Centers for Medicare & Medicaid Services
Center for Medicare (CM)
Hospital and Ambulatory Policy Group
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Average Sale Price (ASP) Data Collection Template/Data Validation Macro

User Manual

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1 OVERVIEW

The Average Sales Price Data Form Addendum A Excel template (available at: http://www.cms.gov/McrPartBDrugAvgSalesPrice/) provides a framework for drug manufacturers to submit their ASP data for current Medicare Part B drugs to CMS. Such data consists of financial, sales, and descriptive data elements.

The Addendum A Excel template has been enhanced to include a validation macro which will ensure that the Center for Medicare (CM)/ Hospital and Ambulatory Policy Group (HAPG) receives complete and correctly formatted data from each manufacturer. The validation macro performs a quality check on the formatting of manufacturers' ASP information.

The ASP Macro does not edit for the validity of data or of calculations, only for whether the contents of the field are correctly formatted. Users are responsible for ensuring that the data entered is technically correct.

Explanatory Messaging

Each cell within the data entry area of the template has been programmed to validate data formatting upon entry. If an invalid format is entered, an error message will be displayed, and the cell will remain highlighted until the error is corrected. Additionally, if a required field is left blank, the macro will provide a message to the user upon exiting that required field (refer to Figure 1 below for sample error message).

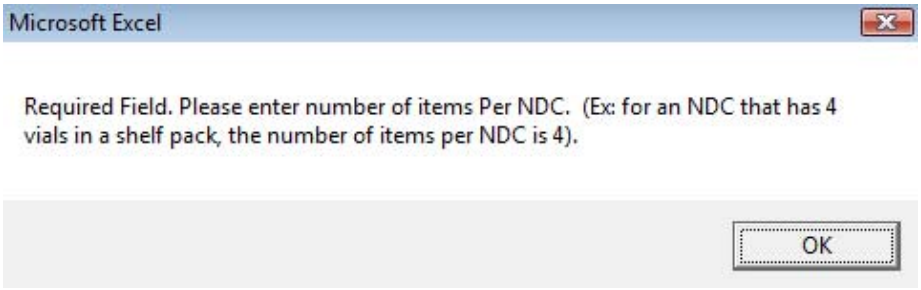

Figure 1: Example of validation macro error message

Secondary Validation Check

The user initiates a secondary validation check by clicking the [**Run ASP Validation**] button (refer to Figure 2) located above the first row of the field descriptions. This prompts the macro to scan all cells that contain data.

Note: The secondary validation check can be run at any time during the data entry process. It can be run more than once.

The secondary check provides an alternate method of data validation in MS Excel. Data that are copied and pasted into the template will override many of the individual cell validations. Therefore, the validation macro should be run after pasting data into the template.

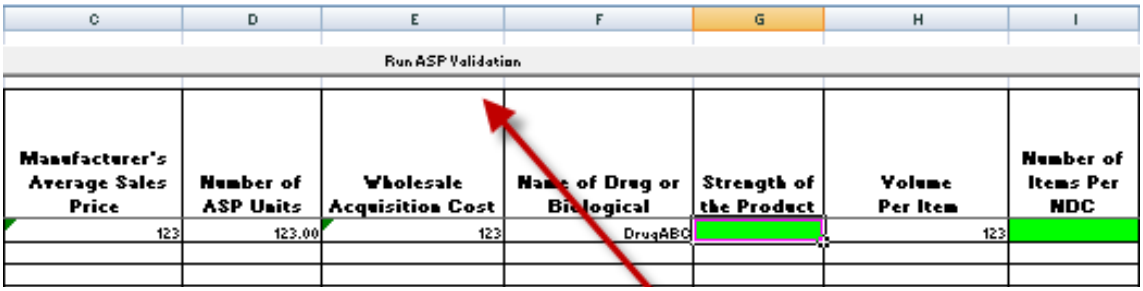

Figure 2: Screenshot of Run ASP Validation Button

2 NAVIGATING THE TEMPLATE

- Open the Addendum A template in Microsoft Excel.
- The first time the template is accessed, the user must accept the digital signature to utilize the validation macro.
- To accept the digital signature, look for the security warning at the top of the page (see Figure 3).

