

CARES Act Amount Information Reporting: Uploading Data From a CSV File

Reference Guide



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CARES Act Amount Information Reporting

Introduction

CARES Act Amount Information Reporting system is intended to provide a portal solution for all registrants or their authorized agents to submit reports on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution in compliance with section 3112(e) of the Coronavirus Aid, Relief, and Economic Security Act.

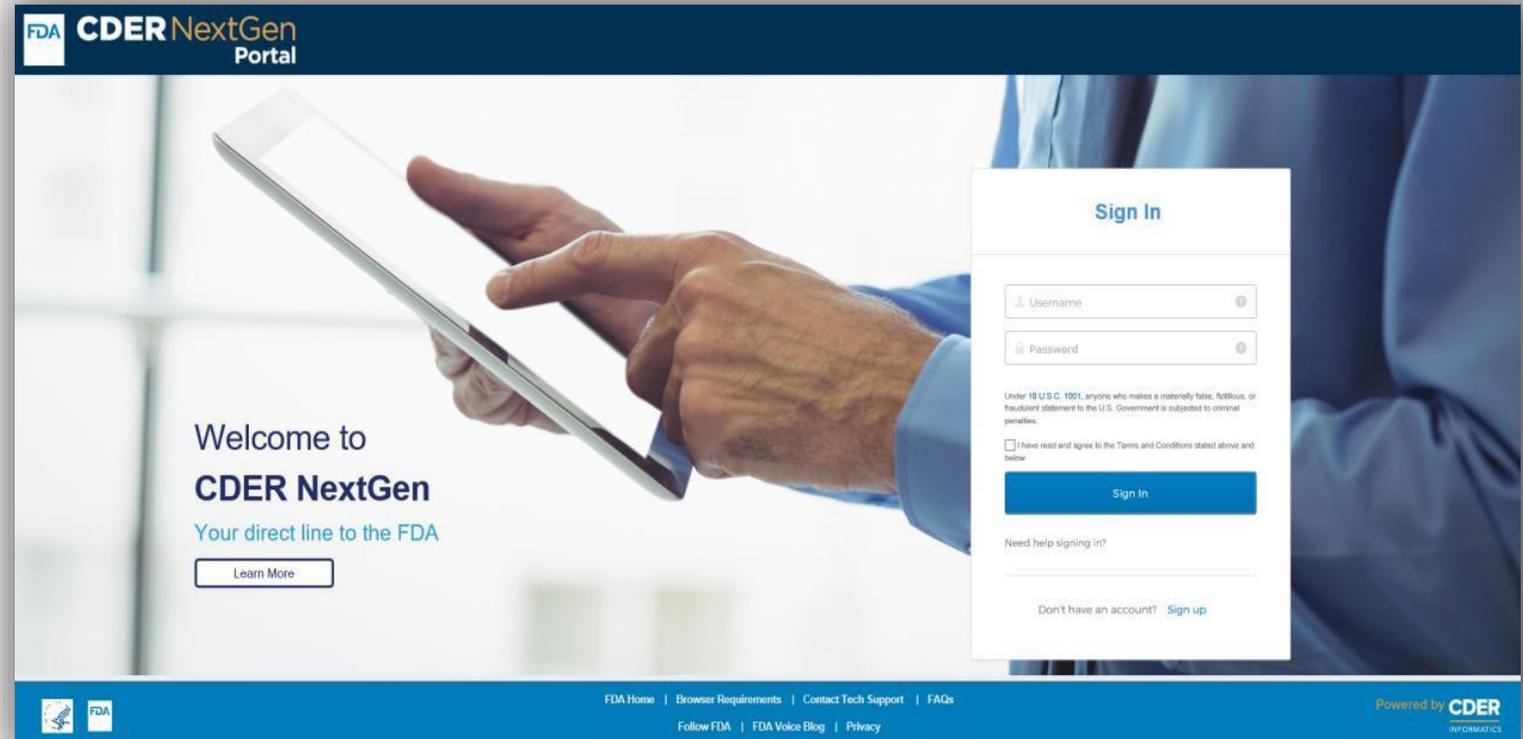
This guide describes how to use the CDER NextGen Portal to **upload data from a comma-separated values (CSV) file** to create and submit a CARES Act Amount Information report to the FDA. It is an expanded version of the original reference guide (**CARES Act Amount Information Reporting**) posted on **the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Drug Shortage Mitigation Efforts** webpage (<https://www.fda.gov/drugs/drug-shortages/coronavirus-aid-relief-and-economic-security-act-cares-act-drug-shortage-mitigation-efforts>).

