

# CARES Act Drug Amount Information Reporting: Custom CSV File Instructions for a Drug Product in Finished Package Form

## PURPOSE

Generalized instructions for creating and populating a custom CSV file for uploading Drug or Biological Product Amount Information. Please refer to the *Technical Conformance Guide – Guidance for Industry* on the [FDA CARES Act Drug Shortage Mitigation Efforts webpage](#) for definitions of the data elements.

**Download the provided *CARES Template for CSV Data Upload* from the NextGen 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](#) 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	J	K	L
1	Establishment DUNS	Business Operation	NDC	Source NDC	Amount Per	Outermost Quantity Manufactured	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Manufactured	Innermost Quantity Distributed	Innermost Package Type	Intended to Fulfill 21 CFR 314.81
2	11111111	Manufacture	12345-678-01		January	10.5		CASE	10	10	BLISTER PACK	No
3	11111111	Manufacture	12345-678-01		February	10		CASE	10	10	BLISTER PACK	No
4	11111111	Manufacture	12345-678-01		March	10		CASE	10	10	BLISTER PACK	No
5	11111111	Manufacture	12345-678-01		April	10		CASE	10	10	BLISTER PACK	No
6	11111111	Manufacture	12345-678-01		May	10		CASE	10.7	10	BLISTER PACK	No
7	11111111	Manufacture	12345-678-01		June	10		CASE	10	10	BLISTER PACK	No
8	11111111	Manufacture	12345-678-01		July	10		CASE	10	10	BLISTER PACK	No
9	11111111	Manufacture	12345-678-01		August	10		CASE	10	10	BLISTER PACK	No
10	11111111	Manufacture	12345-678-01		September	10		CASE	10.8	10	BLISTER PACK	No
11	11111111	Manufacture	12345-678-01		October	10		CASE	10	10	BLISTER PACK	No
12	11111111	Manufacture	12345-678-01		November	10		CASE	10	10	BLISTER PACK	No
13	11111111	Manufacture	12345-678-01		December	10		CASE	10	10	BLISTER PACK	No
14	11111111	Manufacture	12345-678-01	Annual Total		120.5		CASE	121.5	120	BLISTER PACK	No
15	11111111	Manufacture	12345-678-91	January		50	10	CASE	10	10	BLISTER PACK	Yes
16	11111111	Manufacture	12345-678-91	February		50	10	CASE	10	10	BLISTER PACK	Yes
17	11111111	Manufacture	12345-678-91	March		50	10	CASE	10	10	BLISTER PACK	Yes
18	11111111	Manufacture	12345-678-91	April		50	10	CASE	10	10	BLISTER PACK	Yes
19	11111111	Manufacture	12345-678-91	May		50	10	CASE	10	10	BLISTER PACK	Yes
20	11111111	Manufacture	12345-678-91	June		50	10	CASE	10	10	BLISTER PACK	Yes
21	11111111	Manufacture	12345-678-91	July		50	10	CASE	10	10	BLISTER PACK	Yes
22	11111111	Manufacture	12345-678-91	August		50	10	CASE	10	10	BLISTER PACK	Yes
23	11111111	Manufacture	12345-678-91	September		50	10	CASE	10	10	BLISTER PACK	Yes
24	11111111	Manufacture	12345-678-91	October		50	10	CASE	10	10	BLISTER PACK	Yes
25	11111111	Manufacture	12345-678-91	November		0	10	CASE	10	10	BLISTER PACK	Yes
26	11111111	Manufacture	12345-678-91	December		0	0	CASE	10	10	BLISTER PACK	Yes
27	11111111	Manufacture	12345-678-91	Annual Total		500	110	CASE	120	120	BLISTER PACK	Yes

**INSTRUCTION**

When creating a .csv file, enter the following headers in Row 1, Columns A – L. If possible, copy and paste the headers to avoid typos and 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 the Appendix: Figure 3 for instructions on how to preserve leading zeroes to ensure a successful data upload from your custom .csv file.

The file should contain 12 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, D, H, and K will be the same for all 13 rows that signify a single listed drug record.

