

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

PURPOSE

Generalized instructions for populating the provided template for uploading Drug or Biological Product 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 webpage](#) 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.

The steps below outline how to enter one drug or biological product (listed drug) in the template. This process should be repeated for all listed drugs.

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.

It is highly recommended to populate the CSV template by opening the file in Notepad to retain formatting and leading zeros 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 3.0 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.

SECTION 1.0	Listed Drug with Single-Level Packaging	
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: Manufacture Repack Relabel Transfill Positron Emission Tomography Drug Production Copy and paste the value from this list to avoid misspellings or typos.
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 (Source NDC). Enter a Source NDC only if the selected Business Operation in Column B, Row 2 is " Relabel " or " Repack ".	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 E Row 2	Continuing in Column E, 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 F Row 2	Continuing in Column F, Row 2 (Outermost Quantity Manufactured). Enter the Outermost Quantity Manufactured in January .	Can be a whole number or a decimal. If no listed drug was manufactured in the U.S. in January, enter 0. For details, please review guidance QUESTIONS AND ANSWERS (B).
Column G Row 2	Continuing in Column G, Row 2 (Outermost Quantity Distributed (Non-US)). Enter the Outermost Quantity Distributed (Non-US) in January .	Can be a whole number or a decimal. 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).

		<p>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 for industry.</p>
Column H Row 2	Continuing in Column H, Row 2 (Outermost Package Type). Enter the Outermost Package Type.	There is a fixed list of permissible values. Use only values in the Package Type Values tab in the sample data document.
Column I Row 2	Continuing in Column I, Row 2 (Innermost Quantity Manufactured). Leave this column blank for a drug with single-level packaging.	See section 2.0 for entering data for a drug with multi-level packaging.
Column J Row 2	Continuing in Column J, Row 2 (Innermost Quantity Distributed (Non-US)). Leave this column blank for a drug with single-level packaging.	See section 2.0 for entering data for a drug with multi-level packaging.
Column K Row 2	Continuing in Column K, Row 2 (Innermost Package Type). Leave this column blank for a drug with single-level packaging.	See section 2.0 for entering data for a drug with multi-level packaging.
Column L Row 2	<p>Continuing in Column L, Row 2 (Intended to Fulfill 21 CFR 314.81)</p> <p>Enter “Yes” if the CARES Act Drug Amount submission is intended to satisfy the distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a).</p> <p>Monthly values only (Refer to Column L Row 14 instructions for Annual Total)</p>	<p>Permissible values:</p> <p>Yes</p> <p>No</p> <p>Blank</p>
Columns A,B,C,D,H,K Rows 3-14	<p>Copy the information from Row 2, Columns A, B, C, D, H, and K down to Rows 3-14.</p> <p>Column A: Establishment DUNS Column B: Business Operation Column C: NDC Column D: Source NDC (if applicable) Column H: Outermost Package Type Column K: Innermost Package Type</p>	Columns A, B, C, D, H, and K should contain the same data in rows 2- 14.
Column E Row 3-13	<p>Column E, Rows 3-13</p> <p>The remaining months of the year should be listed in these cells (February – December):</p> <p>Column E, Row 3 should be “February”</p> <p>Column E, Row 4 should be “March”</p> <p>etc.</p>	The month must be spelled out in English (as in the template) and not abbreviated.

Column E Row 14	Column E, Row 14 The value " Annual Total " should be listed in the cell.	Rows 2–14 comprise a record for one listed drug.
Column L Row 14	Column L, Row 14 (Annual Total) Enter " Yes " if the CARES Act Drug Amount submission for the listed drug is intended to satisfy the distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a).	Permissible values: Yes No The value listed in this field must match the values listed in the monthly fields for the same drug product (if entered).

The steps below outline how to enter amount information for the remaining months and the total annual amount.