For technical assistance, please email the EDM Support Team (EDMSupport@fda.hhs.gov).

For questions on how to enter or upload data, please email the Drug Amount Reporting Team (DrugAmountReporting@fda.hhs.gov).

CDER NextGen Portal Homepage

Step 1. First, sign in on the CDER NextGen Portal homepage.



CARES Act Amount Information Reporting

CDER NextGen Portal Homepage

Step 2. From the main menu, click **CARES Act Amount Information Reporting**.

The screenshot shows a list of menu items on the CDER NextGen Portal. The items are: 'ALL', 'CDER Standards Recognition', 'CDER Drug Shortage Potential Impact Outreach', 'CARES Act Amount Information Reporting', and 'Controlled Correspondence'. The 'CARES Act Amount Information Reporting' item is highlighted with an orange border. Below each menu item is a brief description of the service.

ALL
CDER Standards Recognition Request to informally recognize voluntary consensus standards related to pharmaceutical quality.
CDER Drug Shortage Potential Impact Outreach Submit a response to a potential shortage impact outreach message sent by FDA to support emergency potential shortage notifications (ex: COVID-19 and other public health emergencies)
CARES Act Amount Information Reporting Submit information on the amount of listed drugs and biological products under section 510(j)(3) of the FD&C Act (as added by Coronavirus Aid, Relief, and Economic Security Act)
Controlled Correspondence Submit correspondence to the Agency, requesting information on a specific element of generic drug product development.

CARES Act Amount Information Reporting

CARES Act Amount Information Report

Step 3. The next screen is the landing page. Draft reports and submitted reports appear here. Click **+ New Report** at the top right of the screen.

CARES Act Amount Information Reporting

Search Submissions

00020506 Draft Last Modified: 11/29/2021, 04:48 PM Reporting Year: 2020 Unsubmitted Draft	00020357 Draft Last Modified: 11/29/2021, 04:48 PM Reporting Year: 2021 Unsubmitted Draft
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CDER NextGen Portal

CARES Act Amount Information Reporting

No CARES Act Volume Reporting Yet
 Submit a new submission using the "+ New Report" button at the top right of your screen.

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CARES Act Amount Information Reporting

CARES Act Amount Information Report

Step 4. On the **Introduction** screen, review the **Getting Started** information for submitting a CARES Act Amount Information Report. Section descriptions of the submission process are displayed.

Step 5. Click **Next**.

The screenshot shows the 'Introduction' screen of the CARES Act Amount Information Reporting Portal. The page is titled 'Introduction' and contains the following sections:

- Getting Started**: Welcome to FDA's CARES Act Information Reporting Portal. Below is a summary of the submission process.
- CARES Act Amount Information Submission Process**:
 - Submitter Information**: Verify Submitter information
 - Submission**: Provide information about your submission, add data to your submission, and submit your data

At the bottom right of the screen, there are two buttons: 'Cancel' and 'Next'. The 'Next' button is highlighted with an orange border.

CARES Act Amount Information Reporting

Submitter Information

Step 6. On the **Submitter Information** screen, select if you are submitting as a **Registrant** or **Authorized Agent**.

Step 7. Review the prepopulated information in the **Profile Information** section, and then click **Next**. Contact technical support if any fields need to be updated.

Submitter Information

Submitter Information

* Are you submitting as a Registrant or an Authorized Agent?

Registrant

Authorized Agent

Profile Information

First Name	Last Name
<input type="text"/>	<input type="text"/>
Email Address	
<input type="text"/>	
Phone Number	Extension
<input type="text"/>	<input type="text"/>
Organization Name	
<input type="text"/>	
Address Line 1	Address Line 2
<input type="text"/>	<input type="text"/>
City	State/Province
<input type="text"/>	<input type="text"/>
Zip Code	Country
<input type="text"/>	<input type="text"/>

CARES Act Amount Information Reporting

Submission

Step 8. In the **Submission** section, select the **year** (calendar year) that the report will cover.

