

# Further Details on using CSV Files

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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	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

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
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

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
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

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)	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
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	50	CASE	1000	250	BLISTER PACK	No
111111111	Manufacture	1234-1234-12		February	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





11111111,Manufacture,1234-1234-12,,January,100,50,CASE,1000,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,February,100,50,CASE,1000,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,March,100,50,CASE,1000,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,April,100,50,CASE,1000,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,May,100,50,CASE,1000,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,June,150,50,CASE,1500,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,July,150,50,CASE,1500,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,August,150,50,CASE,1500,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,September,150,50,CASE,1500,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,October,150,50,CASE,1500,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,November,0,50,CASE,0,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,December,0,50,CASE,0,250,BLISTER PACK,No  
11111111,Manufacture,1234-1234-12,,Annual Total,1250,600,CASE,12500,3000,BLISTER PACK,No  
11111111,API Manufacture,12345-1234-1,,January,200,450,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,February,250,450,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,March,250,450,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,April,650,0,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,May,0,0,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,June,0,0,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,July,0,0,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,August,650,0,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,September,650,0,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,October,0,0,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,November,325,450,CONTAINER,,,,No  
11111111,API Manufacture,12345-1234-1,,December,325,450,CONTAINER,,,,No  
11111111,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 [FDMSupport@fda.hhs.gov](mailto:FDMSupport@fda.hhs.gov).
- For questions regarding report content, please contact (CDER) [DrugAmountReporting@fda.hhs.gov](mailto:DrugAmountReporting@fda.hhs.gov), (CDER) 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](mailto:CVMSurveillance@fda.hhs.gov), as applicable.