

CARES Act Drug Amount Information Reporting: CSV Template Instructions for Active Pharmaceutical Ingredient or Active Pharmaceutical Ingredient for Drugs That Are Formulated with Activity

PURPOSE

Generalized instructions for populating the provided template for uploading an API or an API with Activity Amount Information via a CSV file. Please refer to the *Technical Conformance Guide – Guidance for Industry* on the [FDA CARES Act Drug Shortage Mitigation Efforts page](#) for definitions of the data elements.

Download the *CARES CSV Template for API Data Upload* from the NextGen Portal—CARES Act Drug Amount Information Reporting tool or from the [FDA Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\) Drug Shortage Mitigation Efforts](#) webpage.

REVIEW THE FOLLOWING INFORMATION BEFORE COMPLETING THE CSV FILE

FDA is offering the option to upload a CSV file containing the required CARES Act Drug Amount Information to reduce the burden of submitting large quantities of data to the Agency. For smaller submissions that would be easier to enter manually, it is recommended to utilize **the manual entry method** in the NextGen Reporting tool. For larger submissions, it is recommended to utilize the submission of a CSV file.

For the most efficient processing, files should contain less than 200k rows in total. If a submission contains more than 200k rows, it should be split into separate files which contain less than 200k rows each, and each file should be submitted separately. When splitting files, ensure that the split does not occur between months for a single DUNS – NDC – Business Operation combination; the split should occur after an "Annual Total" row.

It is highly recommended to populate the CSV template by opening the file in Notepad to retain formatting and leading zeroes on reported DUNS and NDCs. However, if you plan to use Excel, please make edits and save the file as .xlsx instead of .csv if making periodic updates. After making your final edits to the document, follow the steps listed below in Section 2.0 to save the document as a .csv extension type so it can be properly uploaded into the NextGen Portal—CARES Act Drug Amount Information Reporting.

Upon making the final edit and before uploading, please make sure you save the file as a .csv extension type file to ensure the file is successfully uploaded into the NextGen Portal—CARES Act Drug Amount Information Reporting.

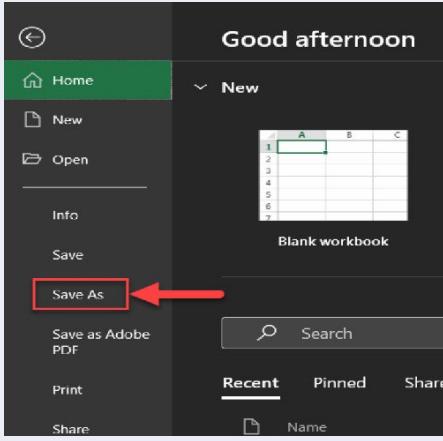
For the data that requires you to use the listed permissible values, copy and paste the value to avoid typos or misspellings.

The steps below outline how to enter one listed Active Pharmaceutical Ingredient (API) or an API with Activity in the template. This process should be repeated for all listed APIs.

