

Further Details on using CSV Files

Ed Hallissey

Project Manager, CARES system
Office of Business Informatics
CDER | US FDA

Reporting Drug Amount Under Section 510(j)(3) of the FD&C Act –
September 8, 2022



Overview

- CSV Format and Examples
- Common CSV Errors
- Resources



Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost Quantity Released	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Released	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Market Unknown
111111111	Manufacture	1234-1234-12		January	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		February	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		March	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		April	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		May	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		June	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		July	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		August	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		September	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		October	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		November	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		December	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		Annual Total	1250		600CASE	12500		3000BLISTER PACK	No

Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost Quantity Released	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Released	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Market Unknown
111111111	Manufacture	1234-1234-12		January	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		February	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		March	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		April	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		May	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		June	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		July	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		August	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		September	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		October	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		November	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		December	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		Annual Total	1250		600CASE	12500		3000BLISTER PACK	No



Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost Quantity Released	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Released	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Market Unknown
111111111	Manufacture	1234-1234-12		January	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		February	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		March	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		April	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		May	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		June	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		July	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		August	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		September	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		October	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		November	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		December	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		Annual Total	1250		600CASE	12500		3000BLISTER PACK	No

Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost	Outermost Quantity Distributed (Non-US)	Outermost	Innermost	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Market Unknown
					Quantity Released		Package Type	Quantity Released			
111111111	Manufacture	1234-1234-12		January	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		February	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		March	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		April	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		May	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		June	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		July	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		August	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		September	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		October	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		November	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		December	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		Annual Total	1250		600CASE	12500		3000BLISTER PACK	No
111111111	API Manufacture	12345-1234-1		January	200		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		February	250		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		March	250		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		April	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		May	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		June	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		July	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		August	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		September	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		October	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		November	325		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		December	325		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		Annual Total	3300		2250CONTAINER				No

Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost Quantity Released	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Released	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Market Unknown
111111111	Manufacture	1234-1234-12		January	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		February	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		March	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		April	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		May	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		June	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		July	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		August	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		September	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		October	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		November	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		December	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		Annual Total	1250		600CASE	12500		3000BLISTER PACK	No
111111111	API Manufacture	12345-1234-1		January	200		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		February	250		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		March	250		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		April	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		May	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		June	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		July	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		August	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		September	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		October	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		November	325		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		December	325		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		Annual Total	3300		2250CONTAINER				No

Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost Quantity Released	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Released	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Market Unknown
111111111	Manufacture	1234-1234-12		January	100		50CASE	1000		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		February	100		50CASE	1000		250BLISTER PACK	No
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111111111	Manufacture	1234-1234-12		August	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		September	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		October	150		50CASE	1500		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		November	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		December	0		50CASE	0		250BLISTER PACK	No
111111111	Manufacture	1234-1234-12		Annual Total	1250		600CASE	12500		3000BLISTER PACK	No
111111111	API Manufacture	12345-1234-1		January	200		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		February	250		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		March	250		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		April	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		May	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		June	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		July	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		August	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		September	650		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		October	0		0CONTAINER				No
111111111	API Manufacture	12345-1234-1		November	325		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		December	325		450CONTAINER				No
111111111	API Manufacture	12345-1234-1		Annual Total	3300		2250CONTAINER				No

Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost Quantity Released	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Released	Innermost Quantity Distributed (Non-US)	Innermost Package Type	Market Unknown
111111111	Manufacture	1234-1234-12		January	100		50 CASE	1000		250 BLISTER PACK	No
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111111111	Manufacture	1234-1234-12		April	100		50 CASE	1000		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		May	100		50 CASE	1000		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		June	150		50 CASE	1500		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		July	150		50 CASE	1500		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		August	150		50 CASE	1500		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		September	150		50 CASE	1500		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		October	150		50 CASE	1500		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		November	0		50 CASE	0		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		December	0		50 CASE	0		250 BLISTER PACK	No
111111111	Manufacture	1234-1234-12		Annual Total	1250		600 CASE	12500		3000 BLISTER PACK	No
111111111	API Manufacture	12345-1234-1		January	200		450 CONTAINER				No
111111111	API Manufacture	12345-1234-1		February	250		450 CONTAINER				No
111111111	API Manufacture	12345-1234-1		March	250		450 CONTAINER				No
111111111	API Manufacture	12345-1234-1		April	650		0 CONTAINER				No
111111111	API Manufacture	12345-1234-1		May	0		0 CONTAINER				No
111111111	API Manufacture	12345-1234-1		June	0		0 CONTAINER				No
111111111	API Manufacture	12345-1234-1		July	0		0 CONTAINER				No
111111111	API Manufacture	12345-1234-1		August	650		0 CONTAINER				No
111111111	API Manufacture	12345-1234-1		September	650		0 CONTAINER				No
111111111	API Manufacture	12345-1234-1		October	0		0 CONTAINER				No
111111111	API Manufacture	12345-1234-1		November	325		450 CONTAINER				No
111111111	API Manufacture	12345-1234-1		December	325		450 CONTAINER				No
111111111	API Manufacture	12345-1234-1		Annual Total	3300		2250 CONTAINER				No
222222222	Transfill	12345-123-12		January	600		100 BAG				Yes
222222222	Transfill	12345-123-12		February	0		90 BAG				Yes
222222222	Transfill	12345-123-12		March	0		100 BAG				Yes
222222222	Transfill	12345-123-12		April	0		100 BAG				Yes
222222222	Transfill	12345-123-12		May	100		100 BAG				Yes
222222222	Transfill	12345-123-12		June	0		0 BAG				Yes
222222222	Transfill	12345-123-12		July	0		100 BAG				Yes
222222222	Transfill	12345-123-12		August	0		0 BAG				Yes
222222222	Transfill	12345-123-12		September	700		0 BAG				Yes
222222222	Transfill	12345-123-12		October	0		0 BAG				Yes
222222222	Transfill	12345-123-12		November	0		400 BAG				Yes
222222222	Transfill	12345-123-12		December	900		0 BAG				Yes
222222222	Transfill	12345-123-12		Annual Total	2300		990 BAG				Yes