SECTION 1.0		Listed Drug with Single-Level Packaging										
COLUMN	A	B	C	D	E	F	G	H	I	J	K	L
HEADER	Establishment DUNS	Business Operation	NDC	Source NDC	Amount Per	Outermost Quantity Manufactured	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Manufactured	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Intended to Fulfill 21 CFR 314.81

COLUMN	HEADER	VALIDATION
A	Establishment DUNS	Exclude hyphens; must be digits only. Include leading zeroes. See the Appendix for instructions on how to preserve leading zeroes in Excel. Must be a 9-digit number.
B	Business Operation	There is a fixed list of permissible values. Use only the values below:  Manufacture Repack Relabel Transfill Positron Emission Tomography Drug Production  *Copy and paste the value from this list to avoid misspellings or typos.
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	Source NDC	Include a Source NDC only if the listed drug is under a "Relabel" or "Repack" Business Operation. 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).
E	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 <sup>th</sup> 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).
F	Outermost Quantity Manufactured	Can be a whole number or a decimal. Contains the outermost quantity manufactured of the listed drug corresponding with the month in Column E. The row corresponding with the "Annual Total" in column E should contain the annual outermost quantity manufactured of the listed drug, or a sum of the amounts entered in the previous 12 rows. If no listed drug was manufactured in the US in a month, enter 0.

<b>G</b>	Outermost Quantity Distributed (Non-US)	<p>Can be a whole number or a decimal.      Contains the outermost quantity distributed of the listed drug corresponding with the month in Column E.      The row corresponding with the "Annual Total" in column E should contain the annual outermost quantity distributed of the listed drug, or a sum of the amounts entered in the previous 12 rows.</p> <p>To be entered only if seeking to use CARES Act Drug Amount Information reporting to satisfy distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a).      If seeking to satisfy requirements under 21 CFR 314.81(b)(2)(ii)(a) and no listed drug was distributed in the foreign market in a month, enter 0.</p> <p>For details, please review QUESTIONS AND ANSWERS (B) in the guidance.</p>
<b>H</b>	Outermost Package Type	<p>See Appendix: <b>Figure 2</b> for permissible values.      *Copy and paste the value from this list to avoid misspellings or typos.</p>
<b>I</b>	Innermost Quantity Manufactured	<p>Can ONLY be a whole number.      Contains the innermost quantity manufactured of the listed drug corresponding with the month in Column E.      The row corresponding with the "Annual Total" in column E should contain the annual innermost quantity manufactured of the listed drug, or a sum of the amounts entered in the previous 12 rows.      If no listed drug was manufactured in the US in a month, enter 0.</p>
<b>J</b>	Innermost Quantity Distributed (Non-US)	<p>Can ONLY be a whole number.      Contains the innermost quantity distributed of the listed drug corresponding with the month in Column E.      The row corresponding with the "Annual Total" in column E should contain the annual innermost quantity distributed of the listed drug, or a sum of the amounts entered in the previous 12 rows.      If no listed drug was distributed in the foreign market in a month, enter 0.</p> <p>For details, please review QUESTIONS AND ANSWERS (B) in the guidance.</p>
<b>K</b>	Innermost Package Type	<p>See the Appendix: <b>Figure 2</b> for permissible values.      These values are also in the Package Type Values tab in the sample data document.      *Copy and paste the value from this list to avoid misspellings or typos.</p>
<b>L</b>	Intended to Fulfill 21 CFR 314.81	<p>Permissible values:      Yes      No      Blank (<i>Monthly values only</i>)</p> <p>"Annual Total" in column E should indicate whether the CARES Act Drug Amount Reporting Information is intended to satisfy distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a).</p>

## 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 <b>1,000,250,CASE</b> with <b>1000,250,CASE</b>
	Quotation marks should be excluded.
	The system will only accept files with the <b>.csv</b> file extension type. Please make sure to save your file as a <b>.csv</b> 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 Operations values (see <b>Figure 2</b> in Appendix).
	All DUNS, Business Operations, and NDC values 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.
	<b>The file used to upload data must be constructed following the instructions above to ensure successful data parsing. Please refer to the downloadable CARES Template for CSV 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 <a href="#">FDA CARES Act implementation page</a>.</b>