SECTION 1.0	Listed Drug which is an API or an API with Activity								
COLUMN	INSTRUCTIONS	VALIDATION							
Column A Row 2	Starting in Column A, Row 2 (Establishment DUNS). Enter an Establishment DUNS number.	Exclude dashes and enter the digits only. Include any leading zeroes. Must be a 9-digit number.							
Column B Row 2	Continuing in Column B, Row 2 (Business Operation). Enter a Business Operation for the Establishment.	There is a fixed list of permissible values. Use only the values below: API Manufacture Manufacture Repack Relabel Transfill Positron Emission Tomography Drug Production							
Column C Row 2	Continuing in Column C, Row 2 (NDC). Enter the NDC of a listed drug.	Must include hyphens and digits. Include any leading zeroes. NDCs must be appropriately formatted in one of the following configurations: 4-4-2 (e.g., 1234-5678-90), 5-4-1 (e.g., 12345-6789-1), 5-3-2 (e.g., 12345-678-90).							
Column D Row 2	Continuing in Column D, Row 2 (Amount Per). The value " January " should appear in the cell.	The month must be spelled out in English (as in the template) and not abbreviated. The months must be listed in calendar order (January through December).							
Column E Row 2	Continuing in Column E, Row 2 (Mass/Volume). Enter the Mass/Volume in January .	Can be a whole number or a decimal. Negative numbers are not allowed. If no listed drug was manufactured in January, enter 0.							
Column F Row 2	Continuing in Column F, Row 2 (Unit of Measure). Enter the Unit of Measure in January .	Enter a valid unit of measure (UOM). Please refer to the acceptable units.							
		<table border="1"> <thead> <tr> <th>API UOM</th> </tr> </thead> <tbody> <tr> <td>Ci</td></tr> <tr> <td>g</td></tr> <tr> <td>kg</td></tr> <tr> <td>L</td></tr> <tr> <td>mg</td></tr> <tr> <td>mL</td></tr> </tbody> </table>	API UOM	Ci	g	kg	L	mg	mL
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Column G Row 2	Continuing in Column G, Row 2 (Activity Unit (IU/U)). Enter the Activity Unit.	<p>Enter a valid unit. Please refer to the acceptable units of measure (UOM) below:</p> <p>Activity UOM</p> <p>U/ml U/mg iU/ml iU/mg USP'U/ml USP'U/mg</p>			
Column H Row 2	Continuing in Column H, Row 2 (Average Activity). Enter the Average Activity, which is the average of all batch activity determined in January.	<p>Can be a whole number, a decimal, or blank.</p> <p>If no listed drug was manufactured in January or activity was not determined, this entry should be blank.</p>			
Column I Row 2	Continuing in Column I, Row 2 (Minimum Activity). Enter the Minimum Activity, which is the minimum activity determined for a batch in January.	<p>Can be a whole number, a decimal, or blank.</p> <p>If no listed drug was manufactured in January or activity was not determined, this entry should be blank.</p>			
Columns A, B, C, F, and G Rows 3-14	<p>Copy the information from Row 2, Columns A, B, C, F, and G down to Rows 3-14.</p> <p>Column A: Establishment DUNS Column B: Business Operation Column C: NDC Column F: Unit of Measure Column G: Activity (Unit of Measure)</p>	<p>Columns A, B, C, F, and G should contain the same data in rows 2-14.</p>			
Column D Row 3-13	<p>Column D, Rows 3-13 The remaining months of the year should be listed in these cells (February through December): Column D, Row 3 should be "February"; Column E, Row 4 should be "March"; etc.</p>	<p>The month must be spelled out in English (as in the template) and not abbreviated.</p>			

Column D Row 14	Column D, Row 14 The value " Annual Total " should be listed in the cell.	Rows 2–14 comprise a record for one listed drug.
The steps below outline how to enter amount information for the remaining months and the total annual amount.		
Column E Rows 3-13 – Monthly Amounts	Column E (Mass/Volume), Rows 3–13 (February–December). Enter the Mass/Volume of the listed drug for the remaining months .	Can be a whole number or a decimal. Negative numbers are not allowed. If no listed drug was manufactured in a particular month, enter 0.
Column E Row 14 – Annual Amount	Column E (Mass/Volume), Row 14 (Annual Total). Enter the Mass/Volume of the listed drug during the reporting year . This should be a total of values entered for January – December.	Can be a whole number or a decimal. Negative numbers are not allowed.
Column H Rows 3-13 – Monthly Amount	Column H (Average Activity), Rows 3-13 (February-December). Enter the Average Activity of the listed drug for the remaining months .	Can be a whole number, a decimal, or blank. If no listed drug was manufactured in a particular month and a zero was entered in column E (Mass/Volume), this entry should be blank for that month. If activity was not determined in a particular month, this entry should be blank for that month.
Column H Row 14 – Annual Amount	Column H (Average Activity), Row 14 (Annual Total). Enter the Average Activity of the listed drug during the reporting year .	Can be a whole number, a decimal, or blank. In the Annual Total row, the Average Activity should be zero (if all values are zeroes), blank (if all values are blanks), or calculated as the average of non-blank values (i.e., sum of non-blank monthly values divided by the number of months with a non-blank value). If Average Activity is blank for every month, this entry should be blank.
Column I Rows 3-13 – Monthly Amount	Column I (Minimum Activity), Rows 3-13 (February-December). Enter the Minimum Activity of the listed drug for the remaining months .	Can be a whole number, a decimal, or blank. If no listed drug was manufactured in a particular month and a zero was entered in column E (Mass/Volume), this entry should be blank for that month. If activity was not determined in a particular month, this entry should be blank for that month.
Column I Row 14 – Annual Amount	Column I (Minimum Activity), Row 14 (Annual Total). Enter the Minimum Activity of the listed drug during the reporting year .	Can be a whole number, a decimal, or blank. For the Annual Total row, the Minimum Activity should be zero (if all values are zeroes), blank (if all values are blanks), or the smallest of the non-blank monthly values. If Minimum Activity is blank for every month, this entry should be blank.