Step 9. If you are submitting a replacement report to a previous submission, check **Yes**. Then, select the report ID of the previous submission from the drop-down menu.

Step 10. Select that you would like to submit product data via **CSV File**.

Step 11. In the confirmation screen, click **Continue**.

This screenshot shows the 'Submission Information' section of the 'Submission' form. A dropdown menu is open for the question 'What year are you submitting for?'. The menu lists '2021' and '2020'. The '2021' option is highlighted in blue. Below the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

This screenshot shows the 'Submission Information' section of the 'Submission' form. The 'What year are you submitting for?' dropdown is set to '2021'. A checkbox labeled 'Are you submitting a replacement report to a previous submission?' is checked 'Yes'. Below this, a dropdown menu for 'Please select the previous submission for which you are submitting a correction report.' shows the ID '00019877' and the date 'Date Submitted: 9/21/2021, 04:34 PM'. At the bottom, there are radio buttons for 'Manually' and 'CSV File', with 'CSV File' selected. A confirmation modal is open at the bottom, titled 'CARES Act Amount Information Report', with a 'Continue' button highlighted in orange. The modal text reads: 'You are submitting a CARES Act Amount Information Replacement Report to a previous submission. Please note, by selecting a Replacement Report your previous submission will be replaced. Select Continue to proceed with the selected data submission method and submission type. After selecting Continue, you will not be able to change these selections. If a change is required, or you do not intend to submit a CARES Act Amount Information Replacement Report, please delete the Submission and start a new report. Select Cancel to return to the previous page.' Buttons for 'Previous', 'Delete', 'Save', and 'Validate' are visible at the bottom of the form.

CARES Act Amount Information Reporting

Submission

Step 12. Click and download the template. There are also instructions that can be downloaded.

Note: The template will download with an **.xlsx** extension. Prior to uploading, save the document with a **.csv** extension.

If a file contains multiple tabs, save each tab as a separate CSV file.

Each file should contain fewer than 200,000 lines.

Submission Information

*What year are you submitting for?

Are you submitting a replacement report to a previous submission?
 Yes

* Please select the previous submission for which you are submitting a correction report.
 Date Submitted: 3/2/2022, 12:29 PM

*Would you like to submit products manually or by uploading data from a csv file?
 Manually
 CSV File

For Uploading Data Using the CSV Template
 Please download and fill out the following template. Once complete, save as a .csv extension type file and return back to the portal to upload data from csv file.
[CARES Template for CSV Data Upload.xlsx](#)

Instructions for Using the CSV Template
[CARES CSV Template Instructions.pdf](#)

For Uploading Data Using a Custom CSV File
 Instructions for Using a Custom CSV File
[CARES CSV Custom File Instructions.pdf](#)

Or drop files

CARES Act Amount Information Reporting

Submission

Step 13. Enter the requested information in the CSV template or construct your own CSV file to match this template. Then, save the document to your computer as a CSV file.

The portal requires that each DUNS–Business Operation–NDC combination have 13 lines, one for each month and one for the annual total.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Establishment DUNS	Business Operation	NDC	Source NDC	Volume Per	Outermost Quantity Relea	Outermost Quantity Dis	Outermost Package	Innermost Quantity Rel	Innermost Quantity Dist	Innermost Packag	Market Unknown
2					January							
3					February							
4					March							
5					April							
6					May							
7					June							
8					July							
9					August							
10					September							
11					October							
12					November							
13					December							
14					Annual Total							

Note: There is a separate document that describes how to enter data into a CSV file: “CARES Act Amount Information Reporting CSV Template Instructions.”

CARES Act Amount Information Reporting

Submission

Step 14. Once all data has been entered into the CSV file, upload the data from the document into the portal by

- (1) clicking **Upload Files** and selecting the CSV file, or
- (2) dragging and dropping the CSV file onto **Or drop files**.

Step 15. When the status bar indicates that the data has finished uploading, click **Done**.

