## Proposed Revised Addendum A

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 0933-0921. The time required to complete this information collection is estimated to average (13 hours) per response, including the time to review instructions, search existingdata resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) orsuggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Bailtimore, Manard 2124-1890. CMS 10110 approx/atXXXIXXXX \* Should you be cutting and pasting data, please use the "Paste Special" function to avoid changing cell formating.

Manufacturer's Name NDC1 NDC2 NDC3 AlternateID Generic Name Brand Name Strength of the PVolume Per Item Number of Items Expiration Date Oate of First Sale FDA Application FDA ApplicatioFDA ApprovalAdditional FDA Additional FDA Additional FDA Additional FDA Additional FDA Apditional FDA Application FDA

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Column A - 1) This is a required free form field	Column B - 1) This is a requred field if Alternate ID is left blank	s Column C - 1) This is a requred field if Alternate ID is left blank	Column D - 1) This is a requred field if Alternate ID is left blank	Column E - 1) This is a required field if NDC1, NDC2, or NDC3 is left blank.		
	2) 5 digit number which identifies the labeler.	2) 4 digit number which identifies the product.	2) 2 digit number which identifies the package size.	2) Numeric or alphanumeric alternate drug identifier (ex. An NHRIC number) can be entered.		

3) Value must be 23 characters or less.

Column F - 1) This is a required field	Column G - 1) This is a required field	Column H - 1) This is a required field	Column I - 1) This is a required free form field	Column J - 1) This is a required field free form field
<ul><li>2) Value must be any positive or negative numbers including zero</li><li>3) Value must include three decimal places</li></ul>	decimal places 3) Must be any valid positive or negative number including	<ul><li>2) WAC must be a valid or positive number including zero</li><li>3) Value must include three decimal places</li></ul>	2) Must be alphanumeric limited to 100 characters	2) Must be alphanumeric limited to 500 characters
<ul> <li>4) ASP should not be greater than WAC</li> <li>but ASP could be greater than WAC</li> </ul>		places. 4) "\$" is not an allowed value.		
5) "\$" is not an allowed value.				
Note: The CMS validation macro will flag an NDC if the ASP is greater than WAC .				

Column K - 1) This is a required free form		Column M - 1) This is not a required field		Column O - 1) This is not a required field
field	·			
	2) Must be limited to	2) Value must be in	2) Value must be in	<ol><li>Data must be</li></ol>
2) Limited to no more		date format	date format	numeric and show
than 12	value.	(MM/DD/YYYY).	(MM/DD/YYYY).	three decimal places.
alphanumeric				
characters.				

Column P - 1) This is a required field	Column Q - 1) This is not a required field		Column S - 1) This is not a required field	Column T - 1) This is not a required field	
a mixture of alpha	2) Data may include a mixture of alpha numeric and numeric values		2) Data may include a mixture of alpha numeric and numeric values	2) Data may include a mixture of alpha numeric and numeric values	
3) Value is limited to 6 or 7 characters	<ol> <li>Value is limited to</li> <li>numeric characters.</li> </ol>	,	3) Value is limited to 4 characters.	3) Value is limited to 6 or 7 characters	
4) Character should not include dashes.		4) Character should not include dashes.		4) Character should not include dashes.	
E) Field should not					

5) Field should not include blanks.

Column U - 1) This is	Column V - 1) This is	Column W - 1) This is	s Column X - 1) This is	Column Y - 1) This is
not a required field	a required field	a required field	a required field if the	
			FDA Approval Type	Freeform field.
<ol><li>Data may include</li></ol>	<ol><li>Value must be in</li></ol>	<ol><li>Must only be</li></ol>	is categorized as	
a mixture of alpha	date format	values in FDA	OTHER.	
numeric and numeric	(MM/DD/YYYY)	approval type list		
values	· · · · · ·	(ANDA, NDA, 510K,	This field should not	
	3) if there is no	BLA, PMA, Human	be populated	
3) Value is limited to	,	Tissue, Vaccine,	otherwise.	
4 characters.	baseline date should			
	be set to 01/01/1965.			
	20 000 10 01/01/10000			