Column F Row 3-13 – Monthly Amounts	Column F (Outermost Quantity Manufactured), Rows 3–13 (February–December). Enter the Outermost Quantity Manufactured of the listed drug for the remaining months .	Can be a whole number or a decimal. If no listed drug was manufactured in the U.S. in a particular month, enter 0.
Column F Row 14 – Annual Amount	Column F (Outermost Quantity Manufactured), Row 14 (Annual Total). Enter the Outermost Quantity Manufactured 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.
Column G Row 3-13 – Monthly Amount	Column G (Outermost Quantity Distributed (Non-US)), Rows 3–13 (February–December). Enter the Outermost Quantity Distributed (Non-US) of the listed drug for the remaining months .	Can be a whole number or a decimal. 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. For details, please review QUESTIONS AND ANSWERS (B) in the guidance for industry.
Column G Row 14 – Annual Amount	Column G (Outermost Quantity Distributed), Row 14 (Annual Total). Enter the Outermost Quantity Distributed 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. 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).

SECTION 2.0	Listed Drug with Multi-Level Packaging	
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: 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 (Source NDC). Enter a Source NDC only if the selected Business Operation in Column B, Row 2 is " Relabel " or " Repack ".	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 E Row 2	Continuing in Column E, 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 F Row 2	Continuing in Column F, Row 2 (Outermost Quantity Manufactured). Enter the Outermost Quantity Manufactured in January .	Can be a whole number or a decimal. If no listed drug was manufactured in the U.S. in January, enter 0. For details, please review guidance QUESTIONS AND ANSWERS (B).

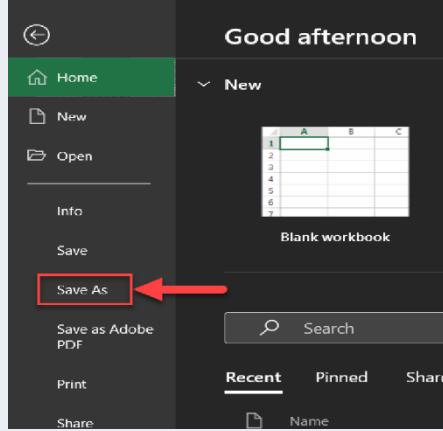
Column G Row 2	Continuing in Column G, Row 2 (Outermost Quantity Distributed (Non-US)). Enter the Outermost Quantity Distributed (Non-US) in January .	<p>Can be a whole number or a decimal.</p> <p>To be entered only if seeking to use CARES Act Drug Amount Information reporting to satisfy distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a).</p> <p>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 for industry.</p>
Column H Row 2	Continuing in Column H, Row 2 (Outermost Package Type). Enter the Outermost Package Type.	There is a fixed list of permissible values. Use only values in the Package Type Values tab in the sample data document.
Column I Row 2	Continuing in Column I, Row 2 (Innermost Quantity Manufactured). Leave this column blank for a drug with single-level packaging.	Must be a whole number. If no listed drug was distributed in the U.S. market in the month of January, enter 0.
Column J Row 2	Continuing in Column J, Row 2 (Innermost Quantity Distributed (Non-US)). Enter the Innermost Quantity Distributed (Non-US) in January .	Must be a whole number. If no listed drug was distributed in the non-U.S. market in the month of January, enter 0.
Column K Row 2	Continuing in Column K, Row 2 (Innermost Package Type). Enter the Innermost Package Type.	There is a fixed list of permissible values. Use only values in the Package Type Values tab in the sample data document.
Column L Row 2	<p>Continuing in Column L, Row 2 (Intended to Fulfill 21 CFR 314.81). Enter “Yes” if the CARES Act Drug Amount submission is intended to satisfy the distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a).</p> <p><i>Monthly Values only (Refer to Column L Row 14 instructions for Annual Total)</i></p>	<p>Permissible values:</p> <p>Yes</p> <p>No</p> <p>Blank</p>
Columns A,B,C,D,H,K Rows 3-14	<p>Copy the information from Row 2, Columns A, B, C, D, H, and K down to Rows 3-14.</p> <p>Column A: Establishment DUNS</p> <p>Column B: Business Operation</p> <p>Column C: NDC</p> <p>Column D: Source NDC (if applicable)</p> <p>Column H: Outermost Package Type</p> <p>Column K: Innermost Package Type</p>	Columns A, B, C, D, H, and K should contain the same data in rows 2-14.