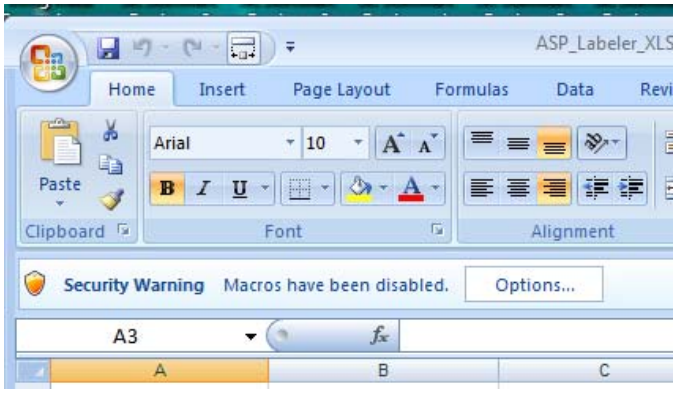

Figure 3: Screenshot of Security Warning section

If a user's system security policies do not allow the use of macros, even if from trusted sources, notify CMS in writing as a part of your submission's cover letter or "Assumptions" document. All submissions must still conform to the data "Field Definitions" described in Section 3.

- Select the Options button to the right of the security warning message. When the next window appears, select the "Trust all documents from this publisher" option and select the "OK" button at the bottom of the screen (see Figure 4). This will enable the macro and enable the spreadsheet to accept data entries. Selection of the "Enable this content" option is also acceptable, but this selection must be made each time the spreadsheet is open.

Note: Once you've accepted the option to "Trust all documents from this publisher", you will not have to perform this step again.

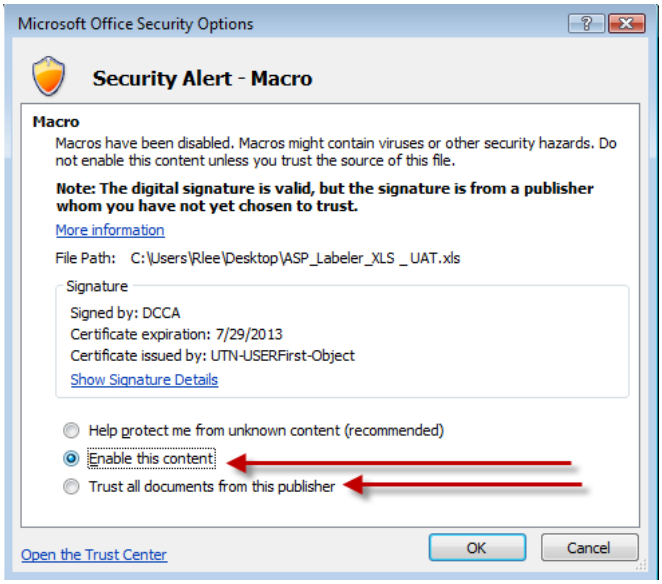

Figure 4: Screenshot of detailed security alert macro

- Enter data into each cell. If the user enters an invalid format or leaves a required field or field combination blank, an error message will be displayed (see Figure 5) and the cell(s) with the incorrect format will be highlighted until the user corrects the error(s) (see Figure 6).

