# CARES Act Drug Amount Information Reporting: Custom CSV File Instructions for a Drug Product Which Is Not in Finished Package Form

	Generalized instructions for creating and populating a custom CSV file for uploading drug or biological product amount
DUDDOCE	information for a drug product which is not in finished package form via a CSV file. Please refer to the Technical Conformance
PURPOSE	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 Portal—CARES Act Drug Amount Information Reporting tool or from the <u>FDA Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Drug Shortage Mitigation Efforts webpage</u> 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

	А	В	С	D	E	F	G	Н	I
1 E	stablishment DUNS	<b>Business Operation</b>	NDC	Source NDC	Amount Per	Quantity Manufactured	Quantity Distributed (Non-US)	Dosage Form Units	Intended to Fulfill 21 CFR 314.81
2	111111111	Manufacture	12345-678-91		January	100	50	TABLET	Yes
3	111111111	Manufacture	12345-678-91		February	100	50	TABLET	Yes
4	111111111	Manufacture	12345-678-91		March	100	50	TABLET	Yes
5	111111111	Manufacture	12345-678-91		April	100	50	TABLET	Yes
5	111111111	Manufacture	12345-678-91		May	100	50	TABLET	Yes
7	111111111	Manufacture	12345-678-91		June	150	50	TABLET	Yes
3	111111111	Manufacture	12345-678-91		July	151	51	TABLET	Yes
Э	111111111	Manufacture	12345-678-91		August	150.25	50.25	TABLET	Yes
0	111111111	Manufacture	12345-678-91		September	150	50	TABLET	Yes
1	111111111	Manufacture	12345-678-91		October	150	50	TABLET	Yes
2	111111111	Manufacture	12345-678-91		November	0	50	TABLET	Yes
3	111111111	Manufacture	12345-678-91		December	0	0	TABLET	Yes
4	111111111	Manufacture	12345-678-91		Annual Total	1250.25	550.25	TABLET	Yes
5	222222222	Transfill	12345-678-01		January	600		CAPSULE	No
6	222222222	Transfill	12345-678-01		February	0		CAPSULE	No
7	222222222	Transfill	12345-678-01		March	0		CAPSULE	No
8	222222222	Transfill	12345-678-01		April	0		CAPSULE	No
9	222222222	Transfill	12345-678-01		May	100		CAPSULE	No
0	222222222	Transfill	12345-678-01		June	0		CAPSULE	No
1	222222222	Transfill	12345-678-01		July	0		CAPSULE	No
2	222222222	Transfill	12345-678-01		August	0		CAPSULE	No
3	222222222	Transfill	12345-678-01		September	700		CAPSULE	No
4	222222222	Transfill	12345-678-01		October	0		CAPSULE	No
5	222222222	Transfill	12345-678-01		November	0		CAPSULE	No
6	222222222	Transfill	12345-678-01		December	900		CAPSULE	No
27	222222222	Transfill	12345-678-01		Annual Total	2300		CAPSULE	No

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, and H will be the same for all 13 rows that signify a single listed drug record.

#### Instruction

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 the Appendix for instructions on how to preserve leading zeroes to ensure a successful data upload from your custom .csv file.

COLUMN	Α	В	С	D	E	F	G	Н	1
HEADER	Establishment DUNS	Business Operation	NDC	Source NDC	Amount Per	Quantity Manufactured	Quantity Distributed (Non-US)	Dosage Form Units	Intended to Fulfill 21 CFR 314.81

SECTION 1.0	Listed drug product w	hich is not in finished package form
COLUMN	HEADER	INSTRUCTIONS AND 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.
В	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 values from this list to avoid misspellings or typos.
с	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	Quantity Manufactured	Can be a whole number or a decimal. Contains the 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 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 particular month, enter 0.
G	Quantity Distributed (Non- US)	Can be a whole number or a decimal. Contains the 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 quantity distributed of the listed drug, or a sum of the amounts entered in the previous 12 rows. 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.
н	Dosage Form Units	Enter a valid dosage form unit of measure. See <b>Appendix: Figure 2</b> for permissible values. *Copy and paste the value from this list to avoid misspellings or typos.
I	Intended to Fulfill 21 CFR 314.81	Permissible values: Yes No Blank (Monthly values only) Enter " <b>Yes"</b> if the CARES Act Drug Amount submission is intended to satisfy the distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a). The value in the "Annual Total" row 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).

#### IMPORTANT

	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 1,000,250,CASE with 1000,250,CASE
	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.
	nclude leading zeroes for DUNS numbers to avoid validation errors. There should be a total of nine digits.
Γ	here should not be any blank rows.
4	void 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

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 at least one Business Operation, and each Business Operation must have at least 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 has 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	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. For example: 007191810;Relabel;62559-2401-1;January;100;;;;; should be updated to 007191810,Relabel,62559-2401-1,January,100;,;; Please ensure the delimiter is a comma and not a tab or other type of punctuation.	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 the CSV file.
Parsing Error	Delimiter character is included in the data (i.e., "VIAL, GLASS")	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. Example: SYRINGE, GLASS should be updated to SYRINGE: GLASS	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 the CSV file.