111111111,Manufacture,1234-1234-12,,January,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,February,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,March,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,April,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,May,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,June,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,July,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,August,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,September,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,October,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,November,0,50,CASE,0,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,December,0,50,CASE,0,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,Annual Total,1250,600,CASE,12500,3000,BLISTER PACK,No
111111111,API Manufacture,12345-1234-1,,January,200,450,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,February,250,450,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,March,250,450,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,April,650,0,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,May,0,0,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,June,0,0,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,July,0,0,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,August,650,0,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,September,650,0,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,October,0,0,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,November,325,450,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,December,325,450,CONTAINER,,,,No
111111111,API Manufacture,12345-1234-1,,Annual Total,3300,2250,CONTAINER,,,,No

Common Parsing Errors

- 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
- Replace all semicolons “;” field delimiters with commas “,”
- Remove all empty lines at the end of the csv file containing commas
- Quotation marks should be excluded
- The system will only accept files with lower case “.csv”
- \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



111111111,Manufacture,1234-1234-12,,January,100,50,CASE,"1,000",250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,February,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,March,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,April,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,May,100,50,CASE,1000,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,June,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,July,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,August,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,September,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,October,150,50,CASE,1500,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,November,0,50,CASE,0,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,December,0,50,CASE,0,250,BLISTER PACK,No
111111111,Manufacture,1234-1234-12,,Annual Total;1250,600;CASE;12500;3000;BLISTER PACK;No
111111111,API Manufacture,12345-1234-1,,January,200,450,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,February,250,450,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,March,250,450,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,April,650,0,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,May,0,0,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,June,0,0,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,July,0,0,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,August,650,0,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,September,650,0,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,October,0,0,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,November,325,450,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,December,325,450,CONTAINER,,,No
111111111,API Manufacture,12345-1234-1,,Annual Total,3300,2250,CONTAINER,,,No

Do I need to return to the CDER NextGen Portal after I have made my submission ?



- Once a submission is made, the system is verifying the details of your submission.
- If the system determines there is an error, then you will be alerted via email that further actions are required – then you must return to the Portal to correct the error and/or take further action.
- If there are no concerns with the submission, you will receive a confirmation email of successful submission. You do not need to take further action. If you return to the Portal, it will indicate successful submission.

NextGen Resources

- [NextGen Portal](#)
- [NextGen Portal Registration Guide](#)
- [Reference Guide for Reporting Amount of Listed Drugs and Biological Products](#)
- [CSV Template](#)  *UPDATED*
- [CSV Instructions](#)  *UPDATED*

Regulatory Information

- [Reporting Amount of Listed Drugs and Biological Products Under Section 510\(j\)\(3\) of the FD&C Act Guidance](#)
- [Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide](#)
- [Proposed Order: Exemption of Certain Categories of Biological Products From Certain Reporting Requirements Under the Federal Food, Drug, and Cosmetic Act](#)

Webinars

- [CARES Act Amount Information Reporting: Uploading Data from a CSV File](#) *UPDATED*
- [CARES Act Amount Information Reporting: Uploading Data from a CSV File \(PDF - 1.44MB\)](#)
- [CARES Act Amount Information Reporting: Entering Data Manually](#)
- [CARES Act Amount Information Reporting: Entering Data Manually \(PDF - 1.19MB\)](#)
- [CDER Small Business and Industry Assistance webinar](#) providing an overview of the drug amount reporting program, including discussions of how FDA uses the drug amount report data and who reports and how (with examples and demonstrations)

Additional Information

- Technical support questions regarding the submission process should be sent to EDMSupport@fda.hhs.gov.
- For questions regarding report content, please contact (CDER) DrugAmountReporting@fda.hhs.gov, (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010, or (CVM) Office of Surveillance and Compliance, 240-402-7082 or CVMSurveillance@fda.hhs.gov, as applicable.