

CARES Act Amount Information Reporting

Reference Guide



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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. This revised reference guide replaces the older version and reflects changes in the final guidance for **CARES Act Drug 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 visit the [NextGen Portal Help Center](#).

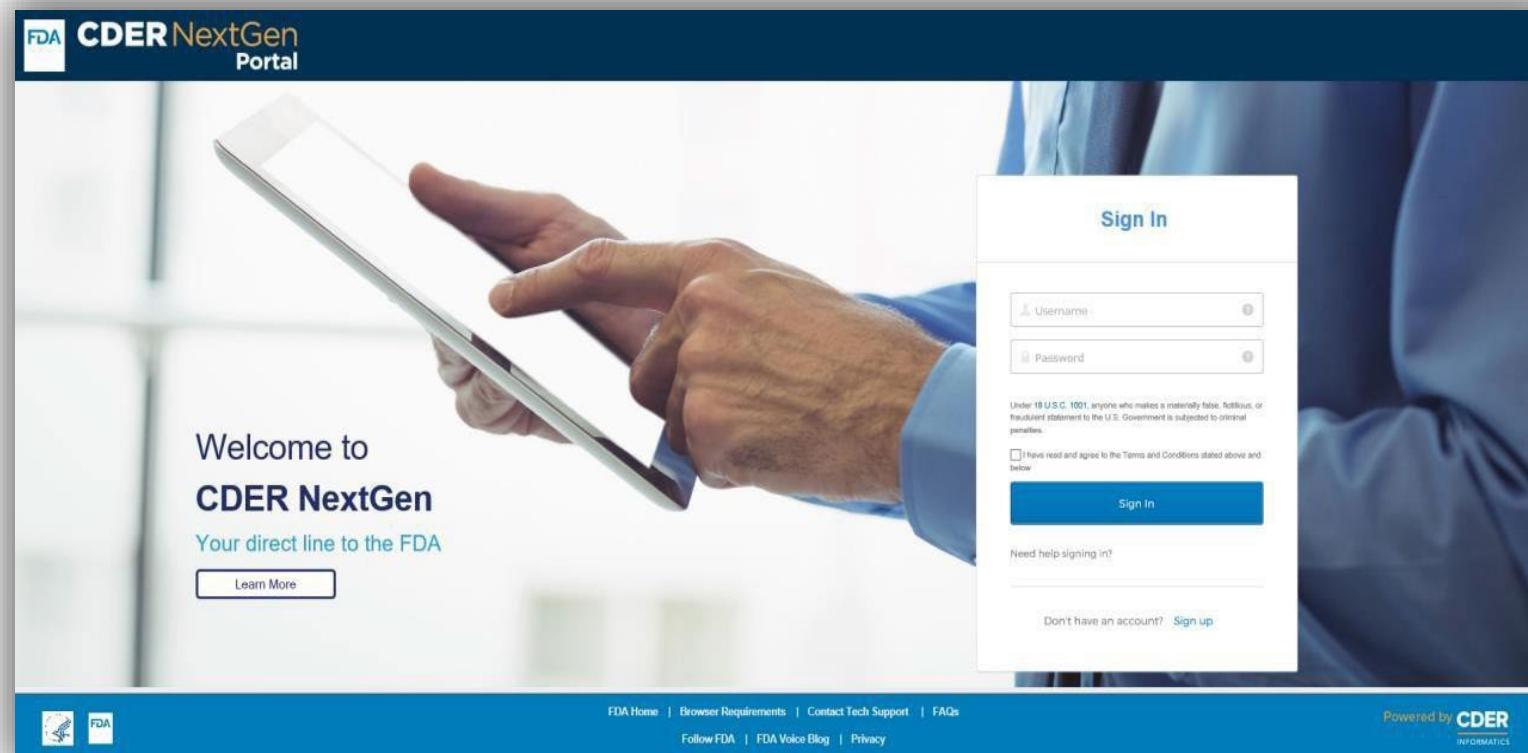
For questions on how to enter or upload data, please email the Drug Amount Reporting Team (DrugAmountReporting@fda.hhs.gov).

CSVFileUploadSubmission

CSV File Upload – Creating a New Report and Entering Submitter Details

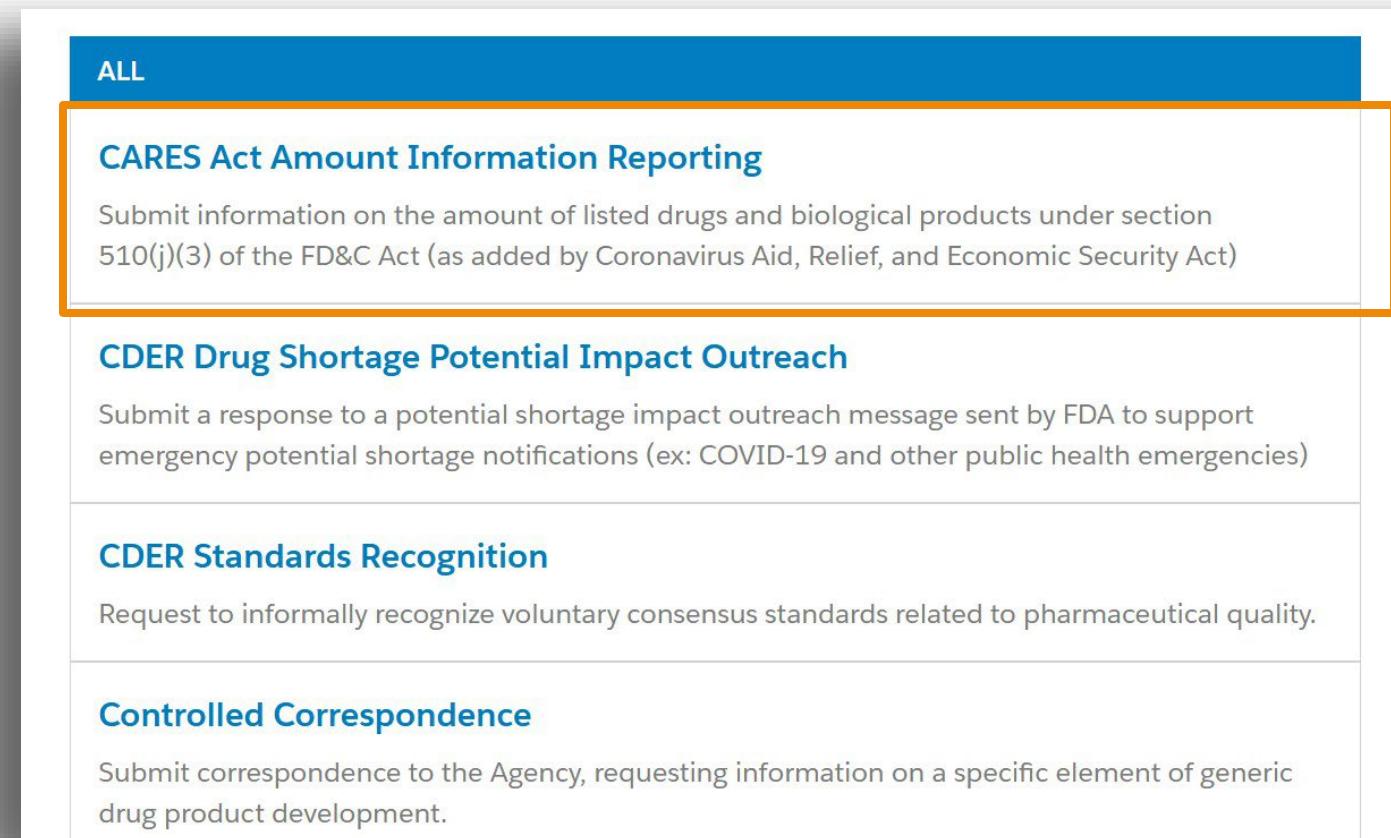
CDER NextGen Portal Homepage

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



CDER NextGen Portal Homepage

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



ALL

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)

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)

CDER Standards Recognition

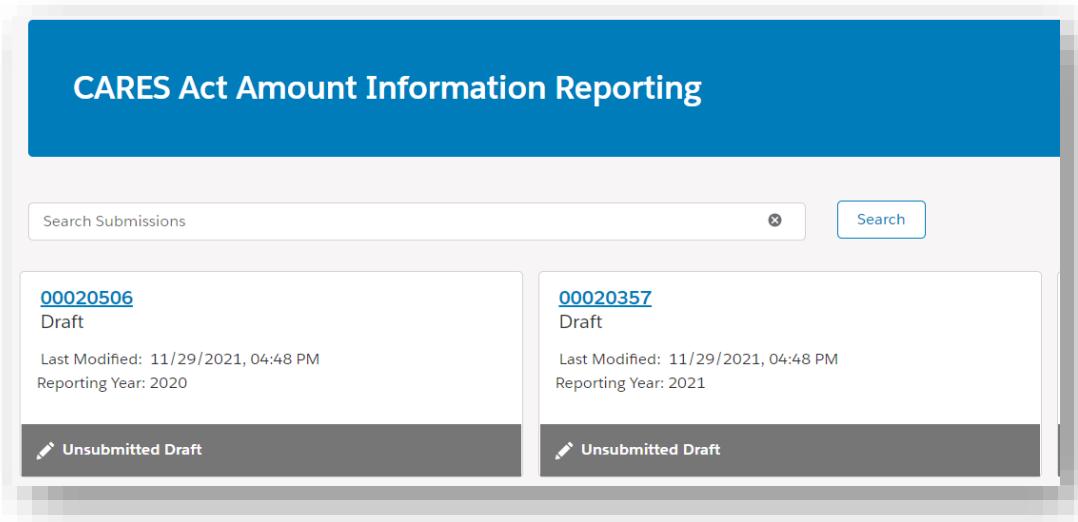
Request to informally recognize voluntary consensus standards related to pharmaceutical quality.

Controlled Correspondence

Submit correspondence to the Agency, requesting information on a specific element of generic drug product development.

CARES Act Amount Information Report

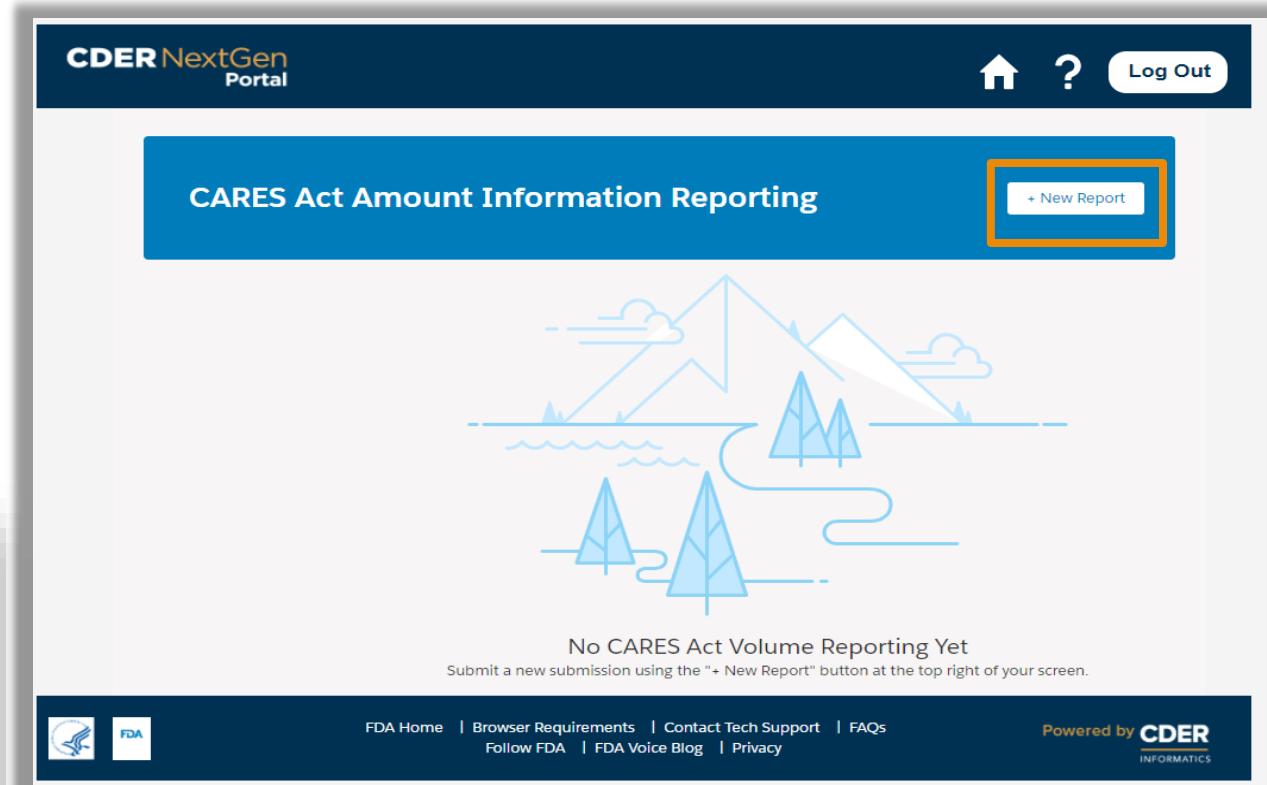
Step 3. The next screen is the landing page. Draft reports and submitted reports appear here. Click **+ New Report** at the top right of the screen.



CARES Act Amount Information Reporting

Search Submissions

Submission ID	Status	Last Modified	Reporting Year
00020506	Draft	11/29/2021, 04:48 PM	2020
00020357	Draft	11/29/2021, 04:48 PM	2021



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.

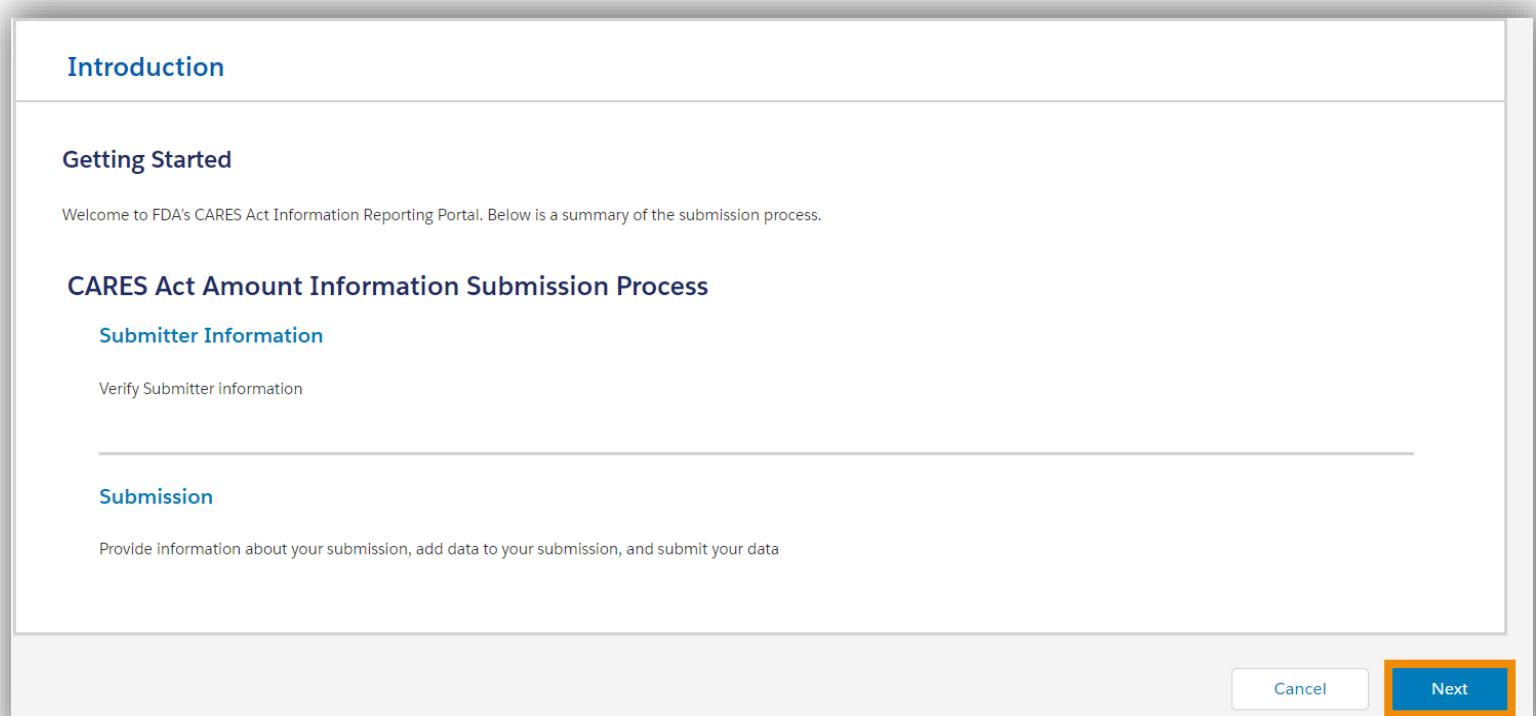
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CARES Act Amount Information Report

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**.



Introduction

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

[Cancel](#) [Next](#)

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

Email Address

Phone Number

Extension

Organization Name

Address Line 1

Address Line 2

City

State/Province

Zip Code

Country

Save

Next

CSVFileUploadSubmission - Finished Package Form

CSV Submission – Finished Package Form

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

Step 9. If you are submitting a new report, leave “Are you submitting a replacement report for a previous submission” blank and proceed to step 10.

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.

Submission

Submission Information

What year are you submitting for?

Select one

2021

2020

Previous Delete Save Validate

Submission

Submission Information

What year are you submitting for?

2021

Are you submitting a replacement report for a previous submission?

Yes

Please select the previous submission for which you are submitting a replacement report.

00027055

Date Submitted: 3/3/2022, 01:44 PM

Previous Delete Save Validate

CSV Submission – Finished Package Form

Step 10. Select that you are reporting on a Drug Product.

Step 11. Select “Yes” that your product is in Finished Package Form.

Step 12. Select that you would like to submit product data via **CSV File**.

Step 13. In the confirmation screen, click **Continue**.

The image shows two screenshots of the FDA Submission interface. The top screenshot displays the 'Submission' page with 'Submission Information' fields. The 'What year are you submitting for?' dropdown is set to '2022'. A question 'Are you submitting a replacement report for a previous submission?' has a 'Yes' checkbox. The bottom section, highlighted with an orange box, contains questions about the product: 'What product are you reporting on?' (radio buttons for 'Drug Product' and 'API or API + Inactive Ingredients', with 'Drug Product' selected), 'Is the drug product in Finished Package Form?' (radio buttons for 'Yes' and 'No', with 'Yes' selected), and 'Would you like to submit the product data manually or by uploading data from a CSV file?' (radio buttons for 'Manually' and 'CSV File', with 'CSV File' selected). The bottom screenshot shows a confirmation dialog titled 'CARES Act Drug Amount Information Report'. It contains a message about submitting an 'Initial CARES Act Drug Amount Information Report' and two buttons: 'Cancel' and 'Continue', with 'Continue' highlighted with an orange box.

CSV Submission – Finished Package Form

Step 14. 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.

The screenshot shows a web-based submission form titled 'Submission' for CARES Act Amount Information Reporting. The 'Submission Information' section contains the following fields:

- * What year are you submitting for? (dropdown menu showing '2020')
- Are you submitting a replacement report for a previous submission? (checkbox for 'Yes')
- * What product are you reporting on? (radio buttons for 'Drug Product' and 'API or API + Inactive Ingredients', with 'Drug Product' selected)
- * Is the drug product in Finished Package Form? (radio buttons for 'Yes' and 'No', with 'Yes' selected)
- * Would you like to submit the product data manually or by uploading data from a CSV file? (radio buttons for 'Manually' and 'CSV File', with 'CSV File' selected)

Below these fields, there is a note: "For uploading Finished Package Data Using the CSV Template" and a "CAUTION: To avoid errors in your submission, refer to and follow the instructions in the reference materials." A link "Please download and fill out the following template [in .CSV](#):" is provided, with the ".CSV" part highlighted in orange. The "Reference Materials" section lists several resources, with the "CARES CSV Template Instructions for Finished Package.pdf" link highlighted in orange:

- Sample Data for CSV Upload
- CARES SAMPLE Data for Finished Package.xlsx
- Instructions for Using the CSV Template
- CARES CSV Template Instructions for Finished Package.pdf**
- Instructions for Creating a Custom CSV File
- CARES CSV Custom File Instructions for Finished Package.pdf**

At the bottom of the form, there is a file upload area with the text "Upload Files" and "Or drop files", and a "Previous" button. On the right side, there are "Delete", "Save", and "Submit" buttons.

