

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

PURPOSE

Instructions for creating and populating a custom CSV file 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 Template for CSV Data Upload* from the NextGen Portal—CARES Act Drug Amount Information Reporting or from the [FDA Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\) Drug Shortage Mitigation Efforts webpage](#) for a reference of how the data should be constructed for a successful data upload.

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.

Below are instructions for how the data should be formatted in the CSV file **if the file is constructed in the Excel application**. If the file is created with a different application, please use this document for reference on the expected headers and expected formatting of the provided values to ensure the system successfully parses the data.

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 can be 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.

Example of an entry for two listed drug records:

Figure 1

	A	B	C	D	E	F	G	H	I
1	Establishment DUNS	Business Operation	NDC	Amount Per	Mass/Volume	Unit Of Measure	Activity (Unit of)	Average Activity	Minimum Activity
2	1111111111	API Manufacture	12345-678-01	January	100	kg	u/mg	194	192
3	1111111111	API Manufacture	12345-678-01	February	150	kg	u/mg	198	190
4	1111111111	API Manufacture	12345-678-01	March	200	kg	u/mg	192	190
5	1111111111	API Manufacture	12345-678-01	April	260	kg	u/mg	200	190
6	1111111111	API Manufacture	12345-678-01	May	100	kg	u/mg	190	190
7	1111111111	API Manufacture	12345-678-01	June	100	kg	u/mg	190	190
8	1111111111	API Manufacture	12345-678-01	July	100	kg	u/mg	190	190
9	1111111111	API Manufacture	12345-678-01	August	100	kg	u/mg	190	190
10	1111111111	API Manufacture	12345-678-01	September	100	kg	u/mg	190	190
11	1111111111	API Manufacture	12345-678-01	October	100	kg	u/mg	190	190
12	1111111111	API Manufacture	12345-678-01	November	100	kg	u/mg	190	190
13	1111111111	API Manufacture	12345-678-01	December	100	kg	u/mg	190	190
14	1111111111	API Manufacture	12345-678-01	Annual Total	1510	kg	u/mg	192	190
15	2222222222	Manufacture	12345-678-91	January	300	mg	USP'U/mg	140	100
16	2222222222	Manufacture	12345-678-91	February	150	mg	USP'U/mg	80	100
17	2222222222	Manufacture	12345-678-91	March	150	mg	USP'U/mg	80	100
18	2222222222	Manufacture	12345-678-91	April	260	mg	USP'U/mg	120	80
19	2222222222	Manufacture	12345-678-91	May	150	mg	USP'U/mg	120	80
20	2222222222	Manufacture	12345-678-91	June	150	mg	USP'U/mg	80	100
21	2222222222	Manufacture	12345-678-91	July	150	mg	USP'U/mg	100	100
22	2222222222	Manufacture	12345-678-91	August	150	mg	USP'U/mg	100	100
23	2222222222	Manufacture	12345-678-91	September	150	mg	USP'U/mg	80	100
24	2222222222	Manufacture	12345-678-91	October	220	mg	USP'U/mg	100	80
25	2222222222	Manufacture	12345-678-91	November	150	mg	USP'U/mg	100	100
26	2222222222	Manufacture	12345-678-91	December	150	mg	USP'U/mg	100	100
27	2222222222	Manufacture	12345-678-91	Annual Total	2130	mg	USP'U/mg	100	80

The file should contain 9 columns.

A single listed drug record should have 13 rows. Each row captures amount data for each month of the year. The final row captures annual amount data. The values for columns A, B, C, F, and G will be the same for all 13 rows that signify a single listed drug record.

SECTION

1.0

INSTRUCTIONS

Listed Drug which is an API or an API with Activity

When creating a .csv file, enter the following headers in Row 1, columns A-I. If possible, copy and paste the headers to avoid typos or misspellings. The headers must be in the same order as below.

When using Microsoft Excel to create the custom .csv file, you will need to account for leading zeroes, as Microsoft Excel does not preserve leading zeroes by default. Please refer to **Figure 2** in the Appendix for instructions on how to preserve leading zeroes to ensure a successful data upload from your custom .csv file.