**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 / Package NDC is missing. Please note: each DUNS must have one Business Operation, and each Business Operation must have one Package NDC. Please delete the old CSV file and upload a corrected CSV file.
- **File Error:** This occurs if the file name includes special characters or if the file name is too long. Please delete the old CSV file and upload a new CSV file.
- **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
<b>Parsing Error</b>	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>For example: 007191810;Relabel;62559-2401-1;January;100,..... should be updated to</p> <p>007191810,Relabel,62559-2401-1,January,100,.....</p> <p>Please ensure the delimiter is a comma and not a tab or other type of punctuation.</p>	<p><b>While processing, the system was not able to successfully parse the file.</b></p> <p><b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b></p>
<b>Parsing Error</b>	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><b>While processing, the system was not able to successfully parse the file.</b></p> <p><b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b></p>

<b>Parsing Error</b>	The number of columns is not consistent with the CSV template	Update CSV file to adhere to the CSV template instructions.	<b>While processing, the system was not able to successfully parse the file.</b>  <b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b>
<b>Parsing Error</b>	Presence of nonprintable characters included in the CSV file	Adhere to the Unicode UTF-8 encoding.	<b>While processing, the system was not able to successfully parse the file.</b>  <b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b>
<b>Parsing Error</b>	End of Line (EOL) Characters not accepted	Ensure that the encoding for the new line character is in UTF-8 format.	<b>While processing, the system was not able to successfully parse the file.</b>  <b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b>
<b>Parsing Error</b>	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.	<b>While processing, the system was not able to successfully parse the file.</b>  <b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b>
<b>Parsing Error</b>	Extra line-end commas	Remove the extra line-end commas provided in the error message.	<b>While processing, the system was not able to successfully parse the file.</b>  <b>Please remove the empty line xx for DUNS 123456789</b>
<b>Parsing Error</b>	Empty comma lines	Remove the empty line(s) provided in the error message.	<b>While processing, the system was not able to successfully parse the file.</b>  <b>Please remove the empty line xx for DUNS 123456789</b>
<b>Parsing Error</b>	Misspelled or duplicate months	Correct the misspelled month or a month that has been entered twice for the line provided in the error message	<b>While processing, the system was not able to successfully parse the file.</b>  <b>ABC month is misspelled on line xx for DUNS 123456789 OR ABC month is entered twice for DUNS 123456789</b>
<b>Parsing Error</b>	Blank 21 CFR 314.81 annual total field	Enter an annual total value in the Intended to Fulfill 21 CFR 314.81 column for the given line provided in the error message	<b>While processing, the system was not able to successfully parse the file.</b>  <b>Intended to Fulfill 21 CFR 314.81 annual total field is blank for DUNS 123456789</b>

<b>Parsing Error</b>	Invalid 21 CFR 314.81 annual total value	Check that the annual total value for Intended to Fulfill 21 CFR 314.81 is either "Yes" or "No."	<p><b>While processing, the system was not able to successfully parse the file.</b></p> <p><b>Intended to Fulfill 21 CFR 314.81 annual total field is invalid for NDC 1234-1234-12 and DUNS 123456789</b></p>
<b>Parsing Error</b>	Mismatch between annual total and monthly 21 CFR 314.81 values	Ensure that the annual total value for Intended to Fulfill 21 CFR 314.81 matches any entered monthly values.  Example: If the annual total value is "Yes," the monthly values can only be "Yes" or blank.	<p><b>While processing, the system was not able to successfully parse the file.</b></p> <p><b>Please confirm that the entry in the Intended to Fulfill 21 CFR 314.81 annual total and monthly fields match (if entered) for NDC 1234-1234-12 and DUNS 123456789</b></p>
<b>Parsing Error</b>	Incorrect value for the Annual Total Line	Cross-check the amounts for all months for the NDC number provided in the error message	<p><b>While processing, the system was not able to successfully parse the file.</b></p> <p><b>Please check the total amounts for NDC 1234-1234-12 and DUNS 123456789</b></p>
<b>Hierarchy Error</b>	DUNS, Business Operation, and/or NDC contains one or more missing values	Ensure that every DUNS, Business Operation, and NDC field contains a value.  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><b>While processing, the system encountered one or more errors related to missing data.</b></p> <p><b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b></p> <p><b>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.</b></p>
<b>Hierarchy Error</b>	Delete cells but not the entire row	Ensure that, when you are removing data, to delete the entire row, not just the data in the cells.	<p><b>While processing, the system encountered one or more errors related to missing data.</b></p> <p><b>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</b></p> <p><b>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.</b></p>