CSV Submission – Finished Package Form

Step 15. 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	Amount Per	Outermost Quantity Manufactured	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Manufactured	Innermost Quantity	Innermost Package Type	Intended to Fulfill 21 CFR 314.81
2	11111111	Manufacture	12345-678-01		January	10.5	CASE		10	10	BLISTER PACK	No
3	11111111	Manufacture	12345-678-01		February	10	CASE		10	10	BLISTER PACK	No
4	11111111	Manufacture	12345-678-01		March	10	CASE		10	10	BLISTER PACK	No
5	11111111	Manufacture	12345-678-01		April	10	CASE		10	10	BLISTER PACK	No
6	11111111	Manufacture	12345-678-01		May	10	CASE		10.7	10	BLISTER PACK	No
7	11111111	Manufacture	12345-678-01		June	10	CASE		10	10	BLISTER PACK	No
8	11111111	Manufacture	12345-678-01		July	10	CASE		10	10	BLISTER PACK	No
9	11111111	Manufacture	12345-678-01		August	10	CASE		10	10	BLISTER PACK	No
10	11111111	Manufacture	12345-678-01		September	10	CASE		10.8	10	BLISTER PACK	No
11	11111111	Manufacture	12345-678-01		October	10	CASE		10	10	BLISTER PACK	No
12	11111111	Manufacture	12345-678-01		November	10	CASE		10	10	BLISTER PACK	No
13	11111111	Manufacture	12345-678-01		December	10	CASE		10	10	BLISTER PACK	No
14	11111111	Manufacture	12345-678-01		Annual Total	120.5	CASE		121.5	120	BLISTER PACK	No
15	11111111	Manufacture	12345-678-91		January	50	10 CASE		10	10	BLISTER PACK	Yes
16	11111111	Manufacture	12345-678-91		February	50	10 CASE		10	10	BLISTER PACK	Yes
17	11111111	Manufacture	12345-678-91		March	50	10 CASE		10	10	BLISTER PACK	Yes
18	11111111	Manufacture	12345-678-91		April	50	10 CASE		10	10	BLISTER PACK	Yes
19	11111111	Manufacture	12345-678-91		May	50	10 CASE		10	10	BLISTER PACK	Yes
20	11111111	Manufacture	12345-678-91		June	50	10 CASE		10	10	BLISTER PACK	Yes
21	11111111	Manufacture	12345-678-91		July	50	10 CASE		10	10	BLISTER PACK	Yes
22	11111111	Manufacture	12345-678-91		August	50	10 CASE		10	10	BLISTER PACK	Yes
23	11111111	Manufacture	12345-678-91		September	50	10 CASE		10	10	BLISTER PACK	Yes
24	11111111	Manufacture	12345-678-91		October	50	10 CASE		10	10	BLISTER PACK	Yes
25	11111111	Manufacture	12345-678-91		November	0	10 CASE		10	10	BLISTER PACK	Yes
26	11111111	Manufacture	12345-678-91		December	0	0 CASE		10	10	BLISTER PACK	Yes
27	11111111	Manufacture	12345-678-91		Annual Total	500	110 CASE		120	120	BLISTER PACK	Yes

Note: There is a separate document that describes how to enter data into a CSV file: “CARES CSV Template Instructions for Finished Package”

CSV Submission – Finished Package Form

Step 16. 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 17. When the status bar indicates that the data has finished uploading, click **Done**.

Step 18. 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 contains four screenshots of the FDA CARES Act Submission portal:

- Submission Page:** Shows the "Submission Information" section with fields for "What year are you submitting for?" (2020), "Are you submitting a replacement report for a previous submission?" (No), "What product are you reporting on?" (Drug Product), "Is the drug product in Finished Package Form?" (Yes), and "Would you like to submit the product data manually or by uploading data from a CSV file?" (CSV File). A note at the bottom provides a template for CSV data.
- Upload Files Dialog:** Shows a file named "CSVFileForTemplate (1).csv" being uploaded. The "Done" button is visible.
- Success Dialog:** A green dialog box displays the message "Success File Uploaded Successfully".
- Save Confirmation Dialog:** A dialog box with the title "Save CARES Act Amount Information Report" and the message "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." It includes "Cancel", "Save", and "Save & Close" buttons.

CSV Submission – Finished Package Form

Step 19. 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 Drug 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.

Report ID: 00141977

Submitter's Contact Information:

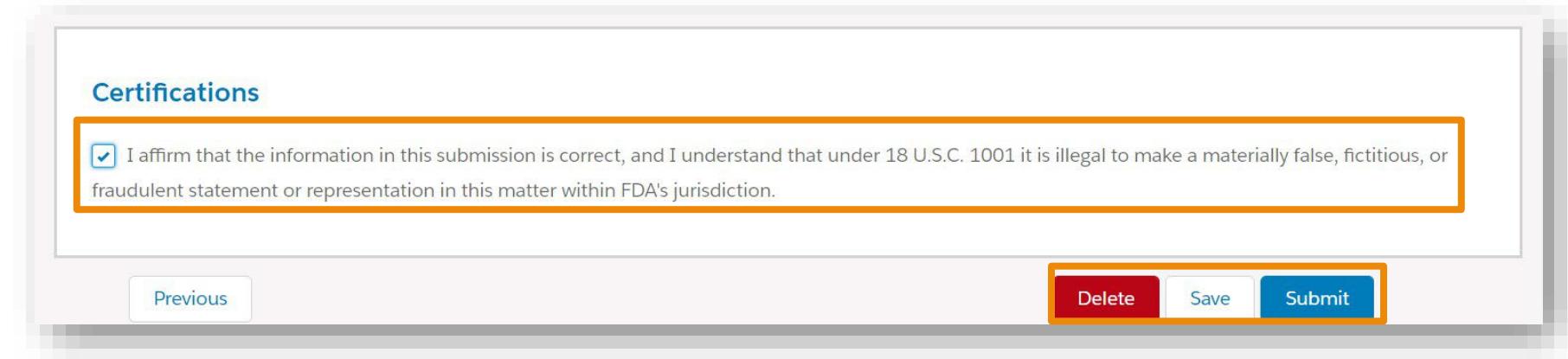
Name	Email	Country	Phone Number	Extension
		United States		

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 monitored. ****

The screenshot shows the CARES Act Amount Information Reporting portal. At the top, there is a message confirming the validation of the data and the need to log in to the FDA CDER NextGen portal. Below this, a table shows the submitter's contact information, with the 'Country' field set to 'United States'. A note for technical support is provided, along with a warning not to reply directly to the message. The main interface shows a list of submissions. One submission, '00027123 Draft', is highlighted with an orange box. The 'Unsubmitted Draft' status is visible. On the right, a 'Submission' form is displayed, showing the 'Submission Information' section. The 'Reporting Year' is set to '2021'. The 'Are you submitting a replacement report to a previous submission?' field is checked. The 'Please select the previous submission for which you are submitting a correction report' dropdown is set to '00026981'. The 'Date Submitted' is '3/2/2022, 12:29 PM'. At the bottom, there are options for manual submission or CSV file upload, with 'CSV File' selected. A message box at the bottom right indicates a successful upload of 'SuccessfulUpload.csv'. The entire screenshot is framed by a large gray border.

CSV Submission – Finished Package Form



The screenshot shows a 'Certifications' section with a checked checkbox and a descriptive text. Below the section are 'Previous', 'Delete', 'Save', and 'Submit' buttons. The 'Submit' button is highlighted with an orange border.

Certifications

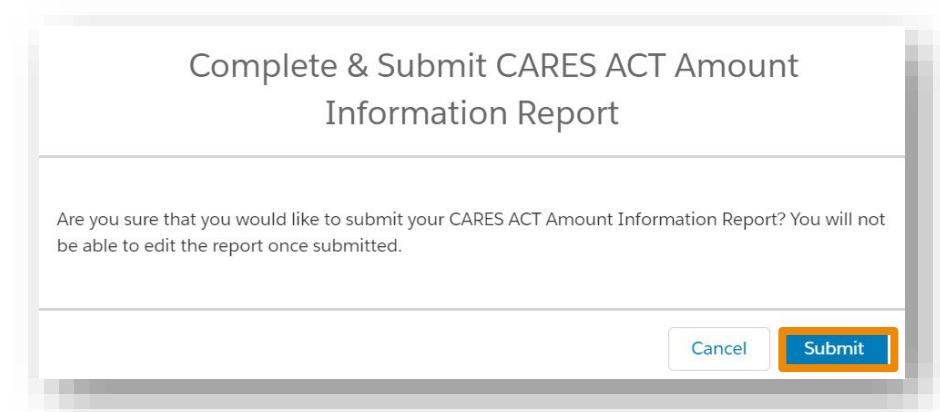
I affirm that the information in this submission is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent statement or representation in this matter within FDA's jurisdiction.

Previous Delete Save **Submit**

Step 20. 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 21. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.



The confirmation screen asks if the user is sure they want to submit the report, with a note that it cannot be edited once submitted. It features 'Cancel' and 'Submit' buttons, with 'Submit' highlighted with an orange border.

Complete & Submit CARES ACT Amount Information Report

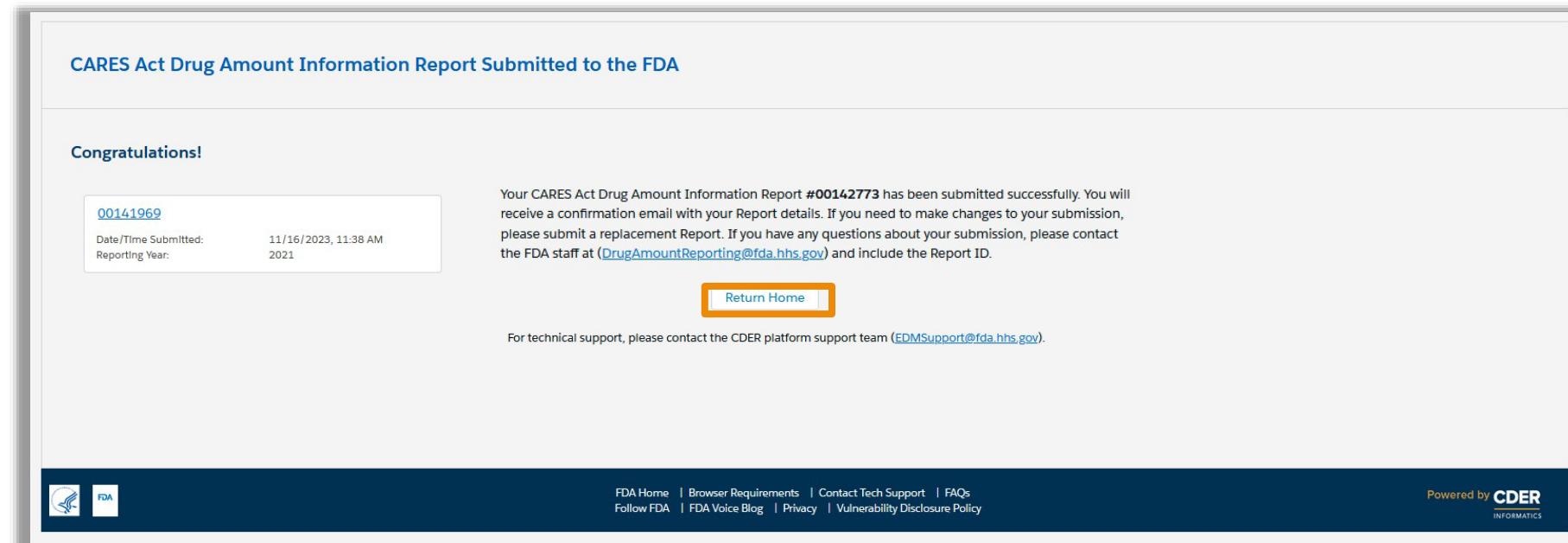
Are you sure that you would like to submit your CARES ACT Amount Information Report? You will not be able to edit the report once submitted.

Cancel **Submit**

CSV Submission – Finished Package Form

Step 22. 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.



CARES Act Drug Amount Information Report Submitted to the FDA

Congratulations!

00141969

Date/Time Submitted: 11/16/2023, 11:38 AM
Reporting Year: 2021

Your CARES Act Drug Amount Information Report #00142773 has been submitted successfully. You will receive a confirmation email with your Report details. If you need to make changes to your submission, please submit a replacement Report. If you have any questions about your submission, please contact the FDA staff at (DrugAmountReporting@fda.hhs.gov) and include the Report ID.

[Return Home](#)

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

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CSVFileUploadSubmission - NotinFinished Package Form

CSV Submission – Not in Finished Package Form

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.

Submission

Submission Information

*What year are you submitting for?

Select one

2021

2020

Previous Delete Save Validate

Submission

Submission Information

*What year are you submitting for?

2021

Are you submitting a replacement report for a previous submission?

Yes

*Please select the previous submission for which you are submitting a replacement report.

00027055

Date Submitted: 3/3/2022, 01:44 PM

Previous Delete Save Validate

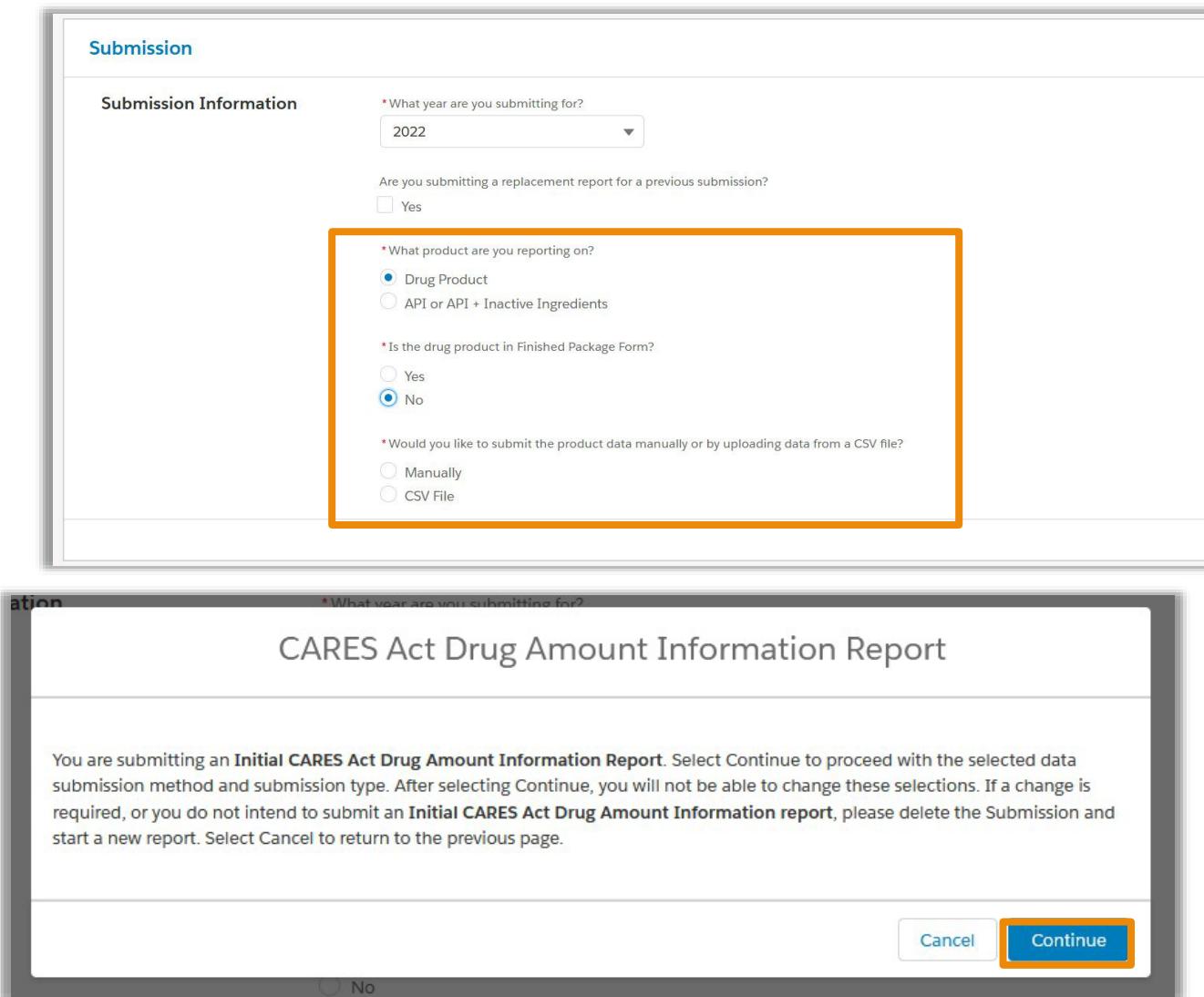
CSV Submission – Not in Finished Package Form

Step 10. Select that you are reporting on a Drug Product.

Step 11. Select “No” that your product is in Finished Package Form.

Step 12. Select that you would like to submit product data via **CSV File**.

Step 13. In the confirmation screen, click **Continue**.



The image shows two screenshots of the FDA Submission interface. The top screenshot displays the 'Submission' screen with 'Submission Information'. It includes fields for 'What year are you submitting for?' (2022), 'Are you submitting a replacement report for a previous submission?' (No), and a large section highlighted with an orange box. This section contains questions: 'What product are you reporting on?' (Drug Product selected), 'Is the drug product in Finished Package Form?' (No selected), and 'Would you like to submit the product data manually or by uploading data from a CSV file?' (CSV File selected). The bottom screenshot shows a confirmation dialog titled 'CARES Act Drug Amount Information Report'. It contains a message about submitting an 'Initial CARES Act Drug Amount Information Report' and two buttons: 'Cancel' and 'Continue', with 'Continue' highlighted with an orange border.

CSV Submission – Not in Finished Package Form

Step 14. 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.

The screenshot shows the 'Submission' interface for a Drug Product not in Finished Package Form. The 'Submission Information' section includes fields for the year (2021), replacement report status (Yes), product type (Drug Product), and whether it's in a finished package form (No). It also asks if data is being submitted manually or via CSV file, with 'CSV File' selected. A note for uploading CSV data is present. Below this, a 'Reference Materials' section lists 'CARES Template for Drug Product not in Finished Package Form CSV Data Upload.csv', 'Sample Data for CSV Upload', and 'CARES SAMPLE Data for Drug Product not in Finished Package Form.xlsx'. A 'Instructions for Using the CSV Template' section contains 'CARES CSV Template Instructions for Drug Product not in Finished Package Form.pdf', 'Instructions for Creating a Custom CSV File', and 'CARES CSV Custom File Instructions for Drug Product not in Finished Package Form.pdf'. At the bottom, there are 'Upload Files' and 'Or drop files' buttons, and navigation buttons for 'Previous', 'Delete', 'Save', and 'Submit'.

CSV Submission – Not in Finished Package Form

Step 15. 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
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
1	1111111111	Manufacture	12345-678-91	January	100	50	TABLET	Yes
2	1111111111	Manufacture	12345-678-91	February	100	50	TABLET	Yes
3	1111111111	Manufacture	12345-678-91	March	100	50	TABLET	Yes
4	1111111111	Manufacture	12345-678-91	April	100	50	TABLET	Yes
5	1111111111	Manufacture	12345-678-91	May	100	50	TABLET	Yes
6	1111111111	Manufacture	12345-678-91	June	150	50	TABLET	Yes
7	1111111111	Manufacture	12345-678-91	July	151	51	TABLET	Yes
8	1111111111	Manufacture	12345-678-91	August	150.25	50.25	TABLET	Yes
9	1111111111	Manufacture	12345-678-91	September	150	50	TABLET	Yes
10	1111111111	Manufacture	12345-678-91	October	150	50	TABLET	Yes
11	1111111111	Manufacture	12345-678-91	November	0	50	TABLET	Yes
12	1111111111	Manufacture	12345-678-91	December	0	0	TABLET	Yes
13	1111111111	Manufacture	12345-678-91	Annual Total	1250.25	550.25	TABLET	Yes
14	2222222222	Transfill	12345-678-01	January	600		CAPSULE	No
15	2222222222	Transfill	12345-678-01	February	0		CAPSULE	No
16	2222222222	Transfill	12345-678-01	March	0		CAPSULE	No
17	2222222222	Transfill	12345-678-01	April	0		CAPSULE	No
18	2222222222	Transfill	12345-678-01	May	100		CAPSULE	No
19	2222222222	Transfill	12345-678-01	June	0		CAPSULE	No
20	2222222222	Transfill	12345-678-01	July	0		CAPSULE	No
21	2222222222	Transfill	12345-678-01	August	0		CAPSULE	No
22	2222222222	Transfill	12345-678-01	September	700		CAPSULE	No
23	2222222222	Transfill	12345-678-01	October	0		CAPSULE	No
24	2222222222	Transfill	12345-678-01	November	0		CAPSULE	No
25	2222222222	Transfill	12345-678-01	December	900		CAPSULE	No
26	2222222222	Transfill	12345-678-01	Annual Total	2300		CAPSULE	No
27	2222222222	Transfill	12345-678-01					

Note: There is a separate document that describes how to enter data into a CSV file: “CARES CSV Template Instructions for Drug Product not in Finished Package”

CSV Submission – Not in Finished Package Form

Step 16. 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 17. When the status bar indicates that the data has finished uploading, click **Done**.