Parsing Error	The number of columns is not consistent with the CSV template	Update CSV file to adhere to the CSV template instructions.	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 the CSV file.
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 the 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 the 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 instruction 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 the 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(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 Fulfil 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/Package NDC/Business Operation are blank	Ensure that at least one Establishment DUNS is entered, at least one Business Operation for every Establishment DUNS is entered, and at least one NDC for every Business Operation is entered.	<ul> <li>While processing, the system encountered one or more errors related to missing data.</li> <li>Please remove the CSV file, correct the data in the file, and upload the updated the CSV file.</li> <li>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.</li> </ul>
Hierarchy Error	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.	<ul> <li>While processing, the system encountered one or more errors related to missing data.</li> <li>Please remove the CSV file, correct the data in the file, and upload the updated the CSV file.</li> <li>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.</li> </ul>

Validation Error	Unique DUNS/NDCs/Source NDCs are not found in the drug registration and listing database	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.	Summary of data that does not match existing values in the drug registration and listing database. 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 Download the following file, Validation_Results.csv for a list of data that does not match values in the drug registration and listing database. 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.
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).	

# Appendix

# Permissible Dosage Form Unit values

# Figure 2

AEROSOL	ENEMA	INJECTION: POWDER:	PASTE: DENTIFRICE	STICK
		LYOPHILIZED: FOR SUSPENSION		
AEROSOL: FOAM	EXTRACT	INJECTION: POWDER: LYOPHILIZED: FOR	PASTILLE	STRIP
		SUSPENSION: EXTENDED RELEASE		
AEROSOL: METERED	FIBER: EXTENDED RELEASE	INJECTION: SOLUTION	PATCH	SUPPOSITORY
AEROSOL: POWDER	FILM	INJECTION: SOLUTION: CONCENTRATE	PATCH: EXTENDED RELEASE	SUPPOSITORY: EXTENDED RELEASE
AEROSOL: SPRAY	FILM: EXTENDED RELEASE	INJECTION: SUSPENSION	PATCH: EXTENDED	SUSPENSION
			RELEASE:	
			ELECTRICALLY	
			CONTROLLED	
ASEPTIC UTERINE INFUSION	FILM: SOLUBLE	INJECTION: SUSPENSION:	PELLET	SUSPENSION
		EXTENDED RELEASE		(INTRAMAMMARY)
BAR: CHEWABLE	FOR SOLUTION	INJECTION: SUSPENSION: LIPOSOMAL	PELLET: IMPLANTABLE	ESUSPENSION/ DROPS
BEAD	FOR SUSPENSION	INJECTION: SUSPENSION:	Pellets: coated:	SUSPENSION: EXTENDED
		SONICATED	EXTENDED RELEASE	RELEASE
BEAD: IMPLANT: EXTENDED RELEASE	FOR SUSPENSION: EXTENDED RELEASE	INSERT	PILL	SUTURE
BLOCK	GAS	INSERT: EXTENDED RELEASE	PINT	SWAB
BLOCK (TYPE C MEDICATED FEED)	GEL	INTRAUTERINE DEVICE	PLASTER	SYRUP
BOLUS	GEL: DENTIFRICE	IRRIGANT	POULTICE	TABLET
Capsule	GEL: METERED	JELLY	POWDER	TABLET WITH SENSOR
CAPSULE: COATED	GENERATOR	KILOGRAM: kg	POWDER: DENTIFRICE	TABLET: CHEWABLE
CAPSULE: COATED PELLETS	GLOBULE	KIT	POWDER: FOR	TABLET: CHEWABLE:
			SOLUTION	EXTENDED RELEASE
CAPSULE: COATED:	GRAFT	LINER: DENTAL	POWDER: FOR	TABLET: COATED
EXTENDED RELEASE			SUSPENSION	