Step 16. Your file is now being processed. You will receive an email once processing is complete. Exit the Submission page by clicking **Save** and **Save & Close**.

The image displays three overlapping screenshots from the CARES Act Amount Information Reporting portal:

- Top Screenshot (Submission Information):** Shows the 'Submission Information' form. The 'What year are you submitting for?' dropdown is set to '2021'. The 'Are you submitting a replacement report to a previous submission?' checkbox is checked 'Yes'. The 'Please select the previous submission for which you are submitting a correction report.' dropdown is set to '00026981', with a 'Date Submitted: 3/2/2022, 12:29 PM' next to it. Under 'Would you like to submit products manually or by uploading data from a csv file?', the 'CSV File' radio button is selected. Below this, there are links for 'CARES Template for CSV Data Upload.xlsx', 'Instructions for Using the CSV Template CARES CSV Template Instructions.pdf', and 'Instructions for Using a Custom CSV File CARES CSV Custom File Instructions.pdf'. At the bottom, the 'Upload Files' and 'Or drop files' buttons are highlighted with an orange box.
- Middle Screenshot (Upload Files):** Shows the 'Upload Files' dialog box. A file named 'CSVFileForTemplate (1).csv' is shown with a progress bar. A 'Done' button is highlighted with an orange box.
- Bottom Screenshot (Submission Confirmation):** Shows the 'Submission Information' form with a green success message: 'Success File Uploaded Successfully'. The 'Delete', 'Save', and 'Submit' buttons are visible at the bottom. A 'Save CARES Act Amount Information Report' dialog box is overlaid on top, containing instructions: 'Select "Save" to save your progress and stay on the page or select "Save and Close" to save your progress and leave the page. Select "Cancel" to return to the current page.' The 'Save', 'Save & Close', and 'Cancel' buttons in this dialog are highlighted with orange boxes.

CARES Act Amount Information Reporting

Submission

Step 17. Once you receive an email confirming the processing of your CSV file, return to the landing page and click on the report ID.

Note: If you need to update your CSV file, please click on the X next to the old filename to remove it and then upload the updated CSV file.

Thank you for your CARES Act Amount Information Submission. We have validated your data and no errors were detected. As a next step, please log in to the FDA CDER NextGen portal, <https://edm.fda.gov>, to proceed with your submission.

Event ID: 00027123

Submitter's Contact Information:

Name	Email	Country	Phone Number	Extension
		United States		

For technical support, contact the CDER Platform Support Team at EDMSupport@fda.hhs.gov.

**** Please do not reply directly to this message. This is an automatically generated email and replies will not be processed.**

CARES Act Amount Information Reporting

Submission

Certifications

I affirm that the information in this submission is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent statement or representation in this matter within FDA's jurisdiction.

Previous Delete Save Submit

Step 18. After validation, the report can be saved or submitted. To submit the report, check the box in the **Certifications** section to affirm that the information you provided in this submission is correct and then click **Submit**.

Click **Save** to keep the report for later or click **Delete** to remove the submission.

Step 19. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.

Complete & Submit CARES ACT Amount Information Report

Are you sure that you would like to submit your CARES ACT Amount Information Report? You will not be able to edit the report once submitted.

Cancel Submit

CARES Act Amount Information Reporting

Submission

Step 20. After clicking on **Submit**, there will be a confirmation screen to confirm your report was submitted to the FDA.

Click **Return Home** to return to the landing page or log out or click **New Report** to submit a new report.

The screenshot shows a confirmation page titled "CARES Act Amount Information Report Submitted to the FDA". Below the title, it says "Congratulations!". On the left, there is a box containing the Report ID "00005218", the submission date and time "10/15/2021, 02:05 PM", and the reporting year "2021". On the right, a message states that the report #00005218 has been submitted successfully and provides contact information for FDA staff at DrugVolumeReporting@fda.hhs.gov. At the bottom, there are two buttons: "Return Home" and "New Report". A footer note provides technical support contact information for the CDER platform support team at EDMSupport@fda.hhs.gov.

CARES Act Amount Information Report Submitted to the FDA

Congratulations!