Step 18. 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 screenshot displays the FDA CARES Act Submission portal with four main windows:

- Submission Information Form:** A large window showing fields for year (2021), replacement report (No), product type (Drug Product), and CSV file upload options (Manually or CSV File). A note about the CSV template is present, along with a 'CAUTION' section and reference materials.
- Upload Files Overlay:** A smaller window showing a file named 'CSVFileForTemplate (1).csv' being uploaded, with a progress bar and a 'Done' button.
- Success Overlay:** A green overlay message 'Success File Uploaded Successfully'.
- Save Confirmation Overlay:** A window prompting to 'Save CARES Act Amount Information Report' with 'Save' and 'Save & Close' buttons.

At the bottom of the main form, a note states: 'Your file is currently being processed and you will receive an email notification once processing is complete. You may exit the application by selecting to Save and Save & Close.'

CSV Submission – Not in Finished Package Form

Step 19. 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 Drug 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.

Report ID: 00141977

Submitter's Contact Information:

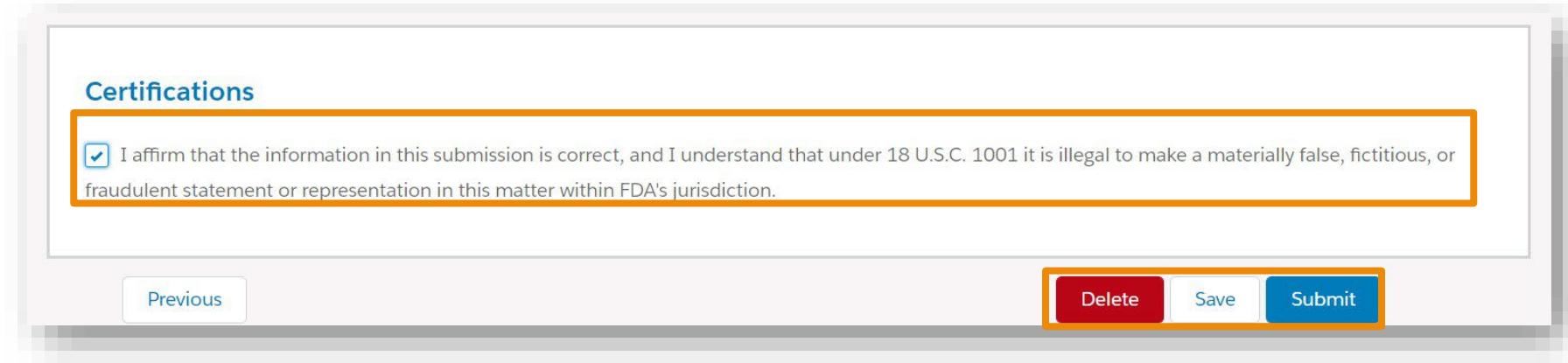
Name	Email	Country	Phone Number	Extension
		United States		

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 monitored. ****

The screenshot shows the CARES Act Amount Information Reporting portal. At the top, a blue header bar displays the title 'CARES Act Amount Information Reporting' and a '+ New Report' button. Below the header, a search bar with placeholder text 'Search Submissions' and a 'Search' button are visible. A dropdown menu icon is also present. The main content area displays a list of submissions. One submission, '00027123 Draft', is highlighted with an orange box. Below this, the 'Submission' section is shown, containing 'Submission Information' fields: 'What year are you submitting for?' (2021), 'Are you submitting a replacement report to a previous submission?' (Yes checked), 'Please select the previous submission for which you are submitting a correction report.' (00026981 selected), and 'Would you like to submit products manually or by uploading data from a csv file?' (CSV File selected). A success message at the bottom states 'SuccessfulUpload.csv Your file has successfully processed. You may proceed by certifying your submission and selecting Submit.'

CSV Submission – Not In Finished Package Form

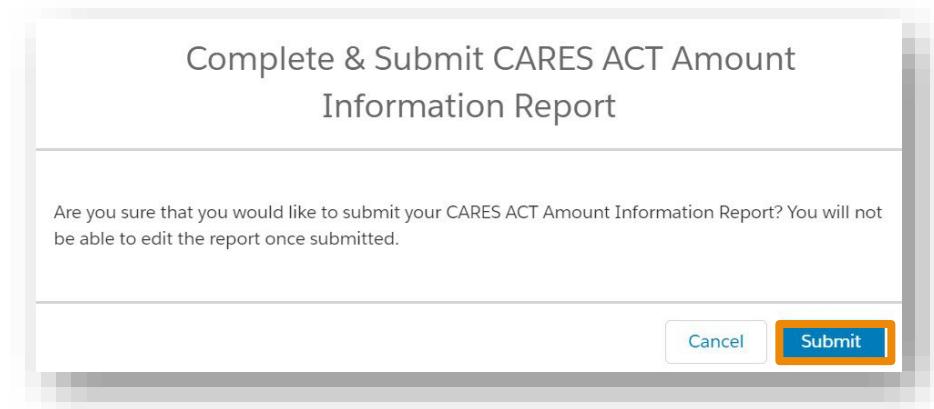


The screenshot shows a web-based form for CSV submission. At the top, there is a section titled "Certifications" with a single checkbox. The checkbox is checked and contains the text: "I affirm that the information in this submission is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent statement or representation in this matter within FDA's jurisdiction." Below this section are three buttons: "Previous", "Delete" (in a red box), "Save" (in a white box), and "Submit" (in a blue box). The "Delete" and "Submit" buttons are highlighted with an orange border.

Step 20. 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 21. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.

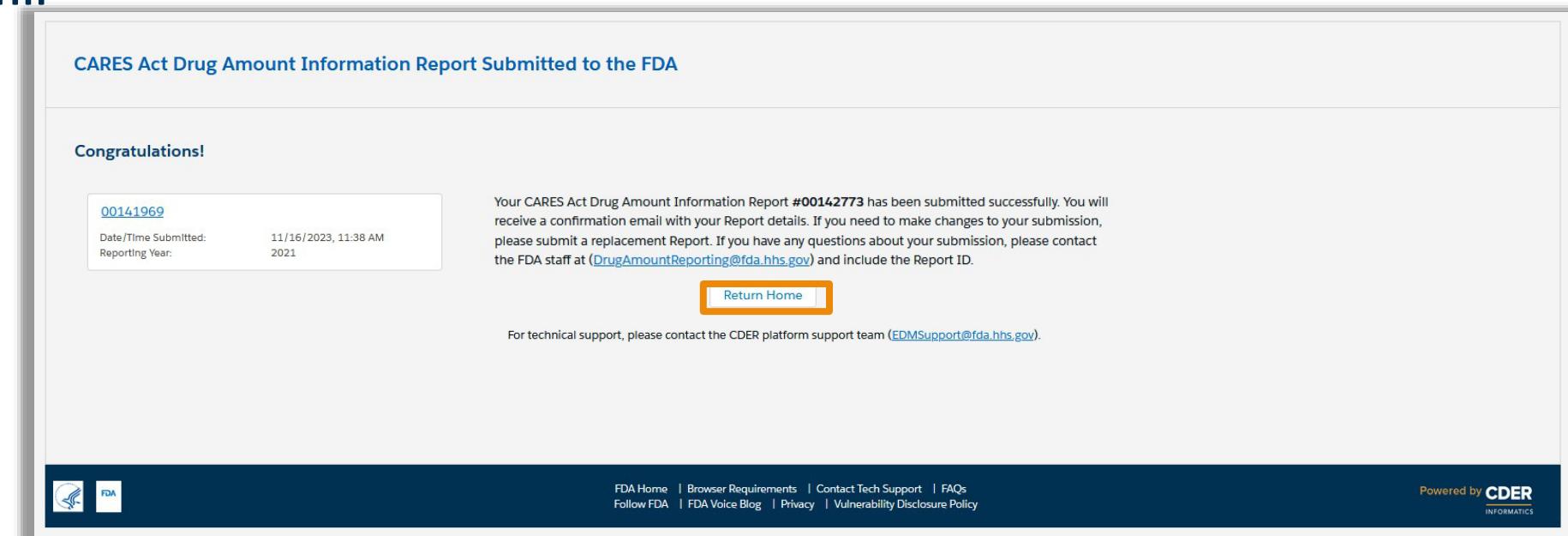


The screenshot shows a confirmation dialog box. The title is "Complete & Submit CARES ACT Amount Information Report". The main text in the dialog box reads: "Are you sure that you would like to submit your CARES ACT Amount Information Report? You will not be able to edit the report once submitted." At the bottom of the dialog box are two buttons: "Cancel" (in a white box) and "Submit" (in a blue box, highlighted with an orange border).

CSV Submission – Not In Finished Package Form

Step 22. 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.



Congratulations!

00141969

Date/Time Submitted: 11/16/2023, 11:38 AM
Reporting Year: 2021

Your CARES Act Drug Amount Information Report #00142773 has been submitted successfully. You will receive a confirmation email with your Report details. If you need to make changes to your submission, please submit a replacement Report. If you have any questions about your submission, please contact the FDA staff at (DrugAmountReporting@fda.hhs.gov) and include the Report ID.

[Return Home](#)

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

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CSVFileUploadSubmission - APIorAPI+InactiveIngredients

CSV Submission – API or API + Inactive Ingredients

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.

Submission

Submission Information

*What year are you submitting for?

Select one

2021

2020

Previous Delete Save Validate

Submission

Submission Information

*What year are you submitting for?

2021

Are you submitting a replacement report for a previous submission?

Yes

*Please select the previous submission for which you are submitting a replacement report.

00027055

Date Submitted: 3/3/2022, 01:44 PM

Previous Delete Save Validate

CSV Submission – API or API + Inactive Ingredients

Step 10. Select that you are reporting on an API or API + Inactive Ingredients.

Step 11. Select that you would like to submit product data via **CSV File**.

Step 12. In the confirmation screen, click **Continue**.

Submission

Submission Information

*What year are you submitting for?
2022

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

*What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients

*Is the drug product in Finished Package Form?
 Yes
 No

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

CARES Act Drug Amount Information Report

You are submitting an **Initial CARES Act Drug Amount Information Report**. 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 an **Initial CARES Act Drug Amount Information report**, please delete the Submission and start a new report. Select Cancel to return to the previous page.

No

Cancel Continue

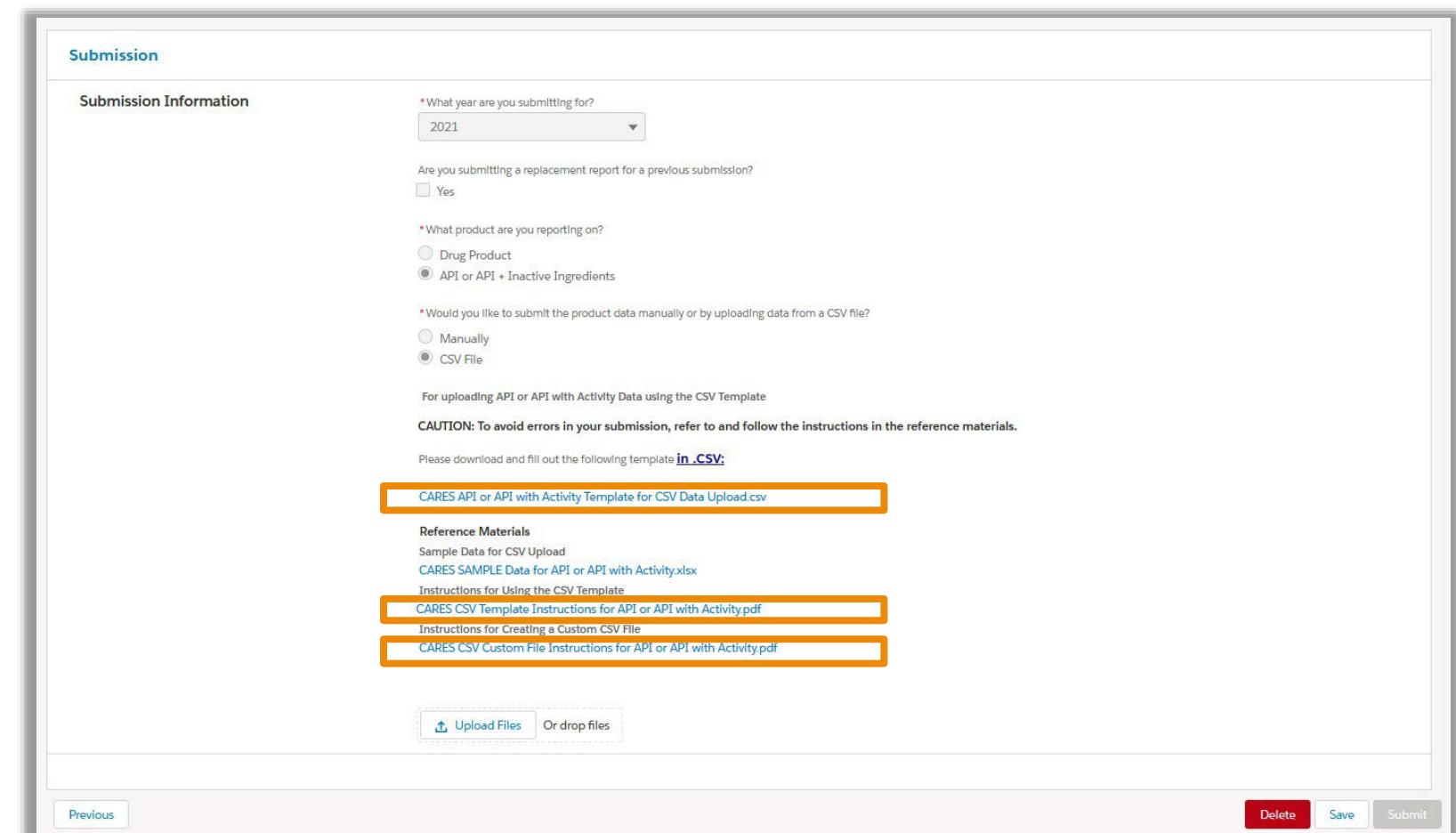
CSV Submission – API or API + Inactive Ingredients

Step 13. 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

Submission Information

* What year are you submitting for?
2021

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

* What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients

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

For uploading API or API with Activity Data using the CSV Template

CAUTION: To avoid errors in your submission, refer to and follow the instructions in the reference materials.

Please download and fill out the following template [in .CSV](#):

CARES API or API with Activity Template for CSV Data Upload.csv

Reference Materials

Sample Data for CSV Upload
CARES SAMPLE Data for API or API with Activity.xlsx

Instructions for Using the CSV Template
CARES CSV Template Instructions for API or API with Activity.pdf

Instructions for Creating a Custom CSV File
CARES CSV Custom File Instructions for API or API with Activity.pdf

Upload Files Or drop files

Previous Delete Save Submit

CSV Submission – API or API + Inactive Ingredients

Step 14. 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
1 Establishment DUNS	Business Operation	NDC	Amount Per	Mass/Volume	Unit Of Measure	Activity (Unit of	Average Activity	Minimum Activity
7 1111111111	API Manufacture	12345-678-01	June	100	kg	u/mg	190	190
8 1111111111	API Manufacture	12345-678-01	July	100	kg	u/mg	190	190
9 1111111111	API Manufacture	12345-678-01	August	100	kg	u/mg	190	190
10 1111111111	API Manufacture	12345-678-01	September	100	kg	u/mg	190	190
11 1111111111	API Manufacture	12345-678-01	October	100	kg	u/mg	190	190
12 1111111111	API Manufacture	12345-678-01	November	100	kg	u/mg	190	190
13 1111111111	API Manufacture	12345-678-01	December	100	kg	u/mg	190	190
14 1111111111	API Manufacture	12345-678-01	Annual Total	1510	kg	u/mg	192	190
15 2222222222	Manufacture	12345-678-91	January	300	mg	USP'U/mg	140	100
16 2222222222	Manufacture	12345-678-91	February	150	mg	USP'U/mg	80	100
17 2222222222	Manufacture	12345-678-91	March	150	mg	USP'U/mg	80	100
18 2222222222	Manufacture	12345-678-91	April	260	mg	USP'U/mg	120	80
19 2222222222	Manufacture	12345-678-91	May	150	mg	USP'U/mg	120	80
20 2222222222	Manufacture	12345-678-91	June	150	mg	USP'U/mg	80	100
21 2222222222	Manufacture	12345-678-91	July	150	mg	USP'U/mg	100	100
22 2222222222	Manufacture	12345-678-91	August	150	mg	USP'U/mg	100	100
23 2222222222	Manufacture	12345-678-91	September	150	mg	USP'U/mg	80	100
24 2222222222	Manufacture	12345-678-91	October	220	mg	USP'U/mg	100	80
25 2222222222	Manufacture	12345-678-91	November	150	mg	USP'U/mg	100	100
26 2222222222	Manufacture	12345-678-91	December	150	mg	USP'U/mg	100	100
27 2222222222	Manufacture	12345-678-91	Annual Total	2130	mg	USP'U/mg	100	80
28								

Note: There is a separate document that describes how to enter data into a CSV file: “CARES CSV Template Instructions for API or API with Activity”

CSV Submission – API or API + Inactive Ingredients

Step 15. 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 16. When the status bar indicates that the data has finished uploading, click **Done**.

Step 17. 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 four screenshots of the FDA CARES Act Submission portal interface:

- Top Left:** The 'Submission' page. It includes fields for 'What year are you submitting for?' (2021), 'What product are you reporting on?' (selected 'API or API + Inactive Ingredients'), and 'Would you like to submit the product data manually or by uploading data from a CSV file?' (selected 'CSV File'). A yellow box highlights the 'Upload Files' and 'Or drop files' button.
- Top Right:** A 'Upload Files' dialog box showing a file named 'CSVFileForTemplate (1).csv' being uploaded.
- Bottom Left:** The 'Submission' page again, but with a green 'Success' message box at the top stating 'File Uploaded Successfully'.
- Bottom Right:** A 'Save CARES Act Amount Information Report' dialog box with buttons for 'Cancel', 'Save', and 'Save & Close'. The 'Save & Close' button is highlighted with a yellow box.

CSV Submission – API or API + Inactive Ingredients

Step 18. Once you receive an email confirming the processing of your CSV file, return to the landing page and click on the report ID.

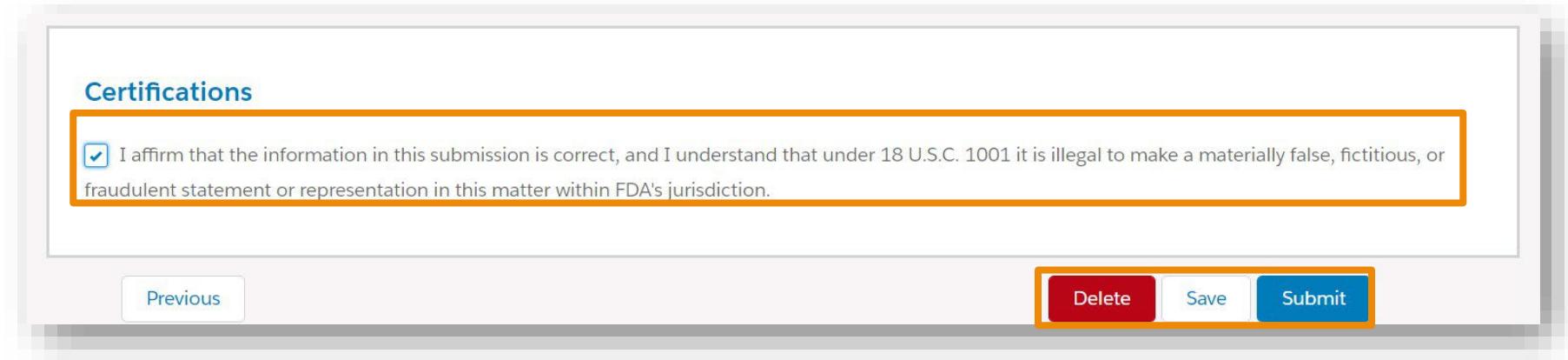
Note: If you need to update your CSV file, please click on the X next to the old filename to remove it and then upload the updated CSV file.