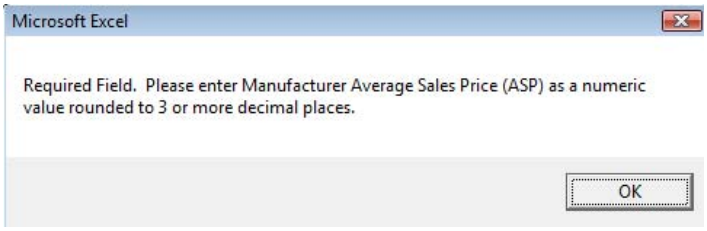

Figure 5: Screenshot of validation macro error message

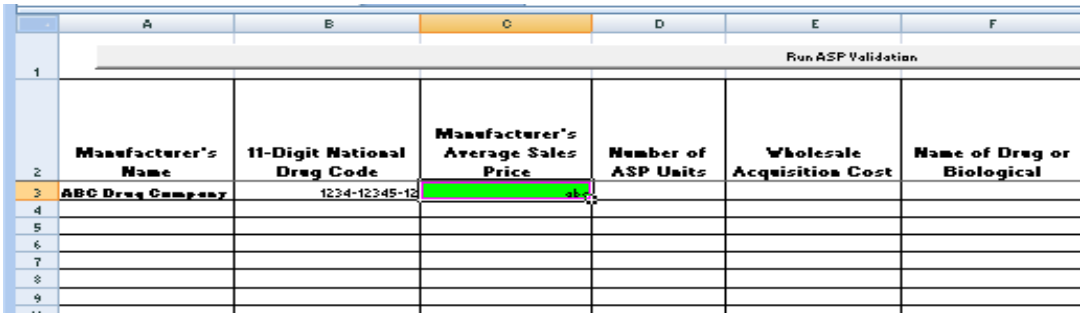

Figure 6: Screenshot of highlighted cell with error

- Upon completion of data entry, select the [**Run ASP Validation**] button located above the first row of the field descriptions to determine if data pass the preliminary validation checks (see Figure 7).

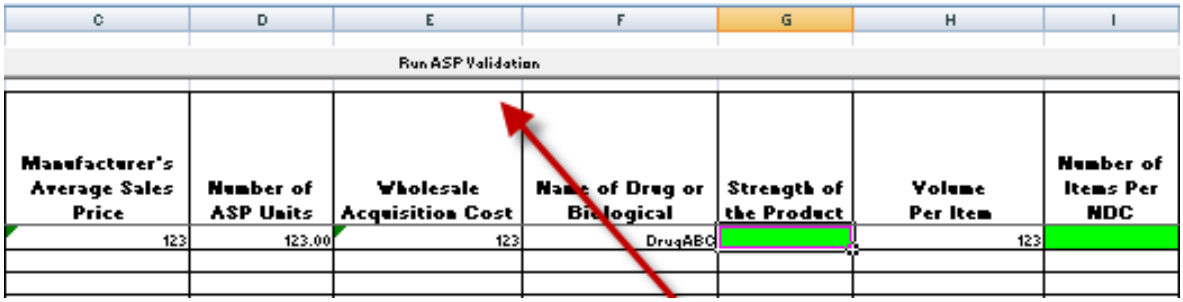

Figure 7: Screenshot of the Run ASP Validation Button

- The user shall correct any highlighted errors before proceeding. Upon completion of all corrections, the user shall run the full validation macro again to confirm there are no additional errors.
- Once the entered data are error free, the user shall submit the template to CMS per the submission instructions at: http://www.cms.gov/McrPartBDrugAvgSalesPrice/.

3 FIELD DEFINITIONS

The validation macro identifies the values listed below as acceptable for each field. All required fields shall contain appropriately formatted data. If no data are present in a required field, the cell with the missing data will be highlighted and an error message will appear. The user must enter properly formatted data before additional data entry can be completed. Fields identified as not required may be left blank.

Depending on the type of product, manufacturers must submit ASP data according to one of the following sets of field definitions.

1. Table 1 contains the field definitions for drugs and biologicals reported on the NDC or CMS-specified unit level.

Most ASP reporting is done at the NDC level where the ASP corresponds to the amount of drug represented by that NDC. However, for a limited number of products, reporting at the NDC unit level is not appropriate and must be done at a CMS-specified unit level. A list of such drug products is maintained on the CMS website at: http://www.cms.gov/McrPartBDrugAvgSalesPrice/. For these drugs and biologicals, manufacturers will still submit ASP sales data for an NDC, but will do so on an ASP unit level specified in this list.