00005218
Date/Time Submitted: 10/15/2021, 02:05 PM
Reporting Year: 2021

Your CARES Act Amount Information Report #00005218 has been submitted successfully. If you need to make changes to your submission, please contact FDA Staff at (DrugVolumeReporting@fda.hhs.gov) and include the Report ID.

[Return Home](#) [New Report](#)

For technical support, please contact the CDER platform support team (EDMSupport@fda.hhs.gov).

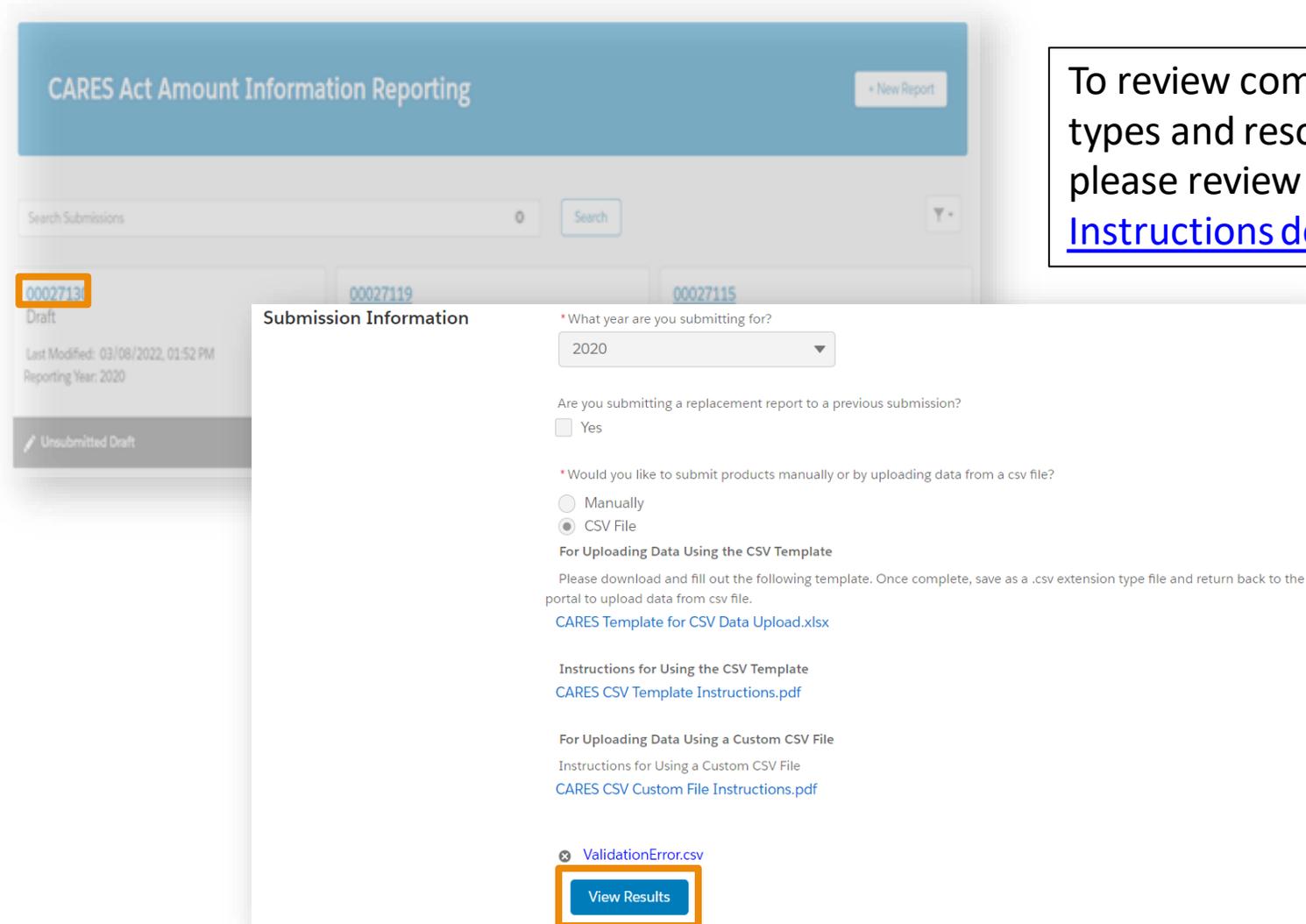
CARES Act Amount Information Reporting

Submission Errors

The email sent after processing is completed will either state that there were no errors or specify one of three different types of errors. Return to the landing page and click on the draft submission to review the error messages and submitted data.