COLUMN	A	B	C	D	E	F	G	H	I
HEADER	Establishment DUNS	Business Operation	NDC	Amount Per	Mass/Volume	Unit of Measure	Activity (Unit of Measure)	Average Activity	Minimum Activity

COLUMN	HEADER	VALIDATION
A	Establishment DUNS	Exclude hyphens, must be digits only. Include leading zeroes. Must be a 9-digit number. See the Appendix for instructions on how to preserve leading zeroes in Excel.
B	Business Operation	There is a fixed list of permissible values. Use only the values below: API Manufacture Manufacture Repack Relabel Transfill Positron Emission Tomography Drug Production
C	NDC	Must include hyphens and digits. Include 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).
D	Amount Per	The values for months January – December must be entered for the first 12 rows of a listed drug record in this column. The 13 th row must contain the value "Annual Total". The months and "Annual Total" must be spelled out in English and not abbreviated. The months must be listed in calendar order (January through December).
E	Mass/Volume	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.
F	Unit of Measure	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> <tr><td>cm²</td></tr> <tr><td>m²</td></tr> <tr><td>ft²</td></tr> </tbody> </table>	API UOM	Ci	g	kg	L	mg	mL	cm ²	m ²	ft ²
API UOM												
Ci												
g												
kg												
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mg												
mL												
cm ²												
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ft ²												
G	Activity (Unit of Measure)	<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>										
H	Average Activity	<p>Can be a whole number or a decimal. If no listed drug was manufactured in a particular month, enter 0.</p> <p>Note: For the Annual Total row, this value should be either zero (if all values are zeroes) or calculated as the sum of non-zero monthly values divided by the number of months with a non-zero value.</p>										
I	Minimum Activity	<p>Can be a whole number or a decimal. If no listed drug was manufactured in a particular month, enter 0.</p> <p>Note: For the Annual Total row, this value should be zero (if all values are zeroes) or the smallest of the non-zero monthly values.</p>										

SECTION 2.0**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 one Business Operation, and each Business Operation must have 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 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 between 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 (i.e., "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 / or are not in the same order as 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	Avoid special characters and blank spaces.	
File Error	Error in file length	Limit file name to 90 characters (excluding the extension).	

IMPORTANT

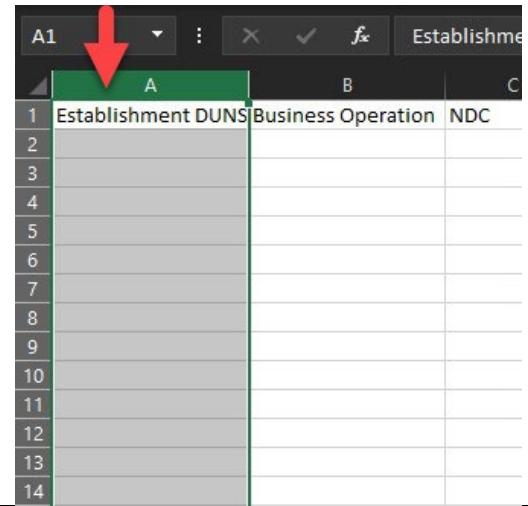
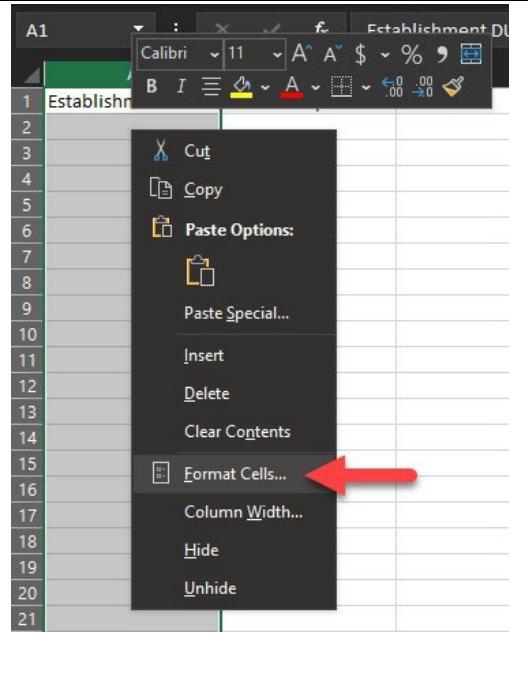
Prior to uploading data from your custom CSV file, please check this list to ensure the data is uploaded successfully.