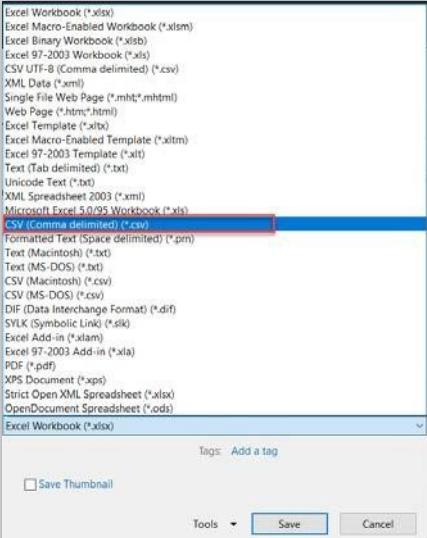
Column E Row 3-13	<p>Column E, Rows 3–13 The remaining months of the year should be listed in these cells (February–December): Column E, Row 3 should be February; Column E, Row 4 should be March etc.</p>	<p>The month must be spelled out in English (as in the Template) and not abbreviated. The months must be listed in calendar order (January through December).</p>
Column E Row 14	<p>Column E, Row 14 The value "Annual Total" should appear in the cell.</p>	<p>Rows 2–14 comprise a record for one listed drug.</p>
Column L Row 14	<p>Column L, Row 14 (Annual Total) Enter "Yes" if the CARES Act Drug Amount submission for the listed drug is intended to satisfy the distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a).</p>	<p>Permissible values: Yes No The value listed in this field must match the values listed in the monthly fields for the same drug product (if entered).</p>

The steps below outline how to enter amount information for the remaining months and the total annual amount.

Column F Row 3-13 – Monthly Amounts	<p>Column F (Outermost Quantity Manufactured), Rows 3–13 (February–December). Enter the Outermost Quantity Manufactured for the remaining months.</p>	<p>Can be a whole number or a decimal. If no listed drug was manufactured in the U.S. in a particular month, enter 0.</p>
Column F Row 14 – Annual Amount	<p>Column F (Outermost Quantity Manufactured), Row 14 (Annual Total). Enter the Outermost Quantity Manufactured during the reporting year. This should be a total of values entered for January–December.</p>	<p>Can be a whole number or a decimal.</p>
Column G Row 3-13 – Monthly Amount	<p>Column G (Outermost Quantity Distributed (Non-US)), Rows 3–13 (February–December). Enter the Outermost Quantity Distributed (Non-US) for the remaining months.</p>	<p>Can be a whole number or a decimal. 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>
Column G Row 14 – Annual Amount	<p>Column G (Outermost Quantity Distributed (Non-US)), Row 14 (Annual Total). Enter the Outermost Quantity Distributed (Non-US) during the reporting year. This should be a total of values entered for January–December.</p>	<p>For details, please review QUESTIONS AND ANSWERS (B) in the industry for guidance. Can be a whole number or a decimal. 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).</p>

		For details, please review QUESTIONS AND ANSWERS (B) in the guidance for industry.
Column I Row 3-13 – Monthly Amount	Column I (Innermost Quantity Manufactured), Rows 3–13 (February–December). Enter the Innermost Quantity Manufactured for the remaining months .	Must be a whole number. If no listed drug was manufactured in the U.S. in a particular month, enter 0.
Column I Row 14 – Annual Amount	Column I (Innermost Quantity Manufactured), Row 14 (Annual Total). Enter the Innermost Quantity Manufactured during the reporting year . This should be a total of values entered for January–December.	Must be a whole number.
Column J Row 3-13 – Monthly Amount	Column J (Innermost Quantity Distributed (Non-US)), Rows 3–13 (February–December). Enter the Innermost Quantity Distributed (Non-US) for the remaining months .	Must be a whole number. 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 no listed drug was distributed in the non-U.S. market in a particular month, enter 0. For details, please review QUESTIONS AND ANSWERS (B) in the guidance for industry.
Column J Row 14 – Annual Amount	Column J (Innermost Quantity Distributed (Non-US)), Row 14 (Annual Total). Enter the Innermost Quantity Distributed (Non-US) during the reporting year . This should be a total of values entered for January–December.	Must be a whole number. 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). For details, please review QUESTIONS AND ANSWERS (B) in the guidance for industry.