<b>Validation Error</b>	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><b>Summary of data that does not match existing values in the drug registration and listing database.</b></p> <p><b>Unique DUNS not Validated in the FDA System:</b>  <b>Unique NDCs not Validated in the FDA System</b>  <b>Unique Source NDCs Not Validated in the FDA System</b></p> <p><b>Download the following file, <a href="#">Validation_Results.csv</a>, for a list of data that does not match values in the drug registration and listing database.</b></p> <p><b>Validation_Results.csv</b></p> <p><b>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.</b></p>
<b>File Error</b>	Error in file name	<p>Avoid special characters and blank spaces.</p>	
<b>File Error</b>	Error in file length	<p>Limit file name to 90 characters (excluding the extension).</p>	

# Appendix

## Permissible Package Type values

**Figure 2**

ALLERGY UNITS	CELL CULTURE INFECTIOUS DOSE 50%	IMPLANT	OUNCES	SYRINGE: PLASTIC
AMB A 1 UNITS	CELLO PACK	INHALATION	PACKAGE	TABLET
AMPULE	CLINICAL UNITS	INHALER	PACKAGE: COMBINATION	TABMINDER
APPLICATOR	COAT	INHALER: REFILL	PACKET	TAMPON
ARBITRARY UNITS	COLONY FORMING UNITS	INSERT	PAIL	TANK
BAG	CONTAINER	INTERNATIONAL UNITS	PARTS	TISSUE CULTURE INFECTIOUS DOSE 50%
BAR	CONTAINER: FLEXIBLE INTERMEDIATE BULK	JAR	PATCH	TON
BEAD	COUNT	JUG	PELLET	TRAY
BILLION UNITS	CUP	KALLIKREIN INHIBITOR UNIT	PERCENT	TROCHE
BIOEQUIVALENT ALLERGY UNITS	CUP: UNIT-DOSE	KILOGRAM	PINT	TUBE
BLISTER	CURIE	KIT	PLAQUE-FORMING UNITS	TUBE: WITH APPLICATOR
BLISTER PACK	CYLINDER	LIMIT OF FLOCCULATION	POUCH	UNIT - CATALYTIC ACTIVITY
BLOCK	D-ANTIGEN UNITS	LITER	POUND	UNITED STATES PHARMACOPEIA UNIT
BOLUS	DAY	LOZENGE	PRESSOR UNITS	UNITS
BOTTLE	DEWAR	MICROCURIE	PROTEIN NITROGEN UNITS	VIAL
BOTTLE: DISPENSING	DIALPACK	MICROGRAM	PROTEIN UNIT	VIAL: DISPENSING
BOTTLE: DROPPER	DISK	MICROLITER	RING	VIAL: GLASS
BOTTLE: GLASS	DOSE PACK	MICROMOLE	SATURATED	VIAL: MULTI-DOSE
BOTTLE: PLASTIC	DROPS	MICRON	SCOOPFUL	VIAL: PATENT DELIVERY SYSTEM
BOTTLE: PUMP	DRUM	MILICURIE	SECOND	VIAL: PHARMACY BULK PACKAGE
BOTTLE: SPRAY	FILM	MILLIEQUIVALENT	SPONGE	VIAL: PIGGYBACK
BOTTLE: UNIT-DOSE	FOCUS-FORMING UNITS	MILLIGRAM	SPRAY	VIAL: PLASTIC

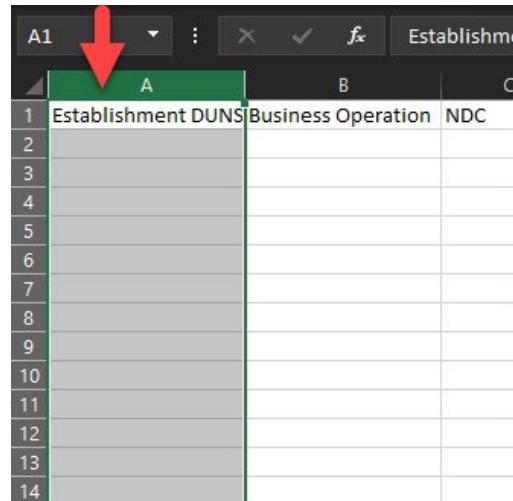
BOTTLE: WITH APPLICATOR	GALLON	MILLILITER	SQUARE CENTIMETER	VIAL: SINGLE-DOSE
BOX	GENERATOR	MILLIMETER	SQUARE FEET	VIAL: SINGLE-USE
BOX: UNIT-DOSE	GRAM	MILLIMOLE	SQUARE METER	WAFER
BULK	HOMEOPATHIC DILUTION	MINUTE	STICK	WEEK
CAN	HOMEOPATHIC POTENCY OF CENTESIMAL KORSAKOVIAN SERIES	MOLE	STRIP	YEAR
CANISTER	HOMEOPATHIC POTENCY OF CENTESIMAL SERIES	MONTH	SUPERSACK	
CAPSULE	HOMEOPATHIC POTENCY OF DECIMAL SERIES	NANOGRAM	SUPPOSITORY	
CARTON	HOMEOPATHIC POTENCY OF MILLESIMAL SERIES	NANOMOLE	SWAB	
CARTRIDGE	HOMEOPATHIC POTENCY OF QUINTAMILLESIMAL SERIES	NOT APPLICABLE	SYRINGE	
CASE	HOUR	OUNCE	SYRINGE: GLASS	