Table 1: Field Definitions for Drugs and Biologicals

Field Name	Field Definition	Valid Values	Required Field
Manufacturer's Name	The reporting manufacturer's name.	Free form field. Alpha and numeric values accepted.	Yes
11-Digit National Drug Code (NDC1)	The NDC1 is the first 5 digits of the 11 digit National Drug Code that identifies the labeler. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.	NDC1 values should be formatted as a 5 digit number. Use a preceding zero(s) as needed (ex: labeler code 1234 shall be reported as 01234).	Yes, if Alternate ID has NOT been entered
11-Digit National Drug Code (NDC2)	The NDC2 is the sixth through the ninth digits of the 11 digit National Drug Code that identifies the product. The 11 digit NDC	NDC2 values should be formatted as a 4 digit number. Use a preceding zero as needed (ex: NDC2 123 shall be reported as 0123).	Yes, if Alternate ID has NOT

Field Name	Field Definition	Valid Values	Required Field
	consists of the NDC1, NDC2, and NDC3, which identify the labeler, product, and package size.		been entered
11-Digit National Drug Code (NDC3)	The NDC3 is the last 2 digits of the 11 digit National Drug Code that identifies the package size. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identify the labeler, product, and package size.	NDC3 values should be formatted as a 2 digit number. Use a preceding zero as needed (ex: NDC3 1 shall be reported as 01).	Yes, if Alternate ID has NOT been entered
Alternate ID	Numeric or alphanumeric alternate identifier (ex: an NHRIC or UPC number) used when an 11 digit NDC is not available.	An alphanumeric alternate ID is 23 characters or less.	Yes, if NDC1, NDC2, NDC3 have NOT been entered
Manufacturer's Average Sales Price	ASP for a corresponding ASP unit rounded to 3 or more decimal places.	Any positive or negative numbers including zero. Value must include at least three decimal places. Do not include dollar sign ($). If no ASP, enter “0.000”.	Yes
Number of ASP Units	The number of ASP units sold.	Any positive or negative numbers including zero. Value must include at least three decimal places. If no units sold, enter “0.000”.	Yes
Wholesale Acquisition Cost (WAC)	The WAC for a corresponding ASP unit in effect on the last day of the reporting period. WAC is defined in Section 1847A(c)(6)(B)	Any positive or negative numbers including zero. Value must include at least three decimal places. Do not include dollar sign ($). If no WAC available, enter “0.000”.	Yes

Field Name	Field Definition	Valid Values	Required Field
	as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." CMS further clarified, in 70 FR 70221, that manufacturers must report WAC for all single source drugs and biologicals (including new drugs) each reporting period. Manufacturers must report the WAC in effect on the last day of the reporting period.		
Name of Drug or Biological	The trade or brand name of the product or the active ingredient name.	This a free form field limited to 100 alphanumeric characters.	Yes
Strength of the Product	The dosage strength of one item (e.g.: 250 mg tablet, 20 mg/ml solution, 1 IU).	This a free form field limited to 500 alphanumeric characters.	Yes
Volume Per Item	The amount in one item (ex: 10 ml in one vial, or 500 tablets in one bottle).	This a free form field limited to 12 alphanumeric characters. Enter "1" for certain forms of drugs (e.g. powders) when "Strength of the Product" indicates the amount of the product per item.	Yes
Number of Items Per NDC	The number of items in the 11-digit NDC (ex: if	Limited to 10 numeric digits.	Yes

Field Name	Field Definition	Valid Values	Required Field
	an NDC packaged as a box contains 4 vials, the number of items per NDC is 4).		
Expiration Date of Final Lot Sold	The expiration date of the final lot sold must be reported to CMS once at the end of utilization of the NDC or when there are no sales for three consecutive quarters. For ASP purposes, "at the end of utilization" means the manufacturer will not make sales of that NDC to any purchaser.	Value should be in the date format (MM/DD/YYYY).	No
Date of First Sale	Report for NDCs first sold on or after 04/01/2006. Report at least once and no later than with the first ASP report.	Value should be in the date format (MM/DD/YYYY).	Yes
Number of CAP Units Excluded	Beginning with the 3Q2006 reporting period, report the number of whole or fractional units administered to a beneficiary by a Part B Drug Competitive Acquisition Program participating physician excluded from the ASP calculation.	Data must be numeric and must include at least three decimal places.	No
FDA Application Number	The application number assigned by the Food and Drug Administration (FDA).	This field is limited to 6 or 7 characters. Data may include a mixture of alpha numeric and numeric values (ex: A123456) or just numeric values (ex: 123456). For entries with only numeric values, use leading zeros if necessary to	Yes