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	

	<p>Locate the desired location to save the file in and select to save it as the CSV (Comma delimited) (*.csv) file extension type.</p> <p>3 Please note: There are several (*.csv) file extension type options. The option labeled CSV (Comma delimited) should be selected.</p>  
4	<p>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.</p>
5	<p>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.</p>

IMPORTANT

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

	<p>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</p>
	<p>Quotation marks should be excluded.</p>
	<p>The system will only accept files with the .csv file extension type. Please make sure to save your file as a .csv file.</p>
	<p>\n, \r, \r\n are all acceptable end of line (EOL) characters.</p>

	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.
	Ensure to avoid duplicate entries or combinations of DUNS / NDCs / Business Operations.

SECTION 4.0 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>For example: 007191810;Relabel;62559-2401-1;January;100; should be updated to</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>

		007191810,Relabel,62559-2401-1,January,100.....	Please ensure the delimiter is a comma and not a tab or other type of punctuation.	
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	<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	End of Line (EOL) Characters not accepted	Ensure that the encoding for the new line character is in UTF-8 format.	<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	Headers do not match the CSV template	Copy and paste headers in the CSV template to avoid errors.	<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	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(s) 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	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	While processing, the system was not able to successfully parse the file. Intended to Fulfill 21 CFR 314.81 annual total field is blank for DUNS 123456789
Parsing Error	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."	While processing, the system was not able to successfully parse the file. Intended to Fulfill 21 CFR 314.81 annual total field is invalid for NDC 1234-1234-12 and DUNS 123456789
Parsing Error	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.	While processing, the system was not able to successfully parse the file. 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
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

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	MILLCURIE	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 KOSAKOVIAN 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.

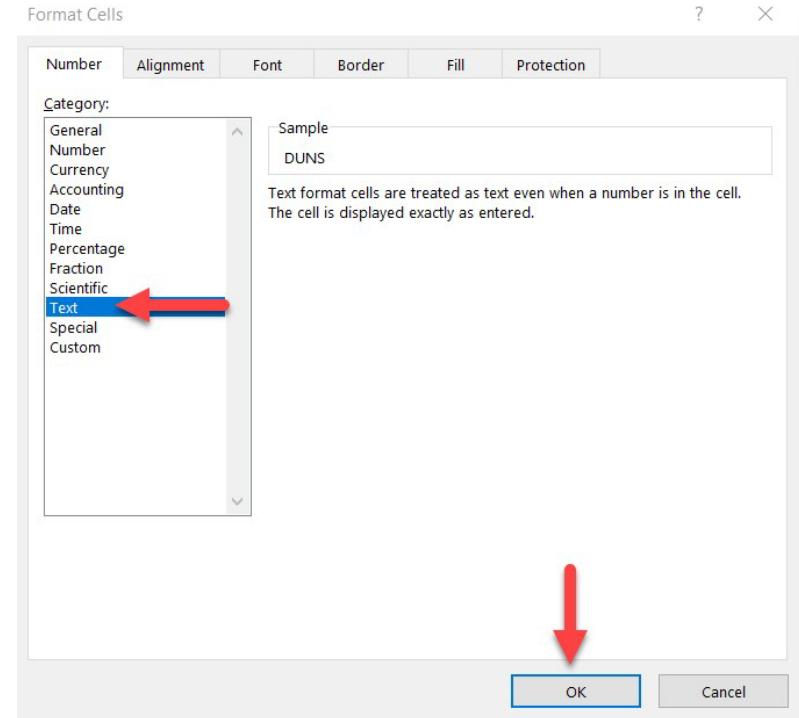
Figure 3

The image shows a Microsoft Excel spreadsheet with three columns: A, B, and C. The first row contains the header 'Establishment DUNS' in cell A1, 'Business Operation' in cell B1, and 'NDC' in cell C1. The data starts from row 2, with 'Establishment DUNS' in cell A2, 'Business Operation' in cell B2, and 'NDC' in cell C2. The following rows (3-14) are empty. A red arrow points to the green header bar above the first row, specifically pointing to the column header 'A'. The second part of the image shows a right-click context menu on cell A1. The menu includes options like Cut, Copy, Paste Options, Insert, Delete, Clear Contents, and Format Cells. A red arrow points to the 'Format Cells...' option in the menu.

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.