CAPSULE: DELAYED RELEASE	GRAM: g	LINIMENT	POWDER: METERED	TABLET: COATED PARTICLES
CAPSULE: DELAYED RELEASE PELLETS	GRANULE	LIPSTICK	POWDER: TYPE A MEDICATED ARTICLE	TABLET: DELAYED RELEASE
CAPSULE: EXTENDED RELEASE	GRANULE (TYPE A MEDICATED ARTICLE)	LIQUID	POWDER: TYPE B MEDICATED FEED	TABLET: DELAYED RELEASE PARTICLES
CAPSULE: FILM COATED: EXTENDED RELEASE	GRANULE (TYPE A MEDICATED ARTICLE: TYPE B MEDICATED FEED)	LIQUID (SOLUTION) - INTRAVENOUS: INTRAMUSCULAR: SUBCUTANEOUS	QUART	TABLET: EFFERVESCENT
CAPSULE: GELATIN COATED	GRANULE (TYPE A MEDICATED ARTICLE: TYPE C MEDICATED FEED)	LIQUID (TYPE A MEDICATED ARTICLE)	RING	TABLET: EXTENDED RELEASE
CAPSULE: LIQUID FILLED	GRANULE (TYPE B MEDICATED FEED)	LIQUID CONCENTRATE	RINSE	TABLET: FILM COATED
CEMENT	GRANULE: DELAYED RELEASE	LIQUID: EXTENDED RELEASE	SALVE	TABLET: FILM COATED: EXTENDED RELEASE
CIGARETTE	GRANULE: EFFERVESCENT	LITER: L	Shampoo	TABLET: FOR SOLUTION
CLOTH	GRANULE: FOR SOLUTION	LOTION	Shampoo: Suspension	TABLET: FOR SUSPENSION
CONCENTRATE	GRANULE: FOR SUSPENSION	LOTION/SHAMPOO	SOAP	TABLET: MULTILAYER
CONCENTRATE SOLUTION	GRANULE: FOR SUSPENSION: EXTENDED RELEASE	LOTION: AUGMENTED	SOLUBLE POWDER	TABLET: MULTILAYER: EXTENDED RELEASE
CONE	GUM	LOZENGE	SOLUBLE POWDER DRINKING WATER	TABLET: ORALLY DISINTEGRATING
CORE: EXTENDED RELEASE	GUM: CHEWING	MEDICATED FEED	SOLUTION	TABLET: ORALLY DISINTEGRATING: DELAYED RELEASE
CREAM	GUM: RESIN	MILLIGRAM: mg	solution/ drops	TABLET: SOLUBLE
CREAM: AUGMENTED	IMPLANT	MILLILITER: mL	Solution: concentrate	TABLET: SUGAR COATED
CRYSTAL	INHALANT	MOUTHWASH	SOLUTION: FOR SLUSH	ΤΑΜΡΟΝ
CULTURE	INJECTABLE: LIPOSOMAL	NOT APPLICABLE	SOLUTION: GEL FORMING / DROPS	ТАРЕ
CURIE: Ci	INJECTION	NUFLOR 2.3% SOLUTION CONCENTRATE 2.2 LITER	SOLUTION: GEL FORMING: EXTENDED RELEASE	TINCTURE

DIAPHRAGM	INJECTION: EMULSION	NUFLOR INJECTION SOLUTION 100ML: 250ML: 500ML	Sponge	TROCHE
DISC	INJECTION: LIPID COMPLEX	OIL	SPRAY	TYPE A MEDICATED ARTICLE
DOUCHE	INJECTION: POWDER: FOR SOLUTION	OINTMENT	SPRAY: METERED	TYPE A MEDICATED ARTICLE & TYPE B MEDICATED FEED (POWDER)
DRESSING	INJECTION: POWDER: FOR SUSPENSION	OINTMENT: AUGMENTED	SPRAY: SUSPENSION	UNASSIGNED
DRUG DELIVERY SYSTEM	INJECTION: POWDER: FOR SUSPENSION: EXTENDED RELEASE	ORAL SOLUTION	SQUARE CENTIMETER: cm2	WAFER
ELIXIR	INJECTION: POWDER: LYOPHILIZED: FOR LIPOSOMAL SUSPENSION	PACKING	STERILE POWDER	WATER SOLUBLE POWDER
EMULSION	INJECTION: POWDER: LYOPHILIZED: FOR SOLUTION	PASTE	STERILE POWDER FOR SUSPENSION	

# Appendix (continued)

## How to preserve leading zeroes in Excel.

## Figure 3

Figure 3	
1. Select the column you wish to enter leading zeroes into.	A1 F   Establishment DUNS Business Operation NDC   2   3   4   5   6   7   8   9   10   11   12   13
2. Right-click and select <b>Format Cells</b> .	A1       : $\pounds$ Etablish       DL         Calibri       11 $A$ $\$$ $\checkmark$ $\%$ $?$ 2       B $I \equiv \pounds \land A \sim \boxplus \lor \%$ $\Re$ $\checkmark$ 3 $\Lambda$ Cut $\checkmark$ $\checkmark$ $\Re$ $\checkmark$ 4 $\Box$ $\Box$ $\Box$ $\Box$ $\Im$ $\checkmark$ 6 $\Box$ Paste Options: $\Box$ $\Box$ $\Box$ $\Box$ 7 $\Box$ $\Box$ $\Box$ $\Box$ $\Box$ $\Box$ $\Box$ 9       Paste Options: $\Box$ $\Box$ $\Box$ $\Box$ $\Box$ $\Box$ 10       Insert $\Box$ $\Box$ $\Box$ $\Box$ $\Box$ $\Box$ 11       Insert $\Box$