Field Name	Field Definition	Valid Values	Required Field
		report 6 digits. Do not use dashes or spaces.	
FDA Application Supplement Number	The application supplement number assigned by the Food and Drug Administration (FDA).	This field is limited to 4 characters. Use the format XXXX for the application supplement number.	No
Additional FDA Application Number #1	The application number assigned by the Food and Drug Administration (FDA).	If the product has more than one FDA Application Number, enter an additional application number here. This field is limited to 6 or 7 characters. Data may include a mixture of alpha numeric and numeric values (ex: A123456) or just numeric values (ex: 123456). For entries with only numeric values, use leading zeros if necessary to report 6 digits. Do not use dashes or spaces.	No
Additional FDA Application Supplement Number #1	The application supplement number assigned by the Food and Drug Administration (FDA).	This field is limited to 4 characters. Use the format XXXX for the supplemental application number.	No
Additional FDA Application Number #2	The application number assigned by the Food and Drug Administration (FDA).	If the product has more than one FDA Application Number, enter an additional application number here. This field is limited to 6 or 7 characters. Data may include a mixture of alpha numeric and numeric values (ex: A123456) or just numeric values (ex: 123456). For entries with only numeric values, use leading zeros if necessary to report 6 digits. Do not use dashes or spaces.	No

Field Name	Field Definition	Valid Values	Required Field
Additional FDA Application Supplement Number #2	The application supplement number assigned by the Food and Drug Administration (FDA).	This field is limited to 4 characters. Use the format XXXX for the supplemental application number.	No
FDA Final Pre-Marketing Approval Date	This is the original date that the FDA granted approval for the drug (NDA), biological (BLA), or pre-marketing application (PMA).	Value should be in the date format (MM/DD/YYYY). If there is no approval date, baseline date should be set to 01/01/1965.	Yes
FDA Approval Type	The type of FDA approval for the product.	Choose a value from the drop down menu (ANDA, NDA, 510K, BLA, PMA, Human Tissue, Vaccine, Other). If Other, specify the type in the column 'Description of FDA Approval Type'.	Yes
Description of FDA Approval Type	If Other was specified in the column 'FDA Approval Type,' please specify the type.	Free form field limited to 255 alphanumeric characters.	Yes, if FDA Approval Type is "Other".
Descriptive Data Corrected	To indicate that a data element other than a manufacturer's ASP or number of ASP units has changed since the last report.	Free form field limited to 255 alphanumeric characters. Describe which data element(s) have been corrected.	No

2. Table 2 contains the field definitions for dermal grafting products.

Some dermal grafting products are not assigned an NDC. Instead, manufacturers identify them using product codes, which can be catalog numbers, Universal Product Codes (UPCs), or other unique identifiers. If an NDC is not available, the UPC or other unique identifier must be entered in the field "Alternate ID". Manufacturers may not convert a UPC or other alternative identifier to an NDC format by adding zeros or removing numbers. Additionally, where the strength of a dermal grafting product must be described in units of area, manufacturers must report in units of square centimeters. Dermal grafting products that are sold in customized or irregularly shaped sheets must be quantified and reported using square centimeters. Other units of measure such as "square inches", "each", "sheet", etc are not acceptable. Dermal grafting products

that are sold in powder, foam, or liquid form must be quantified and reported in metric measures such as grams, milligrams, or milliliters.

Table 2: Field Definitions for Dermal Grafting Products

Field Name	Field Definition	Valid Values	Required Field
Manufacturer's Name	The reporting manufacturer's name.	Free form field. Alpha and numeric values accepted.	Yes
11-Digit National Drug Code (NDC1)	The NDC1 is the first 5 digits of the 11 digit National Drug Code that identifies the labeler. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.	NDC1 values should be formatted as a 5 digit number. Use a preceding zero(s) as needed (ex: labeler code 1234 shall be reported as 01234).	Yes, if Alternate ID has NOT been entered.
11-Digit National Drug Code (NDC2)	The NDC2 is the sixth through the ninth digits of the 11 digit National Drug Code that identifies the product. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identify the labeler, product, and package size.	NDC2 values should be formatted as a 4 digit number. Use a preceding zero as needed (ex: NDC2 123 shall be reported as 0123).	Yes, if Alternate ID has NOT been entered.
11-Digit National Drug Code (NDC3)	The NDC3 is the last 2 digits of the 11 digit National Drug Code that identifies the package size. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identify the labeler, product, and package size.	NDC3 values should be formatted as a 2 digit number. Use a preceding zero as needed (ex: NDC3 1 shall be reported as 01).	Yes, if Alternate ID has NOT been entered

Field Name	Field Definition	Valid Values	Required Field
Alternate ID	Numeric or alphanumeric alternate identifier (ex: an NHRIC number or UPC) used when an 11 digit NDC is not available.	An alphanumeric alternate ID is 23 characters or less.	Yes, if NDC1, NDC2, NDC3 have NOT been entered.
Manufacturer's Average Sales Price	ASP rounded to 3 or more decimal places. Report the ASP per package, as identified by the NDC or alternate ID (ex: for an NDC or Alternate ID that represents a box of five 2 cm x 3cm grafts, report the ASP per box of five).	Any positive or negative numbers including zero. Value must include at least three decimal places. Do not include dollar sign ($). If no ASP, enter "0.000".	Yes
Number of ASP Units	Report the number of packages sold (ex: for an NDC or Alternate ID that represents a box of five 2 cm x 3cm grafts, report the number of boxes sold).	Any positive or negative numbers including zero. Value must include at least three decimal places. If no units sold, enter "0.000".	Yes
Wholesale Acquisition Cost (WAC)	The WAC in effect on the last day of the reporting period. Report the WAC per package. WAC is defined in Section 1847A(c)(6)(B) as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale	Any positive or negative numbers including zero. Value must include at least three decimal places. Do not include dollar sign ($). If no WAC available, enter "0.000".	Yes

Field Name	Field Definition	Valid Values	Required Field
	price guides or other publications of drug or biological pricing data." CMS further clarified, in 70 FR 70221, that manufacturers must report WAC for all single source drugs and biologicals (including new drugs) each reporting period. Manufacturers must report the WAC in effect on the last day of the reporting period.		
Name of Drug or Biological	The trade or brand name of the product or the active ingredient name.	This a free form field limited to 100 alphanumeric characters.	Yes
Strength of the Product	For products sold in sheets: the total square centimeters in one item (ex: a 6cm x 8cm item is 48 sq cm).	This a free form field limited to 500 alphanumeric characters.	Yes
Volume Per Item	Use this field for dermal grafting products that are reported in units of volume, for example liquids. Report the volume amount in one item, include the metric unit of measurement, such as cc or ml. Enter "1" for powders and sheets.	This a free form field limited to 12 alphanumeric characters. Enter "1" for powders and sheets.	Yes
Number of Items Per NDC	The number of items in the 11-digit NDC or Alternative ID (ex: for an NDC or Alternate ID that has 5 grafts in a package, the number of items per NDC is 5).	Limited to 10 numeric digits.	Yes

Field Name	Field Definition	Valid Values	Required Field
Expiration Date of Final Lot Sold	The expiration date of the final lot sold must be reported to CMS once at the end of utilization of the NDC or Alternate ID when there are no sales for three consecutive quarters. For ASP purposes, "at the end of utilization" means the manufacturer will not make sales of that NDC or Alternate ID to any purchaser.	Value should be in the date format (MM/DD/YYYY).	No
Date of First Sale	Report for NDCs/Alternate IDs first sold on or after 04/01/2006. Report at least once and no later than with the first ASP report.	Value should be in the date format (MM/DD/YYYY).	Yes
Number of CAP Units Excluded	Beginning with the 3Q2006 reporting period, report the number of whole or fractional units administered to a beneficiary by a Part B Drug Competitive Acquisition Program participating physician excluded from the ASP calculation.	Data must be numeric and must include at least three decimal places.	No
FDA Application Number	The application number assigned by the Food and Drug Administration (FDA).	This field is limited to 6 or 7 characters. Data may include a mixture of alpha numeric and numeric values (ex: A123456) or just numeric values (ex: 123456). For entries with only numeric values, use leading zeros if necessary to report 6 digits. Do not use dashes or spaces.	Yes
FDA Application Supplement	The application	This field is limited to 4	No

Field Name	Field Definition	Valid Values	Required Field
Number	supplement number assigned by the Food and Drug Administration (FDA).	characters. Use the format XXXX for the application supplement number.	
Additional FDA Application Number #1	The application number assigned by the Food and Drug Administration (FDA).	If the product has more than one FDA Application Number, enter an additional application number here. This field is limited to 6 or 7 characters. Data may include a mixture of alpha numeric and numeric values (ex: A123456) or just numeric values (ex: 123456). For entries with only numeric values, use leading zeros if necessary to report 6 digits. Do not use dashes or spaces.	No
Additional FDA Application Supplement Number #1	The application supplement number assigned by the Food and Drug Administration (FDA).	This field is limited to 4 characters. Use the format XXXX for the supplemental application number.	No
Additional FDA Application Number #2	The application number assigned by the Food and Drug Administration (FDA).	If the product has more than one FDA Application Number, enter an additional application number here. This field is limited to 6 or 7 characters. Data may include a mixture of alpha numeric and numeric values (ex: A123456) or just numeric values (ex: 123456). For entries with only numeric values, use leading zeros if necessary to report 6 digits. Do not use dashes or spaces.	No
Additional FDA Application Supplement Number #2	The application supplement number assigned by the Food and Drug Administration	This field is limited to 4 characters. Use the format XXXX for the supplemental application number.	No

Field Name	Field Definition	Valid Values	Required Field
	(FDA).		
FDA Final Pre-Marketing Approval Date	This is the original date the FDA granted approval for the drug (NDA), biological (BLA), or pre-marketing application (PMA).	Value should be in the date format (MM/DD/YYYY). If there is no approval date, baseline date should be set to 01/01/1965.	Yes
FDA Approval Type	The type of FDA approval for the product.	Choose a value from the drop down menu (ANDA, NDA, 510K, BLA, PMA, Human Tissue, Vaccine, Other). If Other, specify the type in the column 'Description of FDA Approval Type'.	Yes
Description of FDA Approval Type	If Other was specified in the column 'FDA Approval Type,' please specify the type.	Free form field limited to 255 alphanumeric characters.	Yes, if FDA Approval Type is "Other"
Descriptive Data Corrected	To indicate that a data element other than a manufacturer's ASP or number of ASP units has changed since the last report.	Free form field limited to 255 alphanumeric characters. Describe which data element(s) have been corrected.	No

4 TEMPLATE REQUIREMENTS

1. To use this template, a user must have the ability to enable and execute MS Excel-based Visual Basics for Applications (VBA) Macros.
   - If the user is not able to accept macros due to constraints in corporate security policies, CMS should be notified in writing of the security limitations in the user's cover letter.
2. Users shall not add additional columns to the template.
3. Users shall not add, remove or otherwise change columns or column headings within the template.
4. Users shall not submit blank rows between data entries. All data must be submitted in contiguous rows.
5. Users shall not create multiple rows for one NDC or Alternative ID.

5 ACRONYMS

ANDA	Abbreviated New Drug Application
ASP	Average Sale Price
BLA	Biologics License Application
CAP	Competitive Acquisition Program
CM	Center for Medicare
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
FR	Federal Register
HAPG	Hospital and Ambulatory Policy Group
IU	International Units
NDA	New Drug Application
NDC	National Drug Code
NHRIC	National Health Related Items Code
ML	Milliliter
MG	Milligram
MS	Microsoft
PMA	Pre Marketing Approval
VBA	Visual Basic for Applications
WAC	Wholesale Acquisition Cost