STEP NUMBER / ID	INSTRUCTIONS	ILLUSTRATION OF STEP
1	Verify that the sheet / tab containing the data is the active sheet / tab.	
2	Select File and Save As	

Locate the desired location to save the file in and select to save it as the **CSV (Comma delimited) (*.csv)** file extension type.

3

Please note: There are several (*.csv) file extension type options. The option labeled **CSV (Comma delimited)** should be selected.



Save the file.

NOTE: Do not reopen the saved .csv file after saving and prior to uploading. If the saved CSV file needs to be updated before uploading, be sure to save it with the .csv extension.

4

Upload the data from the file into the system by following the instructions in the system. The *.csv file extension type file must be the file selected for data upload.

IMPORTANT

Prior to uploading data from your custom CSV file, please check this list to ensure the data is uploaded successfully.

	The system will parse data using a comma as the field delimiter. Please ensure there are no commas within the values in the CSV file. For example, replace CASE,1,000,250 with CASE,1000,250
	Quotation marks should be excluded.
	The system will only accept files with the .csv file extension type. Please make sure to save your file as a .csv file.
	\n, \r, \r\n are all acceptable end of line (EOL) characters.

	No specific file encoding is enforced. Default and UTF-8 are both acceptable.
	Remove all empty lines at the end of the CSV file that have only commas in them. These rows are usually only visible in a text editor (such as Notepad).
	Ensure that you have included only permissible Business Operation values.
	All DUNS, Business Operations, and NDCs must be entered in separate cells.
	Every cell in columns A (Establishment DUNS), B (Business Operation), and C (NDC) must contain a value.
	Do not include any special characters as separators in a cell.
	Include leading zeroes for DUNS numbers to avoid validation errors. There should be a total of nine digits.
	There should not be any blank rows.

SECTION 3.0**Common CSV File Upload Errors**

There are five error types that may occur when uploading your CSV file:

- **Parsing Error:** This occurs if your CSV file was not able to process successfully. Please delete the old CSV file and upload a corrected CSV file.
- **Hierarchy Error:** This occurs if your CSV file was not processed. This occurs when a DUNS, Business Operation, and/or NDC is missing. Please note: Each DUNS must have at least one Business Operation, and each Business Operation must have at least one NDC. Please delete the old CSV file and upload a corrected CSV file.
- **File Error:** This occurs if the file name includes special characters (including blanks), or the file name is too long (more than 90 characters). Please delete the old CSV file and upload a new CSV file with an updated file name.
- **Scanning Error:** This occurs if your file is corrupt. Please delete the old CSV file and upload a new CSV file.
- **Data Validation Issue:** This occurs if the data provided does not match values in the drug registration and listing database. Please note: You may still submit your CARES Act Drug Amount Information Report with this issue.

If your CSV file upload results in an error, please review the suggested resolutions to the errors in the list below.

Error Type	Common Issue	Resolution	Error Message on User Interface (UI)
Parsing Error	Delimiter character is not a comma	<p>The system will parse data using a comma as the delimiter. Please ensure there are no commas within the values in the CSV file. If punctuation is needed, please use a colon.</p> <p>Please ensure the delimiter is a comma and not a tab or other type of punctuation.</p>	<p>While processing, the system was not able to successfully parse the file.</p> <p>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</p>
Parsing Error	Delimiter character is included in the data (e.g., "VIAL, GLASS").	<p>The system will parse data using a comma as if it contains the delimiter. Please ensure there are no commas within the values in the CSV file. If punctuation is needed, please use a colon.</p> <p>Example: SYRINGE, GLASS should be updated to SYRINGE: GLASS</p> <p>Please ensure the delimiter is a comma and not a tab or other type of punctuation.</p>	<p>While processing, the system was not able to successfully parse the file.</p> <p>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</p>
Parsing Error	The number of columns is not consistent with the CSV template	Update CSV file to adhere to the CSV template instructions	<p>While processing, the system was not able to successfully parse the file.</p> <p>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</p>

