

# Change Summary

## Manufacturers Data Submission Guide v5.0 and v6.0

The changes between version 5.0 and 6.0 of the manufacturers' data submission guides (DSG) are indicated in red in the table below.

Type of change	Template	Version 5.0	Version 6.0	
Update Field:  Labeler Code	Price Increase		<p>Name: Labeler Code Type: Numeric Format: 00000 Max Length: 5 digits</p> <p>Labeler code as assigned by Food and Drug Administration (FDA) These 5 digits should match the first 5 digits of all submitted NDCs in this report.</p> <p><b>Field must be five digits long and maintain leading zeros. Example: 00123</b></p>	
Update Name:  Patent Expiration Date of Original Biologic		<p>Name: Patent Expiration Date Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100 Rule: Must be populated if "Drug Type = S" Rule: If Biosimilar is "N" then Nullable. If "Y" date is required</p>	<p>Name: Patent Expiration Date of Original Biologic Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100 Rule: Must be populated if "Drug Type = S" Rule: If Biosimilar is "N" then Nullable. If "Y" date is required</p> <p><b>The date when all patents on the drug product will expire. Patents owned by the manufacturer (i.e., originator or the inventor). Blanks are acceptable if the drug type field is "N" or "I".</b></p>	The date when all patents on the drug product will expire. Patents owned by the manufacturer (i.e., originator or the inventor). Blanks are acceptable if the drug type field is "N" or "I".
Update Field:  Course of Treatment		<p>Name: Course of Treatment Type: Choice Format: Y, N</p> <p>Y – Course of Treatment is expected to be less than one month or a 30 day supply.</p> <p>N – Course of Treatment is not expected to be less than one month or a 30 day supply</p>	<p>Name: Course of Treatment Type: Choice Format: <b>1, 2, 3</b></p> <p>Is the complete course of treatment expected to be less than one month or a 30-day supply?</p> <p><b>Choice:</b> <b>1= Less than a 30-day supply</b> <b>2= 30-day supply</b> <b>3= Greater than a 30-day supply.</b></p>	
Update Field:  WAC – Effective Date		<p>Effective date of the wholesale acquisition cost increase for the drug product. <b>If the covered drug report is for a new covered drug being introduced to the market, then this field should be the date the product will first be available.</b></p>	<p>Effective date of the wholesale acquisition cost increase for the drug product.</p>	

<b>Update Field:</b>  WAC – Increase (Unit Price)		Amount of wholesale acquisition cost increase per unit of measure for the drug product. Express this as a dollar amount up to 5 decimal places. <b>If the covered drug report is for a new drug being introduced to the market, leave blank.</b>  <b>NOTE: Do not include the dollar sign or commas.</b>	Amount of wholesale acquisition cost increase per unit of measure for the drug product. Express this as a dollar amount up to 5 decimal places.  <b>NOTE: Do not include the dollar sign or commas if nullable do not include any data.</b>
<b>Update Field:</b>  WAC – Increase (Package Price)		Amount of wholesale acquisition cost increase per package of measure for the drug product. Express this as a dollar amount up to 5 decimal places. <b>If the covered drug report is for a new drug being introduced to the market, leave blank.</b>  <b>NOTE: Do not include the dollar sign or commas.</b>	Name: WAC - Increase (Package Price) Type: Numeric Format: 999999.99999 Max Length: 11 digits Rule: Required when “WAC Type” field is “Package” or “Both” Nullable if WAC Type = “Unit”  Amount of wholesale acquisition cost increase per package of measure for the drug product. Express this as a dollar amount up to 5 decimal places.  <b>NOTE: Do not include the dollar sign or commas if nullable do not include any data.</b>
<b>Verify Field:</b>  <b>Patent Expiration Date</b>			After: Non-Financial Factors Name: Patent Expiration Date Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100
<b>New Table:</b> Table Specifications	New Covered Drugs		
<b>New Field:</b>  Labeler Code			Name: Labeler Code Type: Numeric Format: 00000 Max Length: 5 digits  Labeler code as assigned by Food and Drug Administration (FDA) These 5 digits should match the first 5 digits of all submitted NDCs in this report.  Field must be five digits long and maintain leading zeros. Example: 00123
<b>Move Field:</b>  Market Entry Date		From: After Patent Expiration Date	To: After Package Size
<b>Delete Field:</b>  Financial Factors		Name: Financial Factors Type: String Max Length: 5000 characters Format: ABCDE  Rule: value is populated when column "Qualifying Price Increase" is equal to Y	
<b>Delete Field:</b>  Non-Financial Factors		Name: Non-Financial Factors Type: String Max Length: 5000 characters Format: ABCDE  Rule: value is populated when column "Qualifying Price Increase" is equal to Y	

<b>Delete Field:</b>  WAC – Market Entry Date		Name: WAC – Market Entry Date Type: Choice Format: YYYY-MM-DD Min Year: 1990 Max Year: 2100	
<b>Delete Field:</b>  WAC – Market Entry Type		Name: WAC – Market Entry Type Type: Choice Choice: Package, Unit or Both	