The screenshot shows the CARES Act Amount Information Reporting interface. At the top, a success message states: "Thank you for your CARES Act Drug 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." Below this, the Report ID is listed as 00141977. A section for "Submitter's Contact Information" is shown with a table:

Name	Email	Country	Phone Number	Extension
[Redacted]	[Redacted]	United States	[Redacted]	[Redacted]

For technical support, contact the CDER Platform Support Team at EDMSupport@fda.hhs.gov. A note at the bottom of the message area states: "Please do not reply directly to this message. This is an automatically generated email and replies will not be monitored." Below the message area, the main interface shows the "CARES Act Amount Information Reporting" title. A search bar and a "New Report" button are visible. The submission list shows a single entry: "00027123 Draft" with a timestamp of "Last Modified: 03/04/2022, 12:47 PM" and "Reporting Year: 2021". A "Correction to Report: 00026981" is listed. A "Unsubmitted Draft" button is present. The right side of the interface shows the "Submission" form. It includes fields for "Submission Information" (Year: 2021, Yes to replacement), "Previous Submission" (00026981, Date Submitted: 3/2/2022, 12:29 PM), and "Would you like to submit products manually or by uploading data from a csv file?" (radio buttons for "Manually" and "CSV File"). A success message at the bottom right says: "Your file has successfully processed. You may proceed by certifying your submission and selecting Submit." A file name "SuccessfulUpload.csv" is highlighted with an orange box.

CSV Submission – API or API + Inactive Ingredients



The screenshot shows a user interface for CSV submission. At the top, there is a section titled "Certifications" with a checked checkbox and a descriptive text. Below this are "Previous" and "Next" buttons, and a row of "Delete", "Save", and "Submit" buttons. The "Submit" button is highlighted with a blue border.

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.

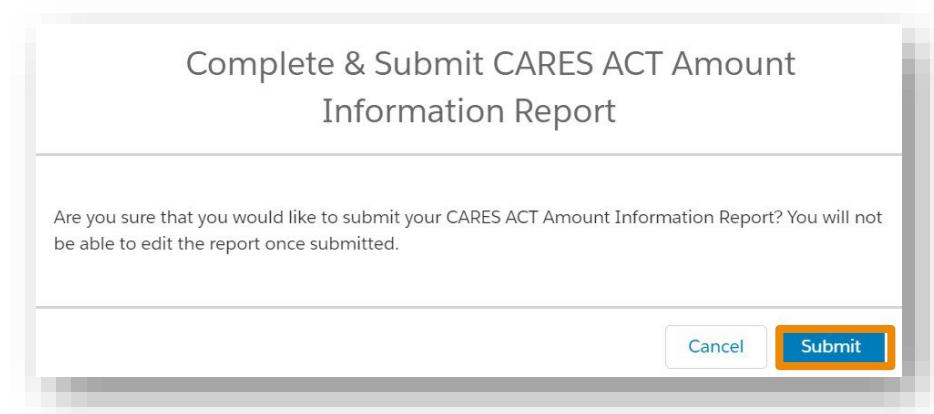
Previous Next

Delete Save Submit

Step 19. 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 20. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.



The screenshot shows a confirmation dialog box. It contains a message asking if the user is sure they want to submit the report, with a note that it cannot be edited once submitted. At the bottom are "Cancel" and "Submit" buttons, with "Submit" being highlighted with a blue border.

Complete & Submit CARES ACT Amount Information Report

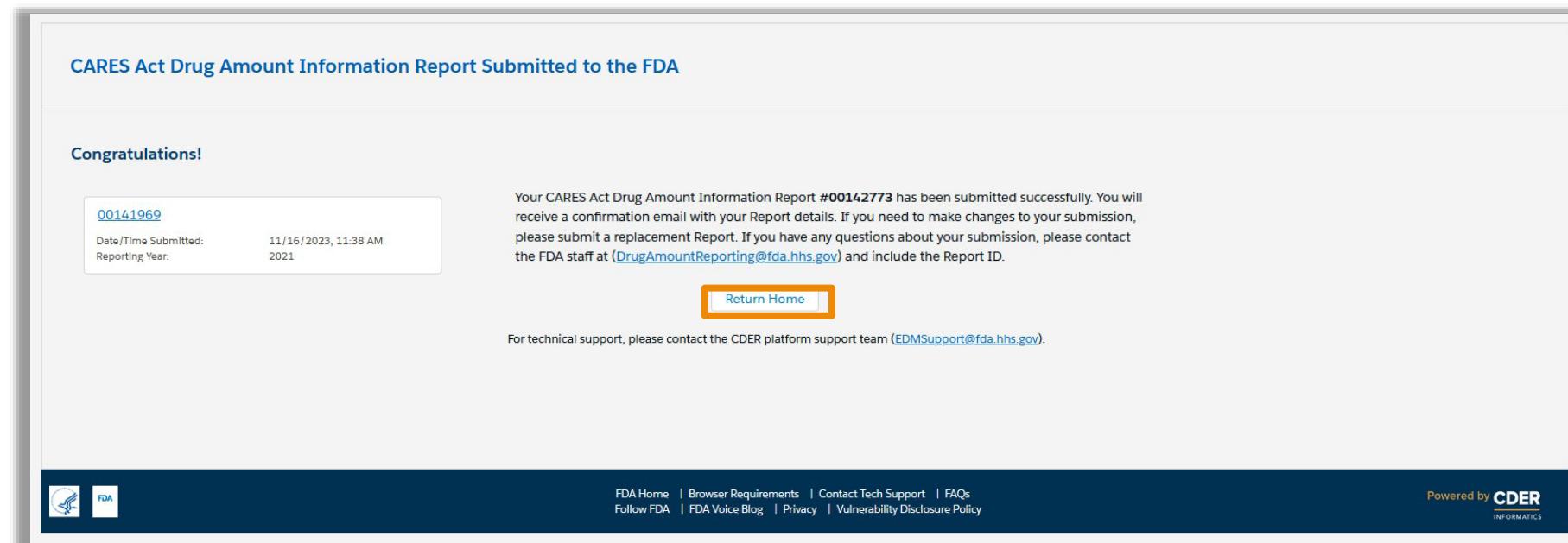
Are you sure that you would like to submit your CARES ACT Amount Information Report? You will not be able to edit the report once submitted.

Cancel Submit

CSV Submission – API or API + Inactive Ingredients

Step 21. 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.



Congratulations!

00141969

Date/Time Submitted: 11/16/2023, 11:38 AM
Reporting Year: 2021

Your CARES Act Drug Amount Information Report #00142773 has been submitted successfully. You will receive a confirmation email with your Report details. If you need to make changes to your submission, please submit a replacement Report. If you have any questions about your submission, please contact the FDA staff at (DrugAmountReporting@fda.hhs.gov) and include the Report ID.

[Return Home](#)

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

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CSVFileSubmissionErrors

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.

The screenshot shows the CARES Act Amount Information Reporting submission interface. On the left, a sidebar displays a list of submissions, with the first one, '00027130 Draft', highlighted. The main content area is titled 'Submission' and contains the following fields:

- Submission Information:**
 - * What year are you submitting for? (2021)
 - Are you submitting a replacement report for a previous submission?
 Yes
 - * What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients
 - * Is the drug product In Finished Package Form?
 Yes
 No
 - * Would you like to submit the product data manually or by uploading data from a CSV file?
 Manually
 CSV File
- For uploading API or API with Activity Data using the CSV Template
- CAUTION: To avoid errors in your submission, refer to and follow the instructions in the reference materials.
- Please download and fill out the following template [in CSV](#).
- CARES API or API with Activity Template for CSV Data Upload.csv
- Reference Materials**
 - Sample Data for CSV Upload
 - CARES SAMPLE Data for API or API with Activity.xlsx
 - Instructions for Using the CSV Template
 - CARES CSV Template Instructions for API or API with Activity.pdf
 - Instructions for Creating a Custom CSV File
 - CARES CSV Custom File Instructions for API or API with Activity.pdf

To review common error types and resolutions, please review the Reference Materials

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. Errors will be listed within your email

Report ID: 00140508

Thank you for your CARES Act Drug Amount Information Submission. While processing your data, one or more validation issues were detected that may require your action, where DUNS and/or NDC values submitted were not found in an automated lookup of drug registration and listing information. This validation check is provided as an aid to assist in the submission of accurate data; it is not exhaustive and does not necessarily constitute an error. 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 file, correct the data in the file, and upload the updated CSV file.

While processing, the system encountered one or more DUNS or NDC values that were not verified in an automated lookup. Please review a list of the data in question by downloading the validation results file:

[Validation_Results.csv](#)

If you feel that your data is accurate after reviewing your validation results, you can proceed with your submission as-is by selecting Submit.

To make a correction, please remove the CSV file, correct the data in the file, and upload the updated CSV file.

Refer to the validation issue email and review the reference materials above to review how to save as a CSV.

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

Report ID: 00141764

Thank you for your CARES Act Drug Amount Information Submission. While processing your data, one or more data hierarchy errors were detected requiring your action. 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. 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 data in the file, and upload the updated CSV file.

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

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.

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

To correct errors in your submission, refer to the hierarchy error email and review the reference materials above to troubleshoot hierarchy errors, and to review how to save as a CSV.

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

Report ID: 00141977

Thank you for your CARES Act Drug Amount Information Submission. While processing your data, one or more parsing errors were detected requiring your action. Please return to FDA CDER NextGen portal, <https://edm.fda.gov>, to perform next steps - review your data, delete the file, correct the data in the file, and upload the updated CSV file

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 CSV file.

To correct errors in your submission, refer to the parsing error email and review the reference materials above to review how to troubleshoot parsing errors and to review how to save as a CSV.

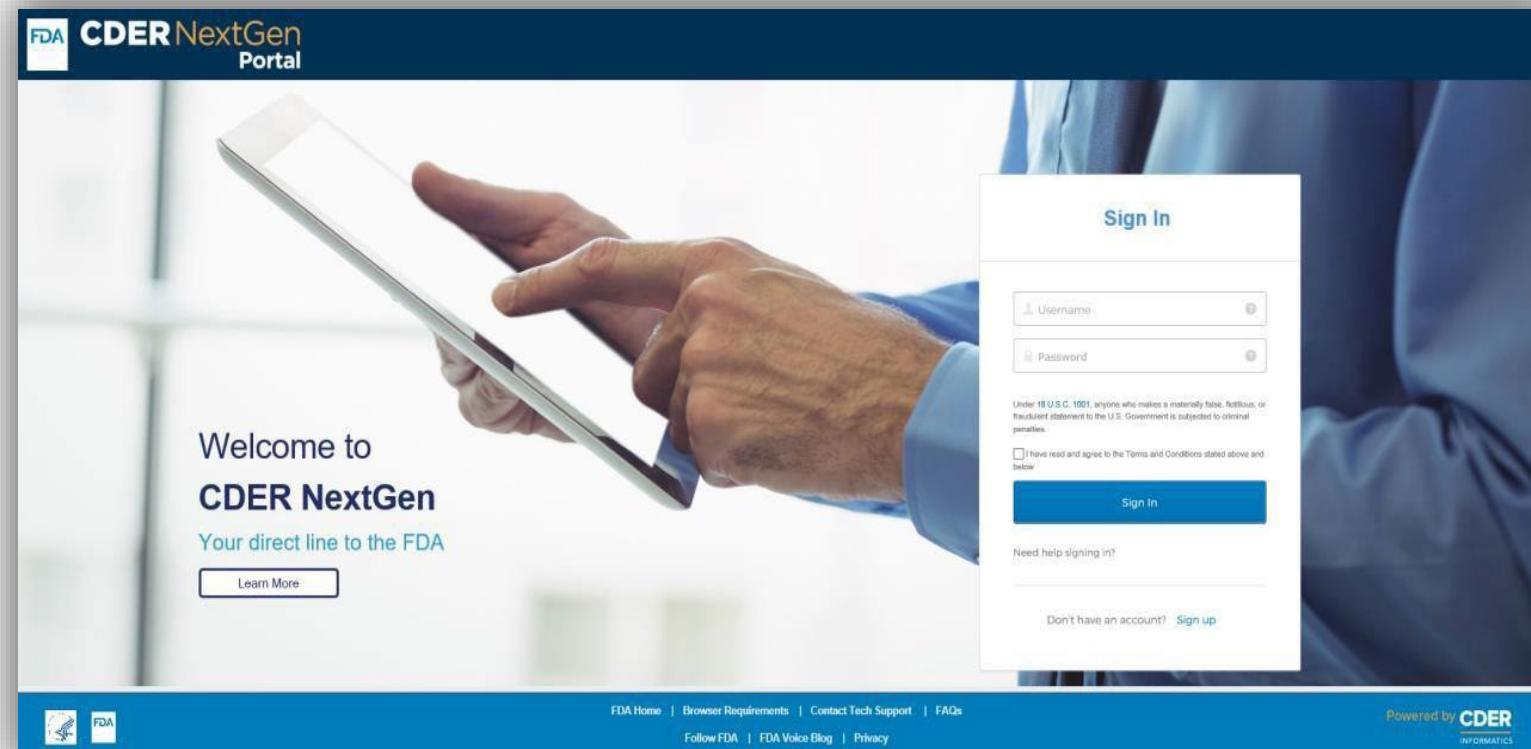
In the case you encounter any issues, please contact EDM Support at EDMSupport@fda.hhs.gov

Manual Submission

ManualSubmission –CreatingaNewReportandEnteringSubmitterDetails

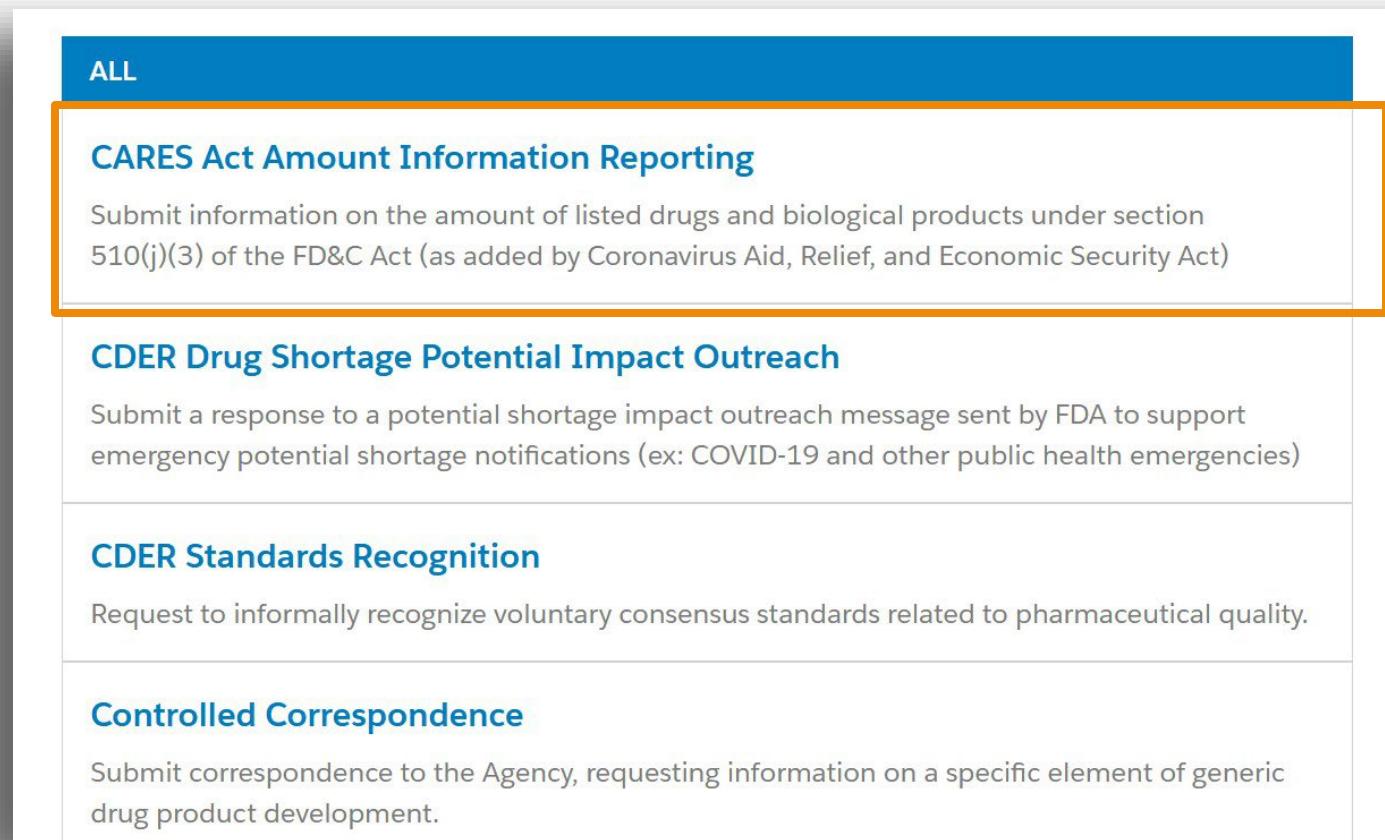
CDER NextGen Portal Homepage

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



CDER NextGen Portal Homepage

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



ALL

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)

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)

CDER Standards Recognition

Request to informally recognize voluntary consensus standards related to pharmaceutical quality.

Controlled Correspondence

Submit correspondence to the Agency, requesting information on a specific element of generic drug product development.

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

Submission ID	Status	Last Modified	Reporting Year	Action
00020506	Draft	11/29/2021, 04:48 PM	2020	<input type="button" value="Unsubmitted Draft"/>
00020357	Draft	11/29/2021, 04:48 PM	2021	<input type="button" value="Unsubmitted Draft"/>

CDER NextGen Portal Home ? Log Out

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.

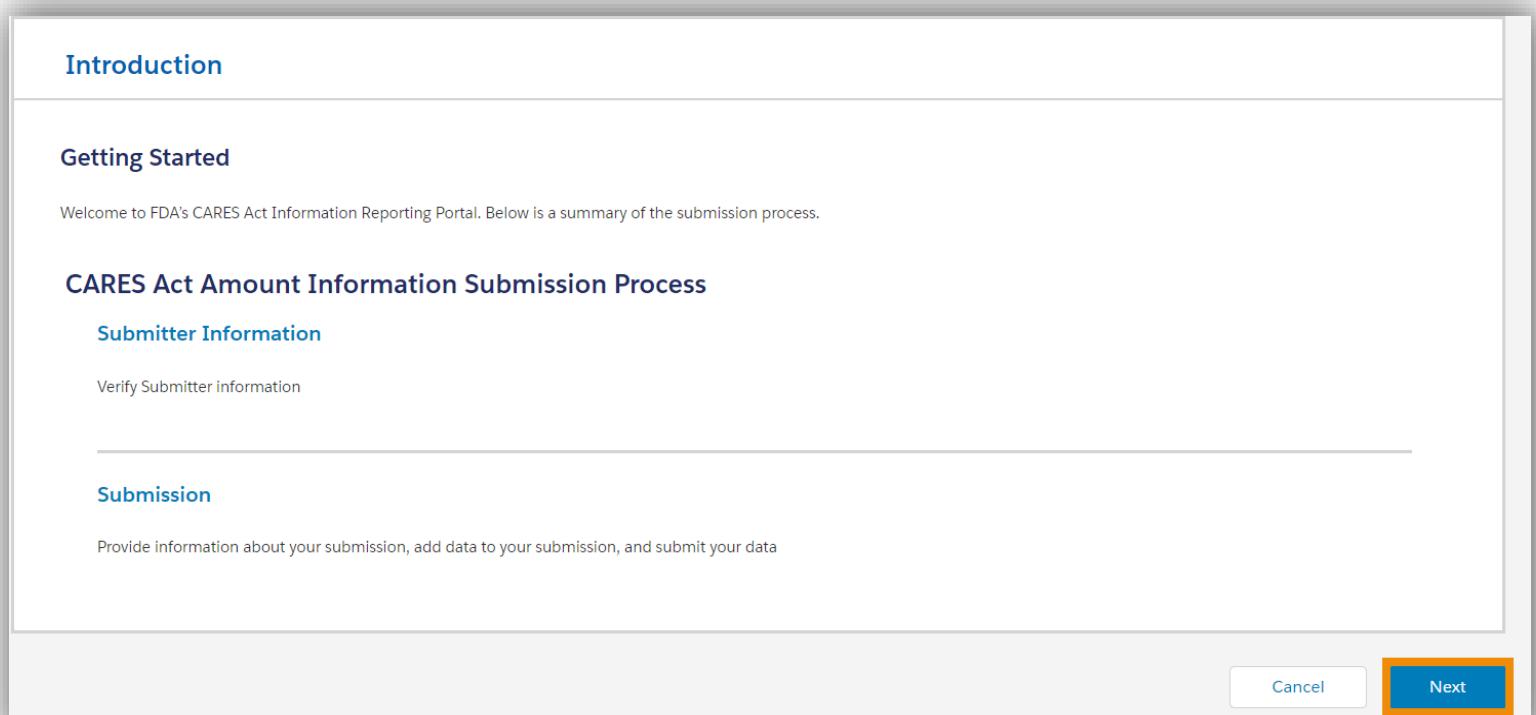
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CARES Act Amount Information Report

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 FDA CARES Act Amount Information Reporting Portal. The screen is divided into sections: 'Getting Started' (which includes a welcome message and a summary of the submission process), 'CARES Act Amount Information Submission Process' (which includes a 'Submitter Information' section with a 'Verify Submitter Information' link), and 'Submission' (which includes a link to provide information about the submission and add data). At the bottom right are 'Cancel' and 'Next' buttons, with 'Next' being highlighted with a yellow border.