## Appendix (continued)

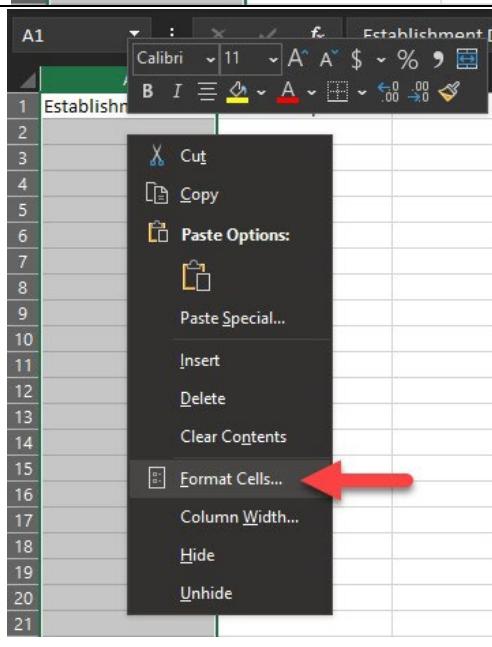
## How to preserve leading zeroes in Excel.

**Figure 3**

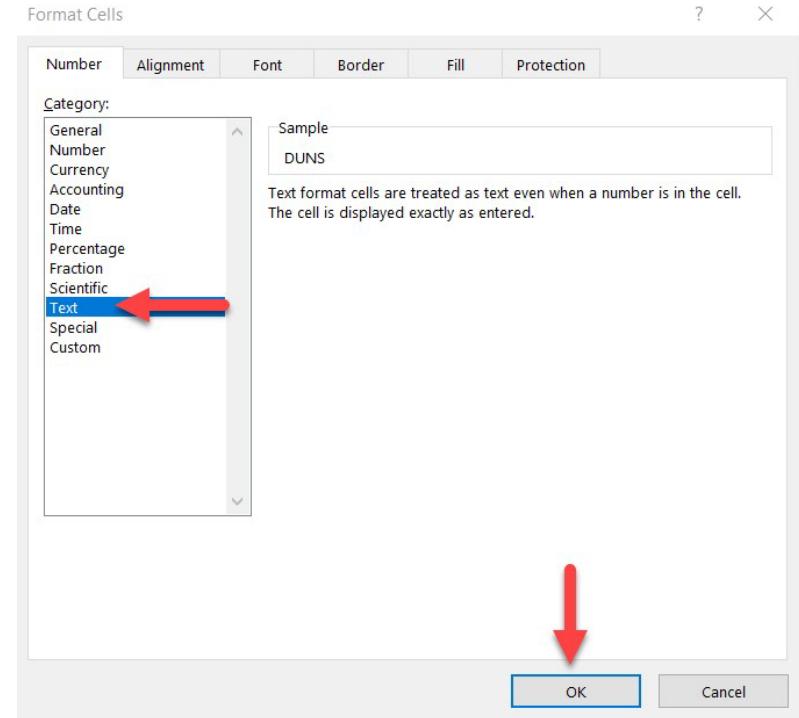
1. Select the column you wish to enter leading zeroes into.



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 in 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 CARES Act Drug Amount Information reporting system. DO NOT REOPEN the file after saving and prior to upload. This will revert the formatting.