	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 .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 commas in them. These rows are usually only visible in a text editor (such as Notepad).
	Ensure that you have included permissible Business Operation values (see Figure 1 and Section 1.0 of this document).
	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.
	Avoid duplicate entries or combinations of DUNS / NDCs / Business Operations.
	The file used to upload data must be constructed following the instructions above to ensure successful data parsing. Please refer to the downloadable CARES CSV Template for API Data Upload for reference and examples of what the expected file should look like. This document can be found in the NextGen Portal—CARES Act Drug Amount Information Reporting tool or the FDA CARES Act Drug Shortage Mitigation Efforts page.

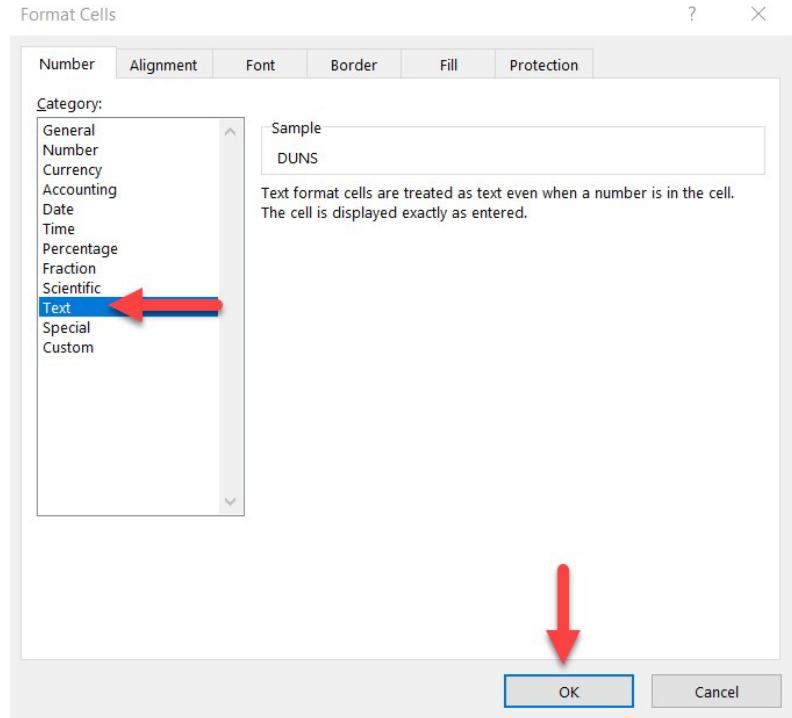
Appendix

How to preserve leading zeroes in Excel.

Figure 2

<p>1. Select the column you wish to enter leading zeroes into.</p>	 <table border="1"><thead><tr><th></th><th>A</th><th>B</th><th>C</th></tr></thead><tbody><tr><td>1</td><td>Establishment DUNS</td><td>Business Operation</td><td>NDC</td></tr><tr><td>2</td><td></td><td></td><td></td></tr><tr><td>3</td><td></td><td></td><td></td></tr><tr><td>4</td><td></td><td></td><td></td></tr><tr><td>5</td><td></td><td></td><td></td></tr><tr><td>6</td><td></td><td></td><td></td></tr><tr><td>7</td><td></td><td></td><td></td></tr><tr><td>8</td><td></td><td></td><td></td></tr><tr><td>9</td><td></td><td></td><td></td></tr><tr><td>10</td><td></td><td></td><td></td></tr><tr><td>11</td><td></td><td></td><td></td></tr><tr><td>12</td><td></td><td></td><td></td></tr><tr><td>13</td><td></td><td></td><td></td></tr><tr><td>14</td><td></td><td></td><td></td></tr></tbody></table>		A	B	C	1	Establishment DUNS	Business Operation	NDC	2				3				4				5				6				7				8				9				10				11				12				13				14			
	A	B	C																																																										
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<p>2. Right-click, and select Format Cells.</p>	 <ul style="list-style-type: none">CutCopyFormat Cells...Paste Special...InsertDeleteClear ContentsColumn Width...HideUnhide																																																												

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	NDC
2	001111111		
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.