Introduction

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

[Cancel](#) [Next](#)

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

Email Address

Phone Number

Extension

Organization Name

Address Line 1

Address Line 2

City

State/Province

Zip Code

Country

Save

Next

ManualSubmission-Finished Package Form

Manual Submission – Finished Package Form

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

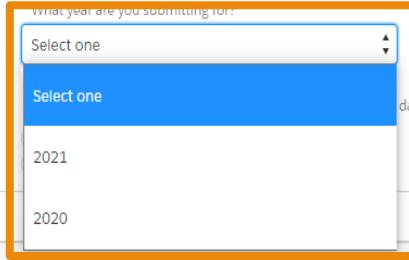
Step 9. If you are submitting a new report, leave “Are you submitting a replacement report for a previous submission” blank and proceed to step 10.

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.

Submission

Submission Information

*What year are you submitting for?



2021

2020

Previous Delete Save Validate

Submission

Submission Information

*What year are you submitting for?



2021

Are you submitting a replacement report for a previous submission?

Yes

*Please select the previous submission for which you are submitting a replacement report.

00027055

Date Submitted: 3/3/2022, 01:44 PM

Previous Delete Save Validate

Manual Submission – Finished Package Form

Step 10. Select that you are reporting on a Drug Product.

Step 11. Select “Yes” that your product is in Finished Package Form.

Step 12. Select that you would like to submit product data **Manually**.

Step 13. In the confirmation screen, click **Continue**.

Submission

Submission Information

* What year are you submitting for?
2022

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

* What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients

* Is the drug product in Finished Package Form?
 Yes
 No

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

CARES Act Drug Amount Information Report

You are submitting an **Initial CARES Act Drug Amount Information Report**. 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 an **Initial CARES Act Drug Amount Information report**, please delete the Submission and start a new report. Select Cancel to return to the previous page.

Cancel Continue

Manual Submission – Finished Package Form

Step 14. To begin to submit product data manually, select **Add Establishment** to enter a DUNS Number.

The screenshot shows a 'Submission' form with the following fields:

- Submission Information**
 - * What year are you submitting for? (dropdown menu showing 2022)
 - Are you submitting a replacement report for a previous submission?
 Yes
 - * What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients
 - * Is the drug product in Finished Package Form?
 Yes
 No
 - * Would you like to submit the product data manually or by uploading data from a CSV file?
 Manually
 CSV File
- Add Establishment** (button highlighted with an orange box)

At the bottom of the form are buttons for **Previous**, **Delete**, **Save**, and **Validate**.

Manual Submission – Finished Package Form

Step 15. On the next screen, enter the 9-digit **DUNS Number** and click **Search**. If necessary, add leading zeroes.

If the search for a DUNS number succeeds, the name and address of the matching establishment is displayed.

If this is the correct establishment, click in the radio button on the left and then click **Select**.

If a different establishment is displayed, check that the DUNS number was correctly entered.

Add Establishment by DUNS Number

Establishment Information

*DUNS Number: 123456789

Search

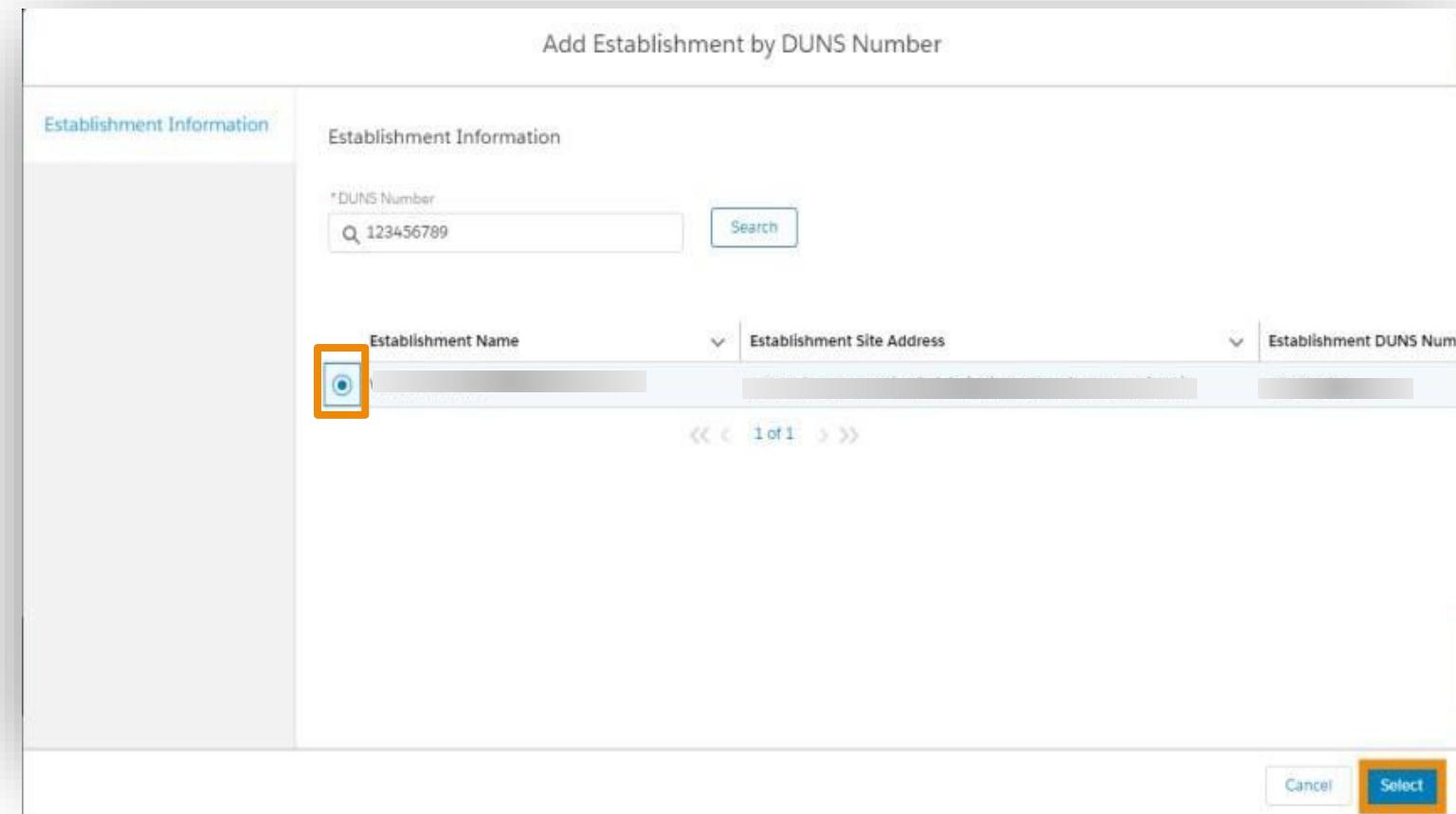
Establishment Name: [Redacted]

Establishment Site Address: [Redacted]

Establishment DUNS Num.: [Redacted]

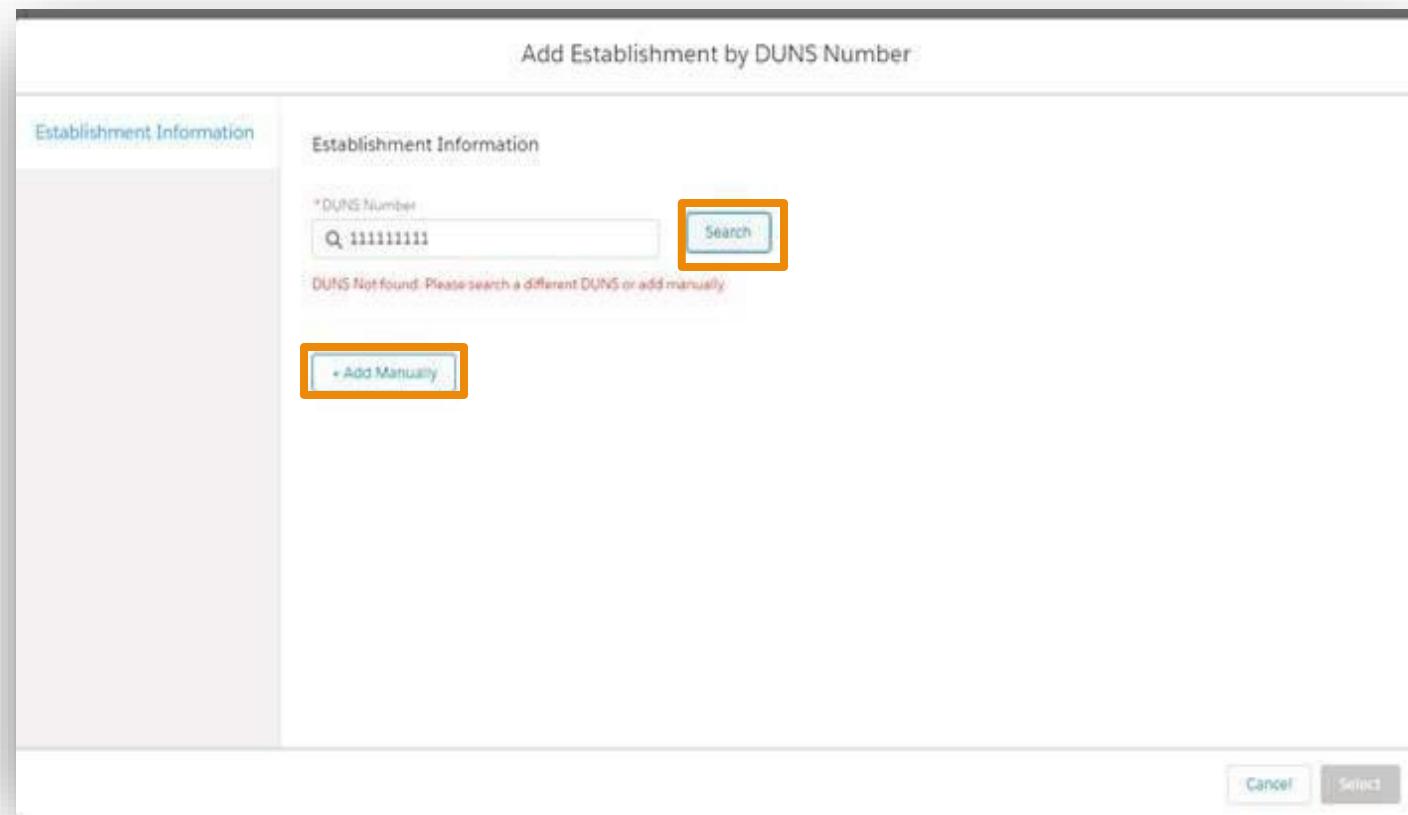
1 of 1

Cancel Select



Manual Submission – Finished Package Form

Step 16. If the search for a DUNS number fails, an error message and an **+Add Manually** button will appear. Click the button to enter establishment information.



Add Establishment by DUNS Number

Establishment Information

*DUNS Number

1111111111

Search

DUNS Not found. Please search a different DUNS or add manually.

+ Add Manually

Cancel Select

Manual Submission – Finished Package Form

Step 17. When **+Add Manually** is clicked, a screen for manually entering establishment information appears.

Enter the requested information and then click **Save**.

Add Establishment by DUNS Number

Establishment Information

Manually Add Establishment Information

*Establishment DUNS Number Back to Search

*Establishment Name

*Address Line 1 Address Line 2

*City *Country

State/Province *Zip Code

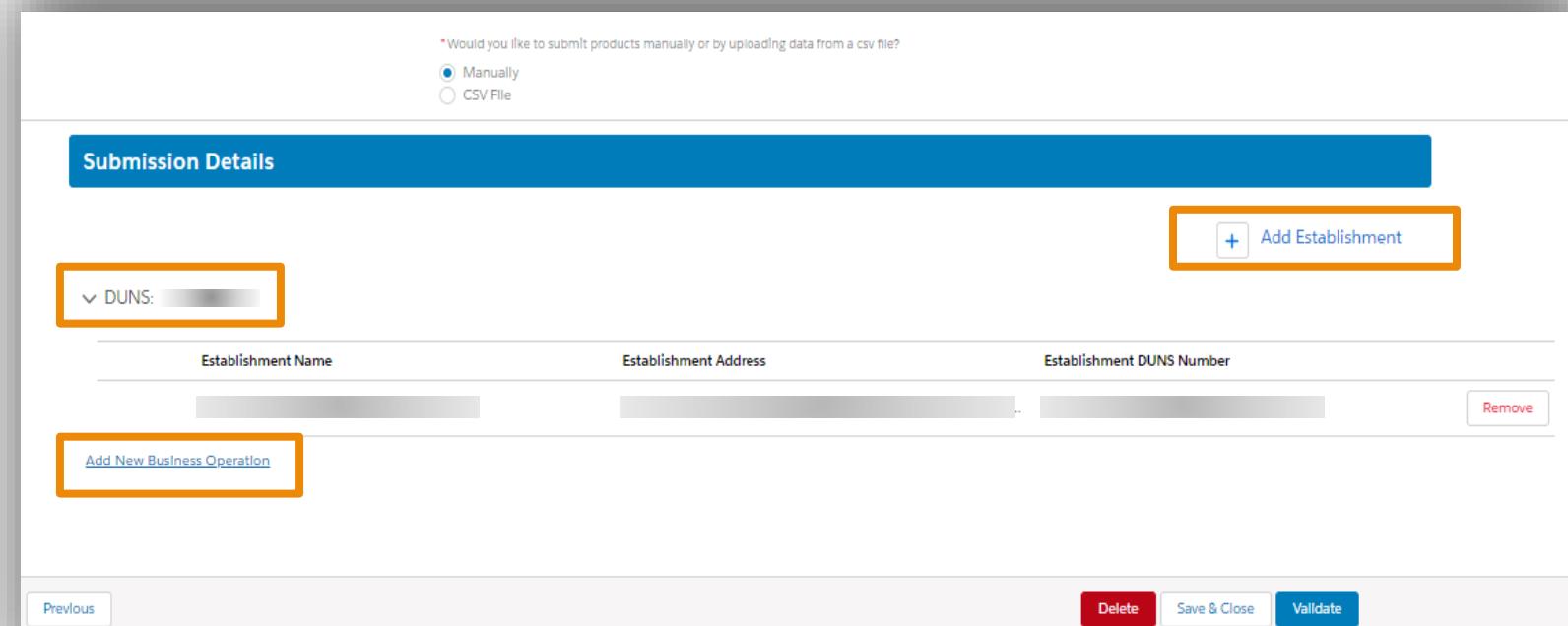
Manual Submission – Finished Package Form

Step 18. After a DUNS number is selected, the Submission screen opens.

Click the arrow next to the DUNS number or click on the DUNS number to expand its entry. Establishment information will be displayed.

Then, click on **Add New Business Operation**.

To enter data for another DUNS number, click on **Add Establishment** and repeat the process of adding a DUNS number.



The screenshot shows a web-based submission interface. At the top, there is a question: "Would you like to submit products manually or by uploading data from a csv file?" with radio buttons for "Manually" (selected) and "CSV File". Below this is a section titled "Submission Details" with a blue header. The first item in this section is a DUNS number, which is expanded, showing an "Establishment Name" (redacted), "Establishment Address" (redacted), and "Establishment DUNS Number" (redacted). To the right of this row is a button labeled "+ Add Establishment". Below the DUNS entry is a button labeled "Add New Business Operation". At the bottom of the screen are navigation buttons: "Previous", "Delete", "Save & Close" (highlighted with a red box), and "Validate".

Manual Submission – Finished Package Form

Step 19. Select an option from the drop-down menu of Business Operations. Each Business Operation can be selected only once, and in any order. Each DUNS can have one Business Operation or multiple Business Operations. There is a **Remove** button next to each DUNS number and Business Operation, if needed.

Step 20. Click **+Add Product** to add a product. Each Business Operation can have one product or multiple products.

The screenshot shows a 'Submission Details' page with a 'Business Operations' section. A dropdown menu is open, showing options: 'Select one', 'Manufacture', 'Repack', 'Relabel', 'Transfill', and 'Positron Emission Tomography Drug Production'. The 'Select one' option is highlighted. To the right of the dropdown is a 'Remove' button. Below the dropdown is a '+Add Product' button, which is highlighted with an orange box. The page also includes fields for 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number', and buttons for 'Delete', 'Save', and 'Validate'.

Manual Submission – Finished Package Form

Step 21. Clicking on **+Add Product** opens a screen to enter an NDC. Enter the **NDC** of the product and then click **Search**.

If the NDC appears on the right, check the box next to it and then click **Select**, which will return you to the **Submission** screen.

If the search fails, and you know the NDC number to be correct, click **+Add Manually**.

SEARCH RESULTS

NDC

Allowable formats are: 1234-1234-12, 12345-123-12, and 12345-1234-1

Search

Add Drug or Biological Product by NDC

NDC

Search

+ Add Manually

Select

Cancel

Manual Submission – Finished Package Form

Step 22. After clicking on **+Add Manually**, enter the NDC number and then click **Add Product**, which will return you to the **Submission** screen.

Add Drug or Biological Product Manually

*NDC
1234-1234-12

Allowable formats are: 1234-1234-12, 12345-123-12 and 12345-1234-1

Back to Search

Cancel Add Product

Manual Submission – Finished Package Form

Outermost Package				Innermost Package				Select Arrow to Enter Monthly Amounts
NDC	Source NDC	Quantity Manufactured	Quantity Distributed(Non-US)	Package Type	Quantity Manufactured	Quantity Distributed(Non-US)	Package Type	
<input type="checkbox"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
<input type="text"/> Annual Total <input type="text"/> Annual Total				<input type="text"/> Annual Total <input type="text"/> Annual Total				<input type="button" value="▼"/>
<input type="button" value="+Add Product"/> <input type="button" value="Remove Product"/>								

Step 23. In the Submission screen, FDA recommends that registrants submit data monthly:

- If Business Operation is Repack or Relabel, click on the **pencil icon** to select Source NDC
- Select **outermost package type** and if applicable, select **innermost package type**
- If applicable, check **Intended to Fulfill 21 CFR 314.81**
- Scroll to the right and click the **Select Arrow to Enter Monthly Amounts** arrow to expand the record so that monthly data can be entered
- If a product has single-level packaging, use only the “Outermost Package” fields
- Enter **Quantity Manufactured** and **Quantity Distributed** (if Intended to Fulfill 21 CFR 314.81 was selected) as whole numbers or decimals
- Annual Total will be reflected as the monthly values are entered

Click **+Add Product** and/or **Remove Product** as needed.

Manual Submission – Finished Package Form

Step 24. For each month, enter the amounts manufactured or distributed. Use whole numbers or decimals.

Fields can be left blank for months during which the product was not manufactured or distributed.

The top row, which contains the NDC number, also contains fields for annual totals. The annual total fields will automatically update when a monthly field is updated.