On the Submission page, click **View Results** to view messages about the error(s). Depending on the error type, you can either

- (1) proceed with the submission or
- (2) remove the CSV file and upload a corrected CSV file.



To review common error types and resolutions, please review the [CSV Instructions document](#).

CARES Act Amount Information Reporting

Submission Errors

The three error types are called **Validation, Hierarchy, and Parsing.**

Validation error: At least one DUNS, NDC, and/or source NDC was found to not match values in the drug listings database. Data may still be submitted without updating.

Hierarchy error: One or more required values are missing.

Parsing error: At least one value could not be processed, such as having an incorrect format or being the wrong data type.

Thank you for your CARES Act Amount Information Submission. While processing your data, one or more validation errors were detected that may require your action. As a next step, please log in to the FDA CDER NextGen portal, <https://edm.fda.gov>, to review your data and determine if a correction is required. You may wish to proceed with this data, or in the case a correction is required, please delete the CSV, correct the CSV, and re-upload the CSV.

Event ID: 00027130

Summary of data that does not match existing values in the drug registration and listing database.

Unique DUNs Not Validated in the FDA System:5
 Unique NDCs Not Validated in the FDA System:1
 Unique Source NDCs Not Validated in the FDA System:2

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 re-upload the CSV file.

You may proceed by certifying your submission and selecting Submit.

In the case you encounter any issues, please contact EDM Support at EDMSupport@fda.hhs.gov

Thank you for your CARES Act Amount Information Submission. While processing your data, one or more hierarchy errors were detected requiring your action. As a next step, please log in to the FDA CDER NextGen portal, <https://edm.fda.gov>, to review your data. Please delete the CSV, correct the CSV, and re-upload the CSV.

Event ID: 00027130

[HierarchyError.csv](#)

While processing, the system encountered one or more errors related to missing data.

Please remove the CSV file, correct the data in the file, and re-upload the CSV file.

Your file must include 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.

In the case you encounter any further issues, please contact EDM Support at EDMSupport@fda.hhs.gov

Thank you for your CARES Act Amount Information Submission. While processing your data, one or more errors were detected requiring your action. As a next step, please log in to the FDA CDER NextGen portal, <https://edm.fda.gov>, to review your data and a correction is required. Please delete the file, correct the csv, and re-upload the CSV.

Event ID: 00027130

[ParsingError.csv](#)

While processing, the system was not able to successfully parse the file.

Please remove the uploaded CSV file, correct the data in the file, and re-upload the CSV file.

Please refer to the [CARES CSV Custom File Instructions.pdf](#) to troubleshoot potential parsing errors. In the case you encounter any issues, please contact EDM Support at EDMSupport@fda.hhs.gov

Technical Support and Resources

CDER NextGen Portal Support & Resources

The [CDER NextGen Portal](#) has many resources for support.

CDER NextGen Portal Announcements

Your portal home page contains **portal announcements** so users are always in the know.



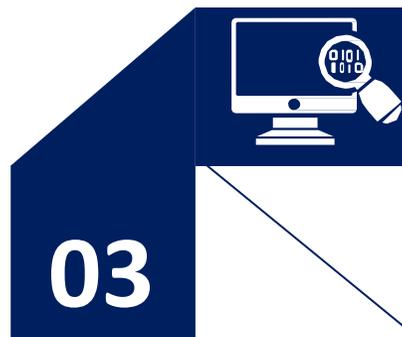
Learn More Information

Everything related to the portal events can be found on the “**Learn More**” link. On the event home page, users can find the “Learn More” link to **Reference Guides and FAQs**.



Technical Support

For all technical support, contact **CDER Platform Support Team** at EDMSupport@fda.hhs.gov.



CDER NextGen Portal Video Tutorial

The “**Video Tutorial**” contains **1-4 minute video clips** on how to complete submissions for events on the portal.