, thereby minimizing time and resources spent on identifying mistakes or errors.						