Outermost Package					Innermost Package				Select Arrow to Enter Monthly Amounts
NDC	Source NDC	Quantity Manufactured	Quantity Distributed(Non-US)	Package Type	Quantity Manufactured	Quantity Distributed(Non-US)	Package Type	Intended to Fulfill 21 CFR 314.81	
<input type="checkbox"/>  <input type="button" value="edit"/>		142.00	40.00	<input type="button" value="edit"/>	30	95	<input type="button" value="edit"/>		
Annual Total					Annual Total				
									<input type="checkbox"/> 
									<input type="checkbox"/> 
									<input type="checkbox"/> 
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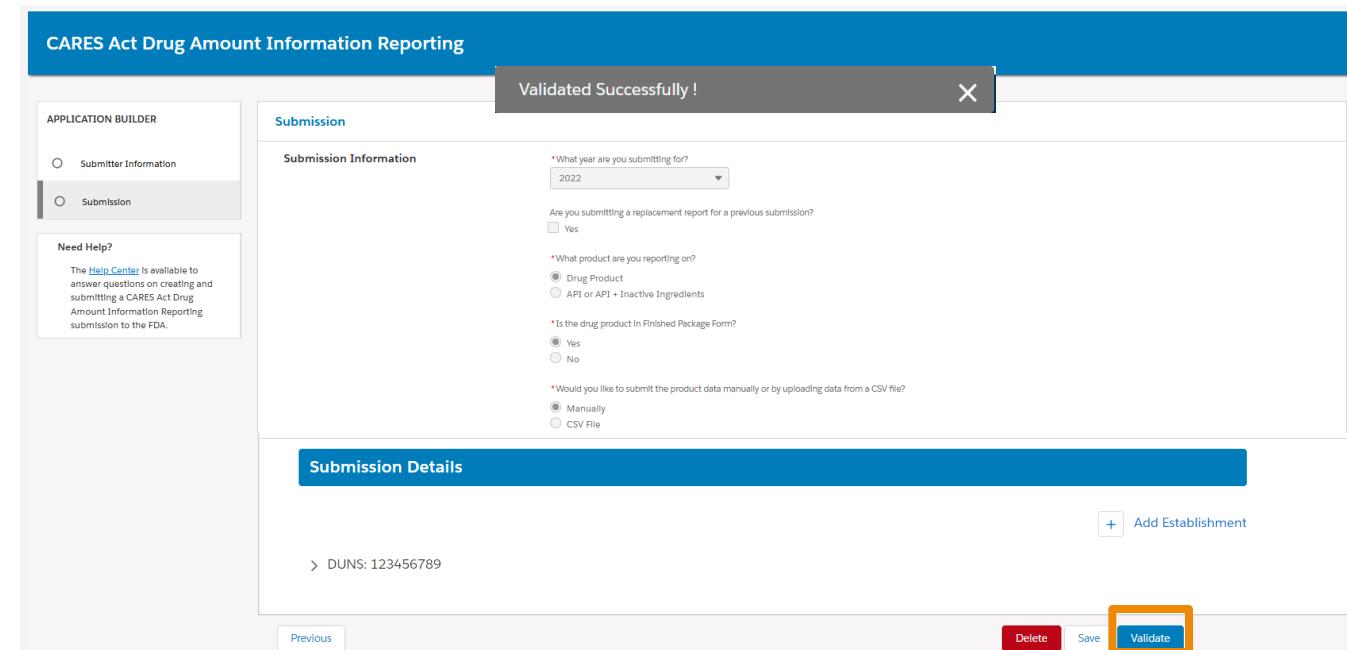
Manual Submission – Finished Package Form

Step 25. Click the **Validate** button at the bottom of the page.

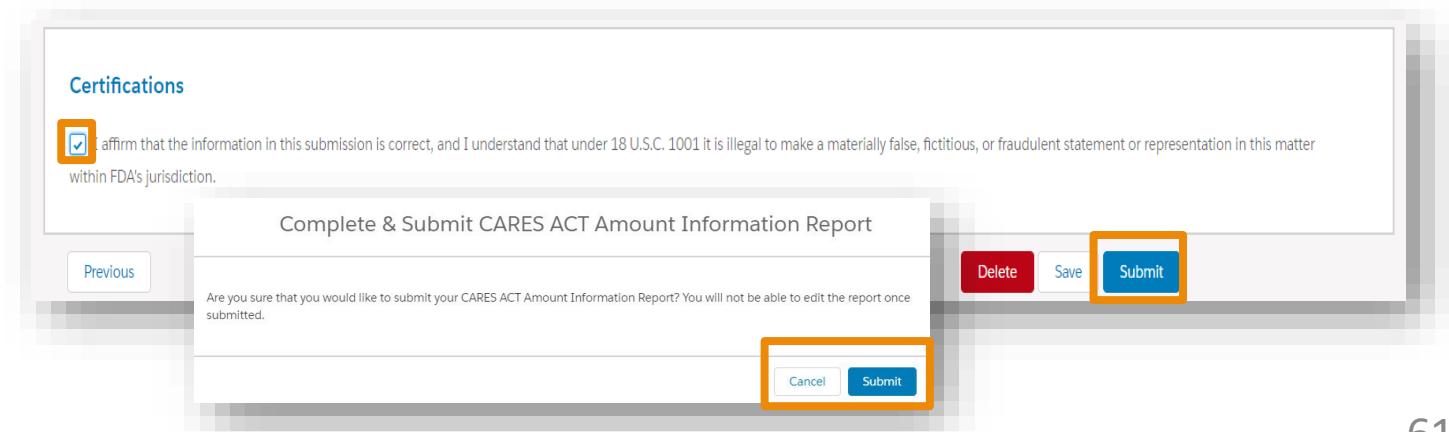
Step 26. If the data has been validated, **Submit** will be active. After validation, the report can be saved or submitted. To submit the report, check the box in the **Certifications** section to affirm that the information you provided in this submission is correct and then click **Submit**.

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

Step 27. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.



The screenshot shows the 'CARES Act Drug Amount Information Reporting' application. On the left, there is a sidebar with 'APPLICATION BUILDER' and 'Submission' tabs, and a 'Need Help?' section with a 'Help Center' link. The main area is titled 'Submission' and contains 'Submission Information' and 'Submission Details' sections. In the 'Submission Information' section, there are fields for 'What year are you submitting for?' (set to 2022), 'Are you submitting a replacement report for a previous submission?' (checkbox 'Yes' is unchecked), 'What product are you reporting on?' (radio buttons for 'Drug Product' and 'API or API + Inactive Ingredients' are shown), 'Is the drug product In Finished Package Form?' (radio buttons for 'Yes' and 'No' are shown, with 'Yes' selected), and 'Would you like to submit the product data manually or by uploading data from a CSV file?' (radio buttons for 'Manually' and 'CSV File' are shown, with 'Manually' selected). The 'Submission Details' section shows 'DUNS: 123456789'. At the bottom, there are 'Delete', 'Save', and 'Validate' buttons, with 'Validate' being highlighted with an orange box.

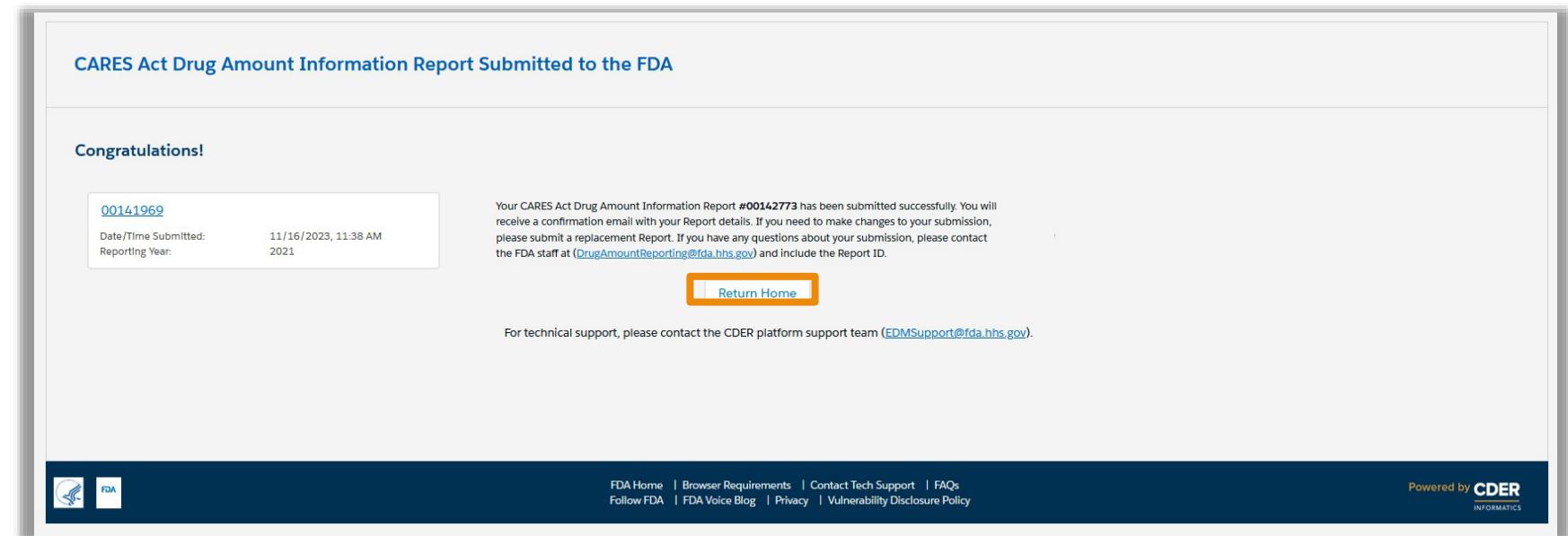


The screenshot shows a confirmation dialog box titled 'Complete & Submit CARES ACT Amount Information Report'. It contains a 'Certifications' section with a checked checkbox and a statement: 'I affirm that the information in this submission is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent statement or representation in this matter within FDA's jurisdiction.' Below this is a message: '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.' At the bottom are 'Delete', 'Save', and 'Submit' buttons, with 'Submit' being highlighted with an orange box. There are also 'Cancel' and 'Submit' buttons at the very bottom of the dialog, with 'Cancel' being highlighted with an orange box.

Manual Submission – Finished Package Form

Step 28. After clicking on **Submit**, there will be a confirmation screen to confirm your report was submitted to the FDA.

Click **Return Home** to log out.



The screenshot shows a confirmation page for a drug amount information report submission. The title is "CARES Act Drug Amount Information Report Submitted to the FDA". A "Congratulations!" message is displayed above a summary box. The summary box contains the Report ID (00141969), Date/Time Submitted (11/16/2023, 11:38 AM), and Reporting Year (2021). To the right, a message states the report was submitted successfully and provides contact information for changes or replacement reports. A "Return Home" button is located below the message. At the bottom, there is footer information including the FDA logo, links to FDA Home, Browser Requirements, Contact Tech Support, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy. The page is powered by CDER INFORMATICS.

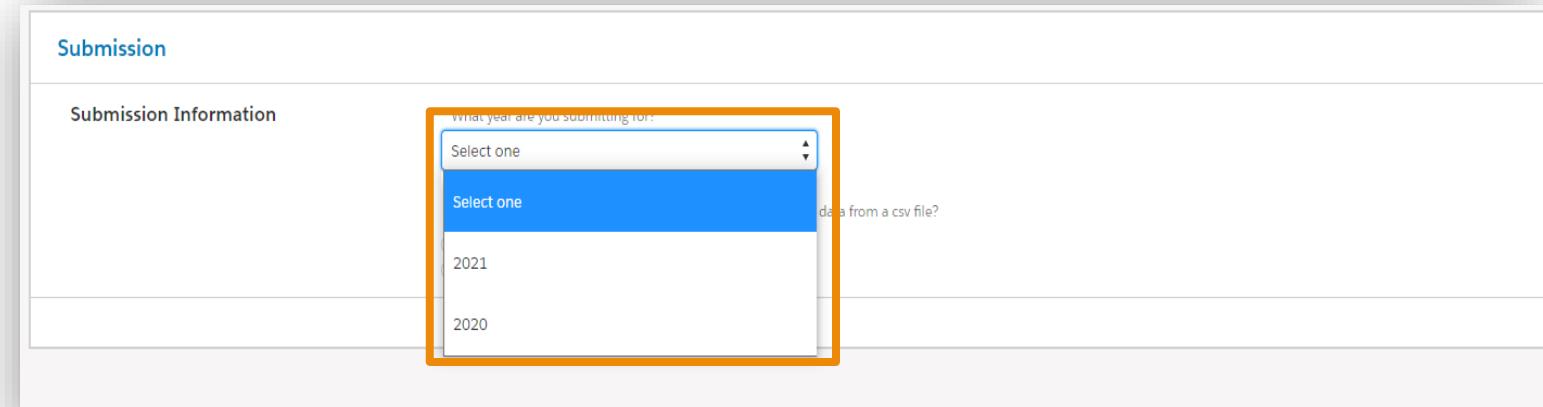
ManualSubmission - Not in Finished Package Form

Manual Submission – Not in Finished Package Form

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

Step 9. If you are submitting a new report, leave “Are you submitting a replacement report for a previous submission” blank and proceed to step 10.

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.



Submission

Submission Information

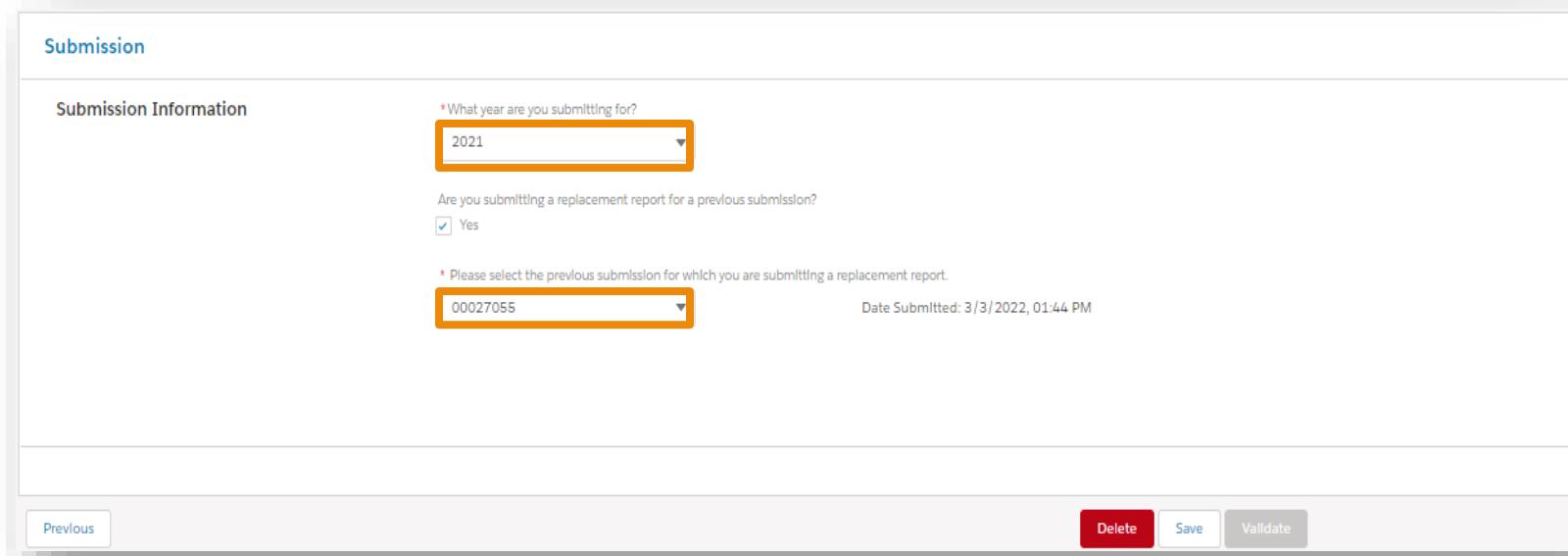
What year are you submitting for?

Select one

2021

2020

Previous Delete Save Validate



Submission

Submission Information

What year are you submitting for?

2021

Are you submitting a replacement report for a previous submission?

Yes

Please select the previous submission for which you are submitting a replacement report.

00027055

Date Submitted: 3/3/2022, 01:44 PM

Previous Delete Save Validate

Manual Submission – Not in Finished Package Form

Step 10. Select that you are reporting on a Drug Product.

Step 11. Select “No” that your product is in Finished Package Form.

Step 12. Select that you would like to submit product data **Manually**.

Step 13. In the confirmation screen, click **Continue**.

Submission

Submission Information

*What year are you submitting for?
2022

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

*What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients

*Is the drug product in Finished Package Form?
 Yes
 No

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

CARES Act Drug Amount Information Report

You are submitting an **Initial CARES Act Drug Amount Information Report**. 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 an **Initial CARES Act Drug Amount Information report**, please delete the Submission and start a new report. Select Cancel to return to the previous page.

Cancel **Continue**

Manual Submission – Not in Finished Package Form

Step 14. To begin to submit product data manually, select **Add Establishment** to enter a DUNS Number.

The screenshot shows a 'Submission' form with the following fields:

- Submission Information**
- *What year are you submitting for?**: A dropdown menu showing '2022'.
- Are you submitting a replacement report for a previous submission?**: A checkbox labeled 'Yes'.
- *What product are you reporting on?**: Radio buttons for 'Drug Product' (selected) and 'API or API + Inactive Ingredients'.
- *Is the drug product in Finished Package Form?**: Radio buttons for 'Yes' (unchecked) and 'No' (selected).
- *Would you like to submit the product data manually or by uploading data from a CSV file?**: Radio buttons for 'Manually' (selected) and 'CSV File'.

At the bottom of the form, there is a button labeled **+ Add Establishment** with a plus sign icon, which is highlighted with an orange rectangular box. Navigation buttons at the bottom include 'Previous', 'Delete', 'Save' (in a red box), and 'Validate'.

Manual Submission – Not in Finished Package Form

Step 15. On the next screen, enter the 9-digit **DUNS Number** and click **Search**. If necessary, add leading zeroes.

If the search for a DUNS number succeeds, the name and address of the matching establishment is displayed.

If this is the correct establishment, click in the radio button on the left and then click **Select**.

If a different establishment is displayed, check that the DUNS number was correctly entered.

Add Establishment by DUNS Number

Establishment Information

*DUNS Number: 123456789

Search

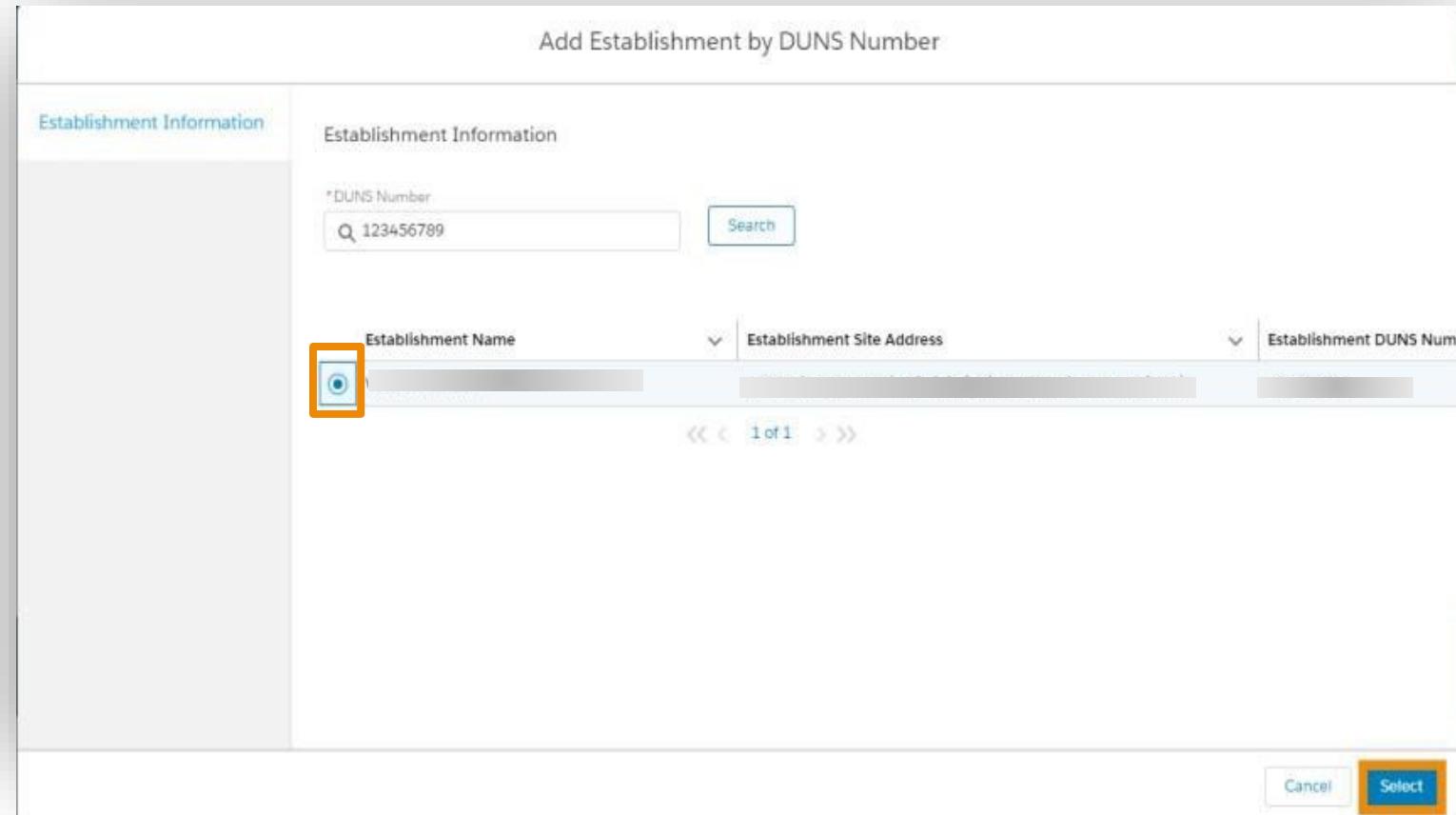
Establishment Name: [Redacted]

Establishment Site Address: [Redacted]

Establishment DUNS Num.: [Redacted]

1 of 1

Cancel Select



Manual Submission – Not in Finished Package Form

Step 16. If the search for a DUNS number fails, an error message and an **+Add Manually** button will appear. Click the button to enter establishment information.

The screenshot shows a search interface for adding an establishment by DUNS number. The search bar contains the number '1111111111'. The 'Search' button is highlighted with an orange box. Below the search bar, an error message reads: 'DUNS Not found. Please search a different DUNS or add manually.' A button labeled '+ Add Manually' is also highlighted with an orange box. At the bottom right of the interface are 'Cancel' and 'Select' buttons.

Manual Submission – Not in Finished Package Form

Step 17. When **+Add Manually** is clicked, a screen for manually entering establishment information appears.

Enter the requested information and then click **Save**.

Add Establishment by DUNS Number

Establishment Information

Manually Add Establishment Information

*Establishment DUNS Number Back to Search

*Establishment Name

*Address Line 1 Address Line 2

*City *Country

State/Province *Zip Code

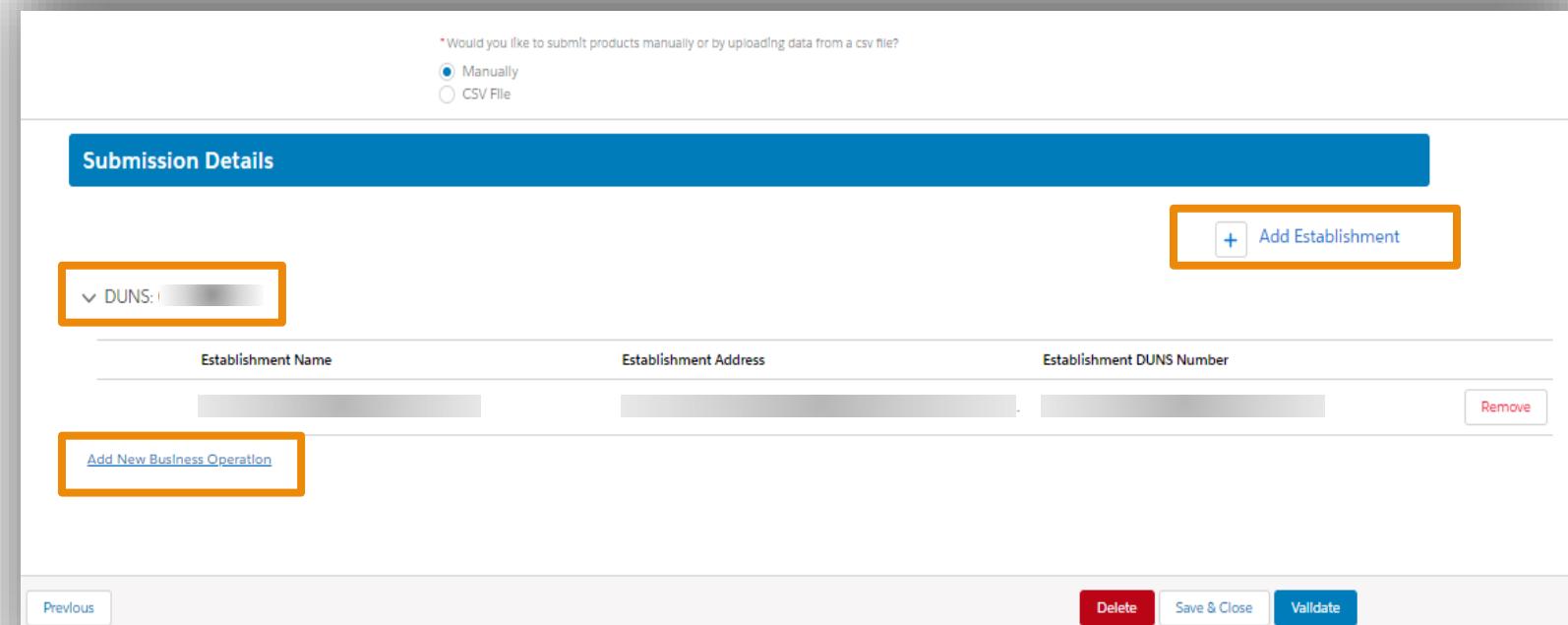
Manual Submission – Not in Finished Package Form

Step 18. After a DUNS number is selected, the Submission screen opens.

Click the arrow next to the DUNS number or click on the DUNS number to expand its entry. Establishment information will be displayed.

Then, click on **Add New Business Operation**.

To enter data for another DUNS number, click on **Add Establishment** and repeat the process of adding a DUNS number.



The screenshot shows a web-based submission interface. At the top, there is a question: "Would you like to submit products manually or by uploading data from a csv file?" with two radio button options: "Manually" (selected) and "CSV File". Below this is a section titled "Submission Details". On the left, there is a dropdown menu labeled "DUNS: [REDACTED]" with an orange border. To the right of the dropdown are three input fields: "Establishment Name" (with a redacted value), "Establishment Address" (with a redacted value), and "Establishment DUNS Number" (with a redacted value). To the right of these fields is a button labeled "Add Establishment" with an orange border. Below the "Establishment Name" field is a link "Add New Business Operation" with an orange border. At the bottom of the screen are three buttons: "Previous", "Delete", "Save & Close", and "Validate".

Manual Submission – Not in Finished Package Form

Step 19. Select an option from the drop-down menu of Business Operations. Each Business Operation can be selected only once, and in any order. Each DUNS can have one Business Operation or multiple Business Operations. There is a **Remove** button next to each DUNS number and Business Operation, if needed.

Step 20. Click **+Add Product** to add a product. Each Business Operation can have one product or multiple products.

The screenshot shows the 'Submission Details' page. At the top right is a blue button with a plus sign and the text 'Add Establishment'. Below it is a section for 'DUNS' with three input fields: 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. To the right of the 'Establishment DUNS Number' field is a red-outlined 'Remove' button. Below this is a note: '* Select the Business Operation.' A dropdown menu is open, showing 'Select one' at the top, followed by 'Manufacture', 'Repack', 'Relabel', 'Transfill', and 'Positron Emission Tomography Drug Production'. To the right of the dropdown is a red-outlined 'Add Product' button. At the bottom right are 'Delete', 'Save', and 'Validate' buttons. On the far left, there is a 'Previous' button.

Manual Submission – Not in Finished Package Form

Step 21. Clicking on **+Add Product** opens a screen to enter an NDC. Enter the **NDC** of the product and then click **Search**.

If the NDC appears on the right, check the box next to it and then click **Select**, which will return you to the **Submission** screen.

If the search fails, and you know the NDC number to be correct, click **+Add Manually**.

The screenshot shows a search interface for adding a drug or biological product by NDC. On the left, a 'SEARCH RESULTS' panel displays an NDC entry with a search icon and a note: 'Allowable formats are: 1234-1234-12, 12345-123-12, and 12345-1234-1'. Below this is a 'Search' button. On the right, a list of NDCs is shown with checkboxes. A specific NDC entry is highlighted with a blue box. In the bottom right corner of the interface, there is a 'Select' button.

Manual Submission – Not in Finished Package Form

Step 22. After clicking on **+Add Manually**, enter the NDC number and then click **Add Product**, which will return you to the **Submission** screen.

Add Drug or Biological Product Manually

*NDC
1234-1234-12

Allowable formats are: 1234-1234-12, 12345-123-12 and 12345-1234-1

Back to Search

Cancel Add Product

Manual Submission – Not in Finished Package Form

NDC	Quantity Manufactured	Quantity Distributed(Non-US)	Dosage Form Units	Intended to Fulfill 21 CFR 314.81	Select Arrow to Enter Monthly Amounts
<input type="checkbox"/> [REDACTED]	12.00 <i>Annual Total</i>	35.00 <i>Annual Total</i>	LITER: L	<input checked="" type="checkbox"/>	
+Add Product Remove Product					

Step 23. In the Submission screen FDA recommends that registrants submit data monthly:

- If Business Operation is Repack or Relabel, click on the **pencil icon** to select **Source NDC**
- Click the **pencil icon** to enter the **dosage form units**
- If applicable, check **Intended to Fulfill 21 CFR 314.81**
- Scroll to the right and click the **Select Arrow to Enter Monthly Amounts** arrow to expand the record so that monthly data can be entered
- Enter **Quantity Manufactured** and **Quantity Distributed** (if Intended to Fulfill 21 CFR 314.81 was selected) as whole numbers or decimals
- Annual Totals will be reflected as the monthly values are entered

Click **+Add Product** and/or **Remove Product** as needed.

Manual Submission – Not in Finished Package Form

Step 24. For each month, enter the amounts manufactured or distributed. Use whole numbers or decimals.

Fields can be left blank for months during which the product was not manufactured or distributed.

The top row, which contains the NDC number, also contains fields for annual totals. The annual total fields will automatically update when a monthly field is updated. Also, annual totals can be entered directly into the top row.

NDC	Quantity Manufactured	Quantity Distributed(Non-US)	Dosage Form Units	Intended to Fulfill 21 CFR 314.81	Select Arrow to Enter Monthly Amounts
<input type="checkbox"/> [REDACTED]	40.00 Annual Total	40.00 Annual Total	LITER: L	<input checked="" type="checkbox"/>	
January	10.00	10.00			
February	20.00	20.00			
March	10.00	10.00			

Manual Submission – Not in Finished Package Form

Step 25. Click the **Validate** button at the bottom of the page.

Step 26. If the data has been validated, **Submit** will be active. 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 27. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.

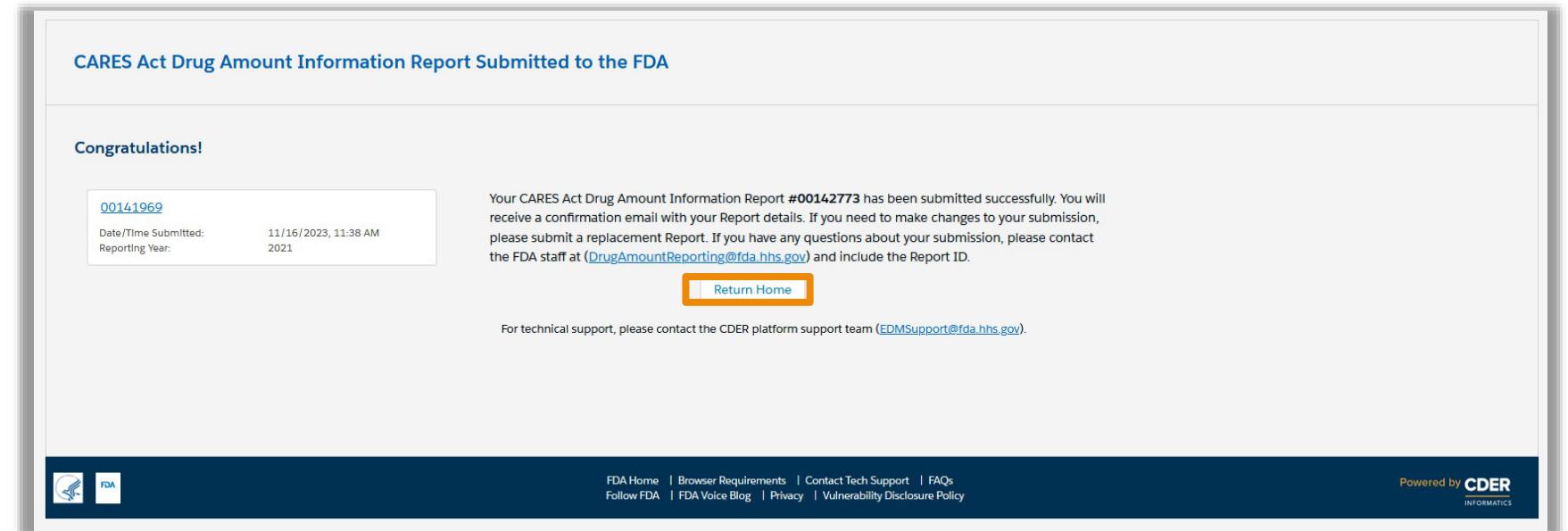
The screenshot shows the 'CARES Act Drug Amount Information Reporting' application. On the left, there is a sidebar with 'APPLICATION BUILDER' and 'Submission' tabs, and a 'Need Help?' section with a 'Help Center' link. The main area is titled 'Submission' and contains 'Submission Information' and 'Submission Details' sections. In the 'Submission Information' section, there are fields for 'What year are you submitting for?' (set to 2022), 'Are you submitting a replacement report for a previous submission?' (unchecked), 'What product are you reporting on?' (radio buttons for 'Drug Product' and 'API or API + Inactive Ingredients' are visible), 'Is the drug product In Finished Package Form?' (radio buttons for 'Yes' and 'No' are visible), and 'Would you like to submit the product data manually or by uploading data from a CSV file?' (radio buttons for 'Manually' and 'CSV File' are visible). The 'Submission Details' section shows 'DUNS: 123456789'. At the bottom, there are 'Delete', 'Save', and 'Validate' buttons, with 'Validate' being highlighted with an orange box.

The screenshot shows a confirmation dialog box titled 'Complete & Submit CARES ACT Amount Information Report'. It contains a message: '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.' Below the message are 'Cancel' and 'Submit' buttons, both highlighted with orange boxes.

Manual Submission – Not in Finished Package Form

Step 28. After clicking on **Submit**, there will be a confirmation screen to confirm your report was submitted to the FDA.

Click **Return Home** to log out.



The screenshot shows a confirmation page for a drug amount information report submission. The title is "CARES Act Drug Amount Information Report Submitted to the FDA". A "Congratulations!" message is displayed. A summary box shows the Report ID (00141969), Date/Time Submitted (11/16/2023, 11:38 AM), and Reporting Year (2021). The main content area states that the report has been submitted successfully and provides contact information for support. A "Return Home" button is at the bottom left, and a footer at the bottom right includes links to FDA Home, Browser Requirements, Contact Tech Support, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy, along with a note that the site is powered by CDER INFORMATICS.

ManualSubmission - APIorAPI+InactiveIngredients

Manual Submission – API or API + Inactive Ingredients

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

Step 9. If you are submitting a new report, leave “Are you submitting a replacement report for a previous submission” blank and proceed to step 10.

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.

Submission

Submission Information

What year are you submitting for?

Select one

2021

2020

Previous Delete Save Validate

Submission

Submission Information

What year are you submitting for?

2021

Are you submitting a replacement report for a previous submission?

Yes

Please select the previous submission for which you are submitting a replacement report.

00027055

Date Submitted: 3/3/2022, 01:44 PM

Previous Delete Save Validate

Manual Submission – API or API + Inactive Ingredients

Step 10. Select that you are reporting on an API or API + Inactive Ingredients.

Step 11. Select that you would like to submit product data **Manually**.

Step 12. In the confirmation screen, click **Continue**.

Submission

Submission Information

*What year are you submitting for?
2021

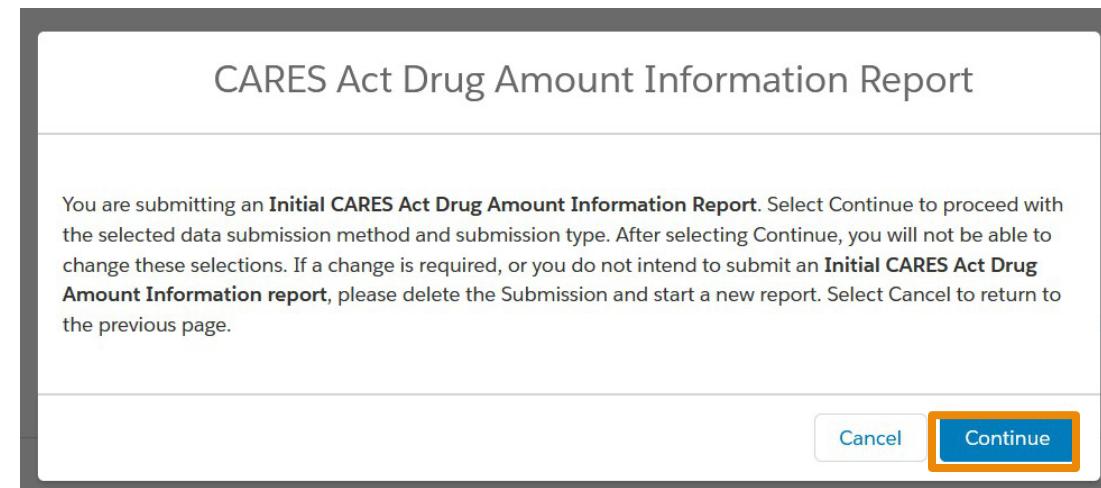
Are you submitting a replacement report for a previous submission?
 Yes

*What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients

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

+ Add Establishment

Previous Delete Save Validate



Manual Submission – API or API + Inactive Ingredients

Step 13. To begin to submit product data manually, select **Add Establishment** to enter a DUNS Number.

Submission

Submission Information

*What year are you submitting for?
2021

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

*What product are you reporting on?
 Drug Product
 API or API + Inactive Ingredients

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

[Previous](#) [Delete](#) [Save](#) [Validate](#)

[+ Add Establishment](#)

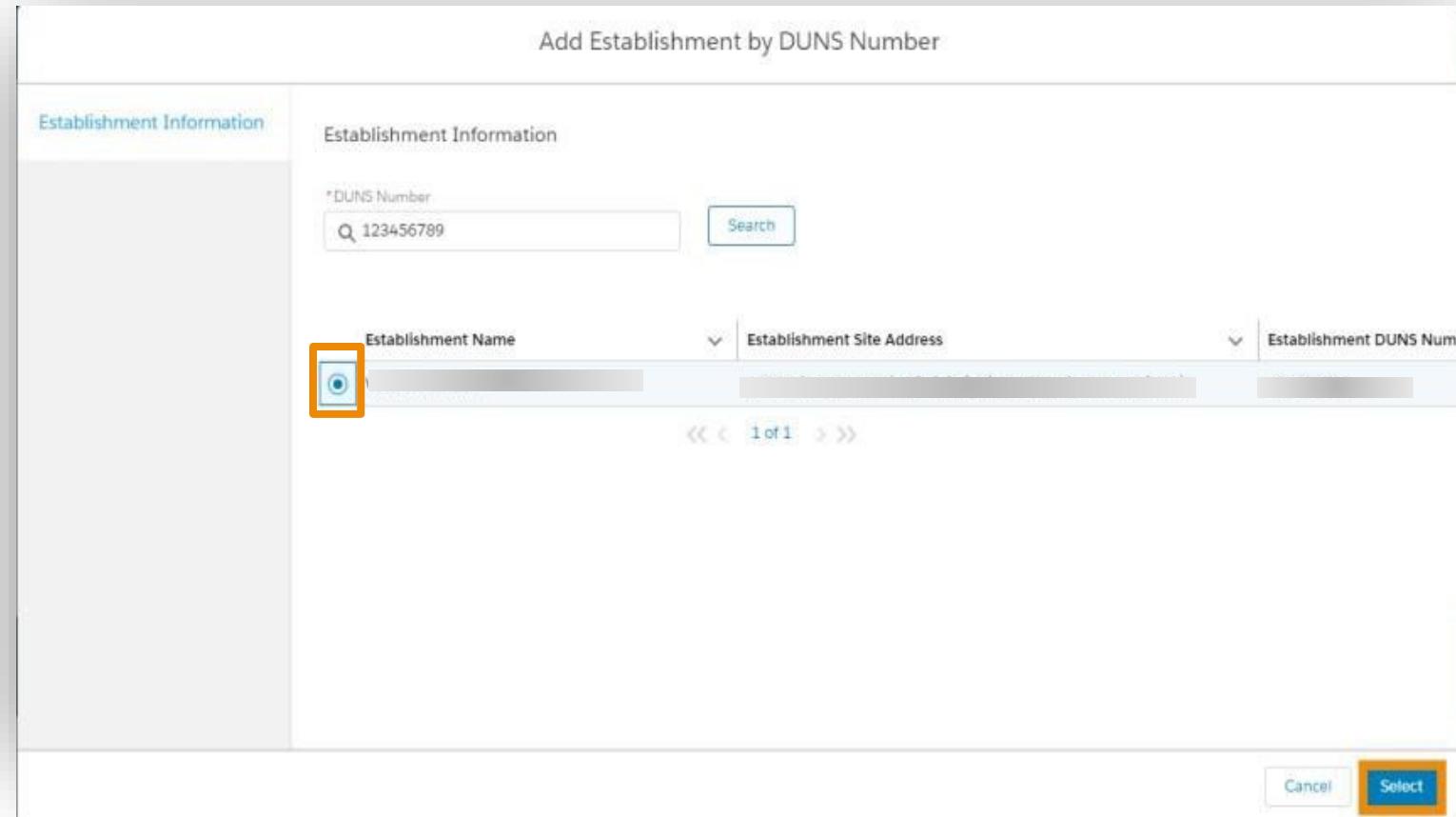
Manual Submission – API or API + Inactive Ingredients

Step 14. On the next screen, enter the 9-digit **DUNS Number** and click **Search**. If necessary, add leading zeroes.

If the search for a DUNS number succeeds, the name and address of the matching establishment is displayed.

If this is the correct establishment, click in the radio button on the left and then click **Select**.

If a different establishment is displayed, check that the DUNS number was correctly entered.



Add Establishment by DUNS Number

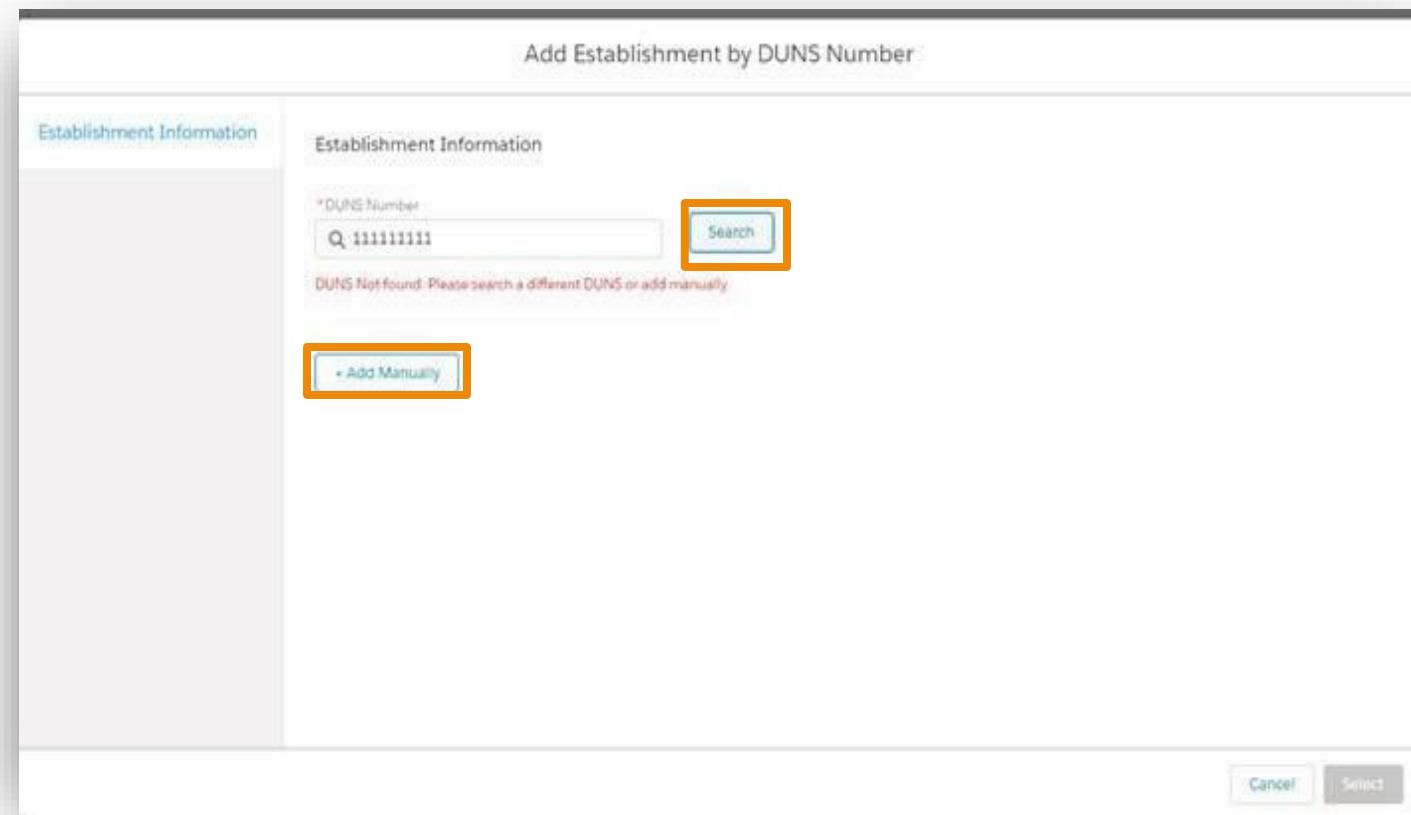
Establishment Information			
	Establishment Name	Establishment Site Address	Establishment DUNS Num.
<input type="radio"/>	Establishment Name (highlighted with orange box)	Establishment Site Address	Establishment DUNS Num.

<< < 1 of 1 > >>

Cancel Select

Manual Submission – API or API + Inactive Ingredients

Step 15. If the search for a DUNS number fails, an error message and an **+Add Manually** button will appear. Click the button to enter establishment information.



Add Establishment by DUNS Number

Establishment Information

*DUNS Number
1111111111

Search

DUNS Not found. Please search a different DUNS or add manually.

+ Add Manually

Cancel Select

Manual Submission – API or API + Inactive Ingredients

Step 16. When **+Add Manually** is clicked, a screen for manually entering establishment information appears.

Enter the requested information and then click **Save**.

Add Establishment by DUNS Number

Establishment Information

Manually Add Establishment Information

*Establishment DUNS Number Back to Search

*Establishment Name

*Address Line 1 Address Line 2

*City *Country

State/Province *Zip Code

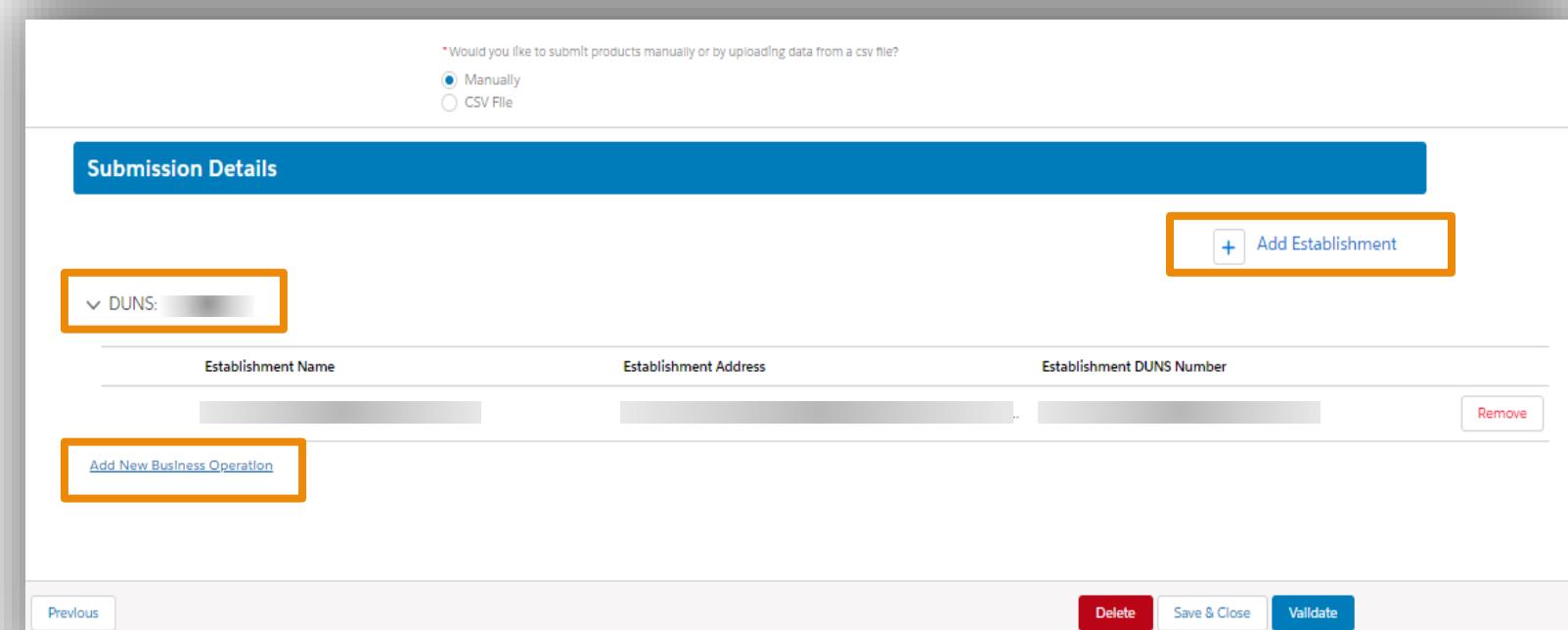
Manual Submission – API or API + Inactive Ingredients

Step 17. After a DUNS number is selected, the Submission screen opens.

Click the arrow next to the DUNS number or click on the DUNS number to expand its entry. Establishment information will be displayed.

Then, click on **Add New Business Operation**.

To enter data for another DUNS number, click on **Add Establishment** and repeat the process of adding a DUNS number.



The screenshot shows a web-based submission interface. At the top, there is a question: "Would you like to submit products manually or by uploading data from a csv file?" with radio buttons for "Manually" (selected) and "CSV File". Below this is a section titled "Submission Details". On the left, a box labeled "DUNS:" is expanded, showing a blurred DUNS number. To the right of this box is a button labeled "Add Establishment" with a plus sign. In the center, there are fields for "Establishment Name" (blurred), "Establishment Address" (blurred), and "Establishment DUNS Number" (blurred). Below these fields is a button labeled "Add New Business Operation". At the bottom of the screen are navigation buttons: "Previous", "Delete", "Save & Close" (in a red box), and "Validate".

Manual Submission – API or API + Inactive Ingredients

Step 18. Select an option from the drop-down menu of Business Operations. Each Business Operation can be selected only once, and in any order. Each DUNS can have one Business Operation or multiple Business Operations. There is a **Remove** button next to each DUNS number and Business Operation, if needed.

Step 19. Click **+Add Product** to add a product. Each Business Operation can have one product or multiple products.

The screenshot shows the 'Submission Details' page with a DUNS number (123456789) selected. The 'Business Operations' dropdown menu is open, showing options: 'Select one', 'API Manufacture', 'Manufacture', 'Repack', 'Relabel', and 'Positron Emission Tomography Drug Production'. The 'Add Product' button is highlighted with an orange box. At the bottom right, there are 'Delete', 'Save', and 'Validate' buttons.

Manual Submission – API or API + Inactive Ingredients

Step 20. Clicking on **+Add Product** opens a screen to enter an NDC. Enter the **NDC** of the product and then click **Search**.

If the NDC appears on the right, check the box next to it and then click **Select**, which will return you to the **Submission** screen.

If the search fails, and you know the NDC number to be correct, click **+Add Manually**.

SEARCH RESULTS

NDC

Allowable formats are: 1234-1234-12, 12345-123-12, and 12345-1234-1

Search

Add Drug or Biological Product by NDC

NDC

Search

+ Add Manually

Select

Manual Submission – API or API + Inactive Ingredients

Step 21. After clicking on **+Add Manually**, enter the NDC number and then click **Add Product**, which will return you to the **Submission** screen.

Add Drug or Biological Product Manually

*NDC
1234-1234-12

Allowable formats are: 1234-1234-12, 12345-123-12 and 12345-1234-1

Back to Search

Cancel Add Product

Manual Submission – API or API + Inactive Ingredients

NDC	Mass/Volume	Unit Of Measure	Activity (Unit of Measure) <small>ⓘ</small>	Average Activity	Minimum Activity	Select Arrow to Enter Monthly Amounts
<input type="checkbox"/>	10.00 <small>Annual Total</small>	L	<input type="button" value=""/>	10.00 <small>Annual Average</small>	5.00 <small>Annual Minimum</small>	<input type="button" value="▼"/>
<small>+Add Product Remove Product</small>						

Step 22. In the Submission screen FDA recommends that registrants submit data monthly:

- Click the **pencil icon** to enter the **Unit of Measure** for API Mass/Volume
- If applicable, Click the **pencil icon** to enter the **Unit of Measure for Activity**
- Scroll to the right and click the **Select Arrow to Enter Monthly Amounts arrow** to expand the record so that monthly data can be entered
- Enter **Mass/Volume** as whole numbers or decimals
- If applicable, enter **Average Activity** and **Minimum Activity** as whole numbers or decimals
- Annual Total, Annual Average Activity, and Annual Minimum Activity will be reflected as the monthly values are entered

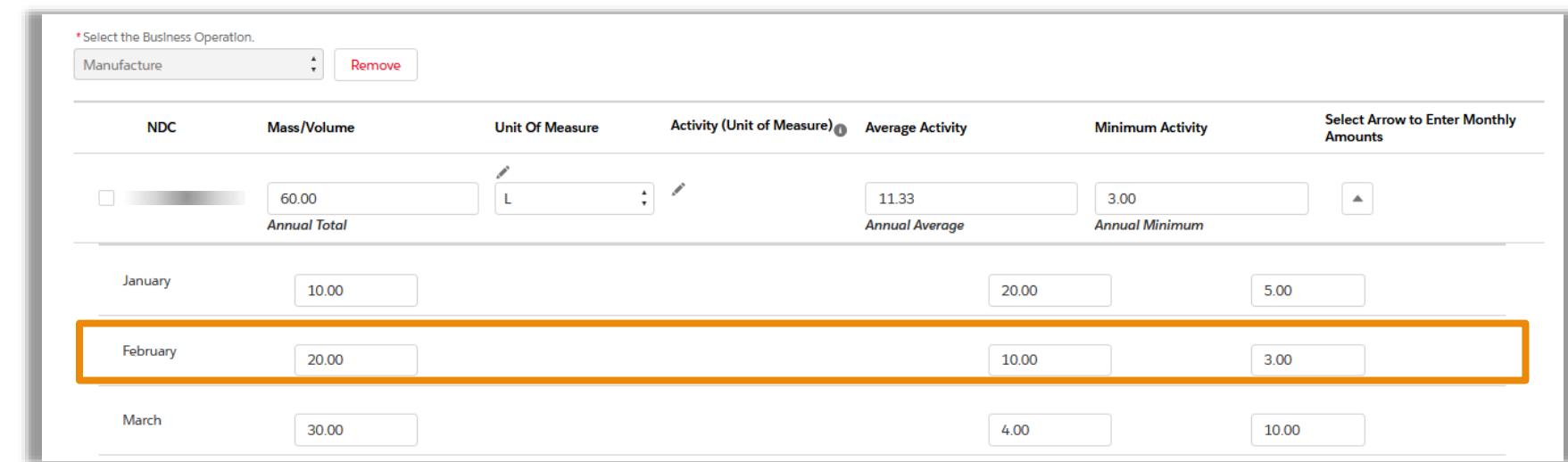
Click **+Add Product** and/or **Remove Product** as needed.

Manual Submission – API or API + Inactive Ingredients

Step 23. For each month, enter the Mass/Volume and Average Activity and Minimum Activity if applicable. Use whole numbers or decimals.

Fields can be left blank for months.

The top row, which contains the NDC number, also contains fields for annual totals. The annual total fields will automatically update when a monthly field is updated.



* Select the Business Operation.						
Manufacture		Remove				
NDC	Mass/Volume	Unit Of Measure	Activity (Unit of Measure)	Average Activity	Minimum Activity	Select Arrow to Enter Monthly Amounts
	60.00 Annual Total	L		11.33 Annual Average	3.00 Annual Minimum	
January	10.00			20.00	5.00	
February	20.00			10.00	3.00	
March	30.00			4.00	10.00	

Manual Submission – API or API + Inactive Ingredients

Step 24. Click the **Validate** button at the bottom of the page.

Step 27. If the data has been validated, **Submit** will be active. 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 28. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.

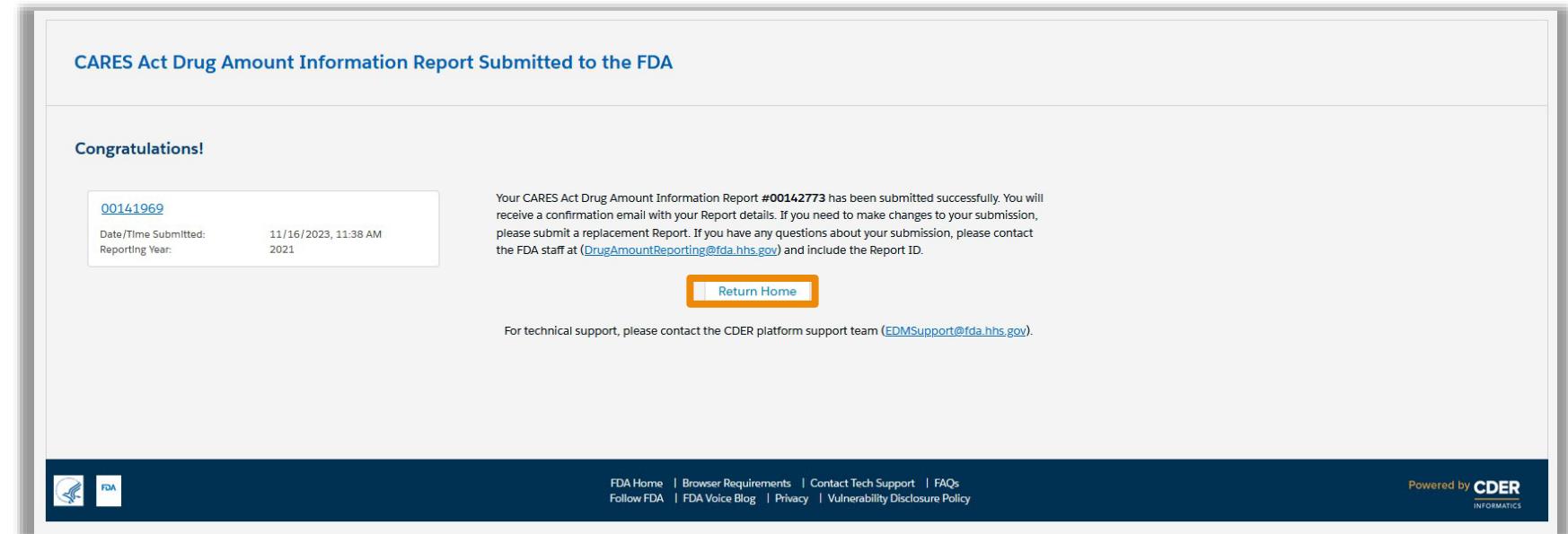
The screenshot shows the 'CARES Act Drug Amount Information Reporting' application. On the left, there is a sidebar with 