Parsing Error	Presence of nonprintable characters included in the CSV file	Adhere to the Unicode UTF-8 encoding	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.
Parsing Error	End of Line (EOL) Characters not accepted	Ensure that the encoding for the new line character is in UTF-8 format	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.
Parsing Error	Headers do not match the CSV template	Copy and paste headers in the CSV template to avoid errors	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.
Parsing Error	Extra line-end commas	Remove the extra line-end commas provided in the error message.	While processing, the system was not able to successfully parse the file. Please remove the empty line xx for DUNS 123456789

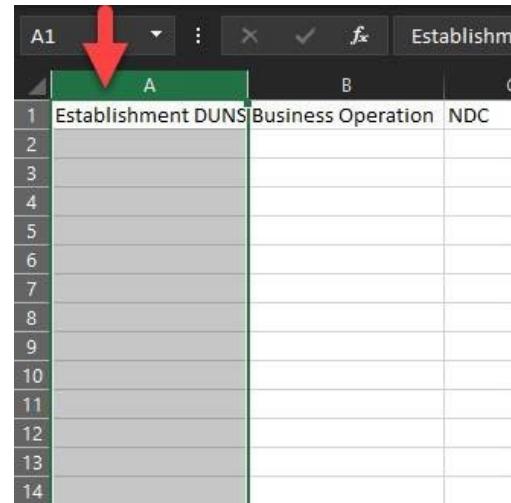
Parsing Error	Empty comma lines	Remove the empty line provided in the error message	While processing, the system was not able to successfully parse the file. Please remove the empty line xx for DUNS 123456789
Parsing Error	Misspelled or Duplicate Months	Correct the misspelled month or a month that has been entered twice for the line provided in the error message	While processing, the system was not able to successfully parse the file. ABC month is misspelled on line xx for DUNS 123456789 OR ABC month is entered twice for DUNS 123456789
Parsing Error	Incorrect value for the Annual Total Line	Cross-check the amounts for all months for the NDC number provided in the error message	While processing, the system was not able to successfully parse the file. Please check the total amounts for NDC 1234-1234-12 and DUNS 123456789

Hierarchy Error	DUNS, Business Operation, and/or NDC contains one or more missing values	<p>Ensure that every DUNS, Business Operation, and NDC field contains a value.</p> <p>Ensure that at least one Establishment DUNS, at least one Business Operation for every Establishment DUNS is entered, and at least one NDC for every Business Operation is entered.</p>	<p>While processing, the system encountered one or more errors related to missing data.</p> <p>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</p> <p>Your file must contain at least one Establishment DUNS, at least one Business Operation for every Establishment DUNS entered, and at least one NDC for every Business Operation entered</p>
Hierarchy Error	Delete cells but not the entire row	<p>Ensure that, when you are removing data, to delete the entire row, not just the data in the cells</p>	<p>While processing, the system encountered one or more errors related to missing data.</p> <p>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</p> <p>Your file must contain at least one Establishment DUNS, at least one Business Operation for every Establishment DUNS entered, and at least one NDC for every Business Operation entered</p>
Validation Error	Unique DUNS/NDCs/Source NDCs are not found in the drug registration and listing database	<p>Ensure that correct DUNS, NDCs, and Source NDCs are entered. Please note: If you entered correct DUNS, NDCs, and Source NDCs, please continue with the CARES Act Drug Amount Information Report submission.</p>	<p>Summary of data that does not match existing values in the drug registration and listing database.</p> <p>Unique DUNs not Validated in the FDA System: Unique NDCs not Validated in the FDA System Unique Source NDCs Not Validated in the FDA System</p> <p>Download the following file, Validation_Results.csv, for a list of data that does not match values in the drug registration and listing database.</p> <p>Validation_Results.csv Upon reviewing your data, you may wish to proceed with this data or make a correction. To make a correction, please remove the CSV file, correct the data in the file, and upload the updated CSV file.</p>
File Error	Error in file name	<p>Avoid special characters and blank spaces.</p>	
File Error	Error in file length	<p>Limit file name to 90 characters (excluding the extension).</p>	

Appendix

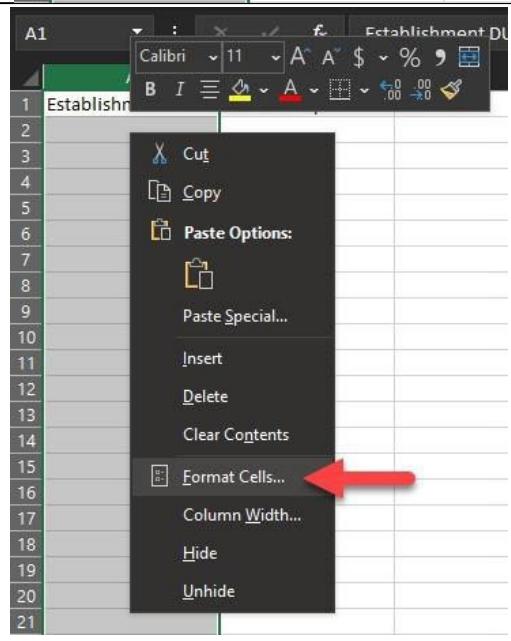
How to preserve leading zeroes in Excel.

1. Select the column you wish to enter leading zeroes into.

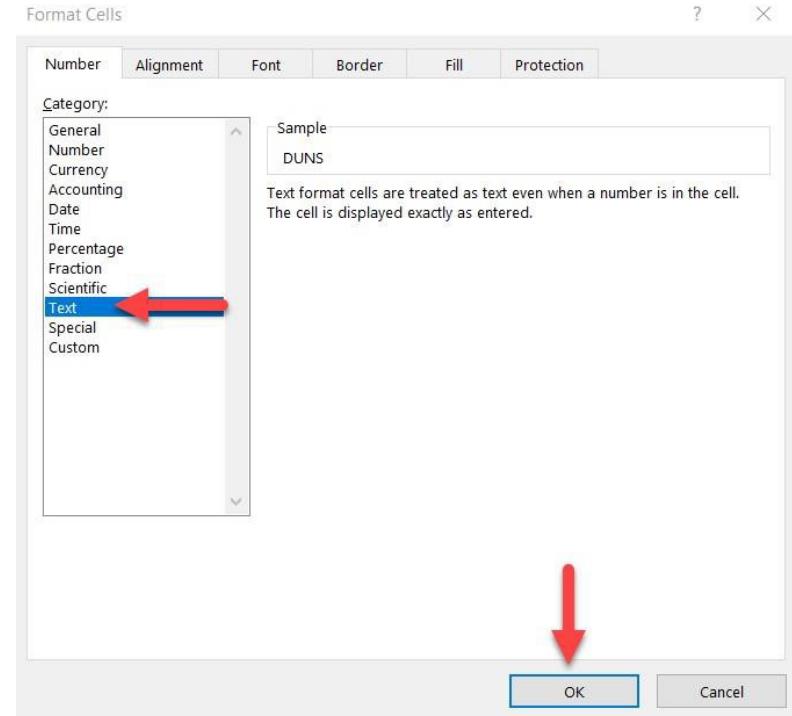


A1	A	B	C
1	Establishment DUNS	Business Operation	NDC
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			

2. Right-click, and select **Format Cells...**.



3. Select **Text** and click **OK**.



You may now enter leading zeroes into this column. Values
4. with leading zeroes can also be copied and pasted in at this
step. They do not have to be entered manually.

	A	B	C
1	Establishment	DUNS	Business Operation
2	001111111		NDC
3	001111111		
4			
5			
6			
7			
8			
9			

IMPORTANT: Enter leading zeroes where needed, then save the file, and upload the data into the NextGen Portal—CARES Act Drug Amount Reporting system. DO NOT REOPEN the file after saving and prior to upload. This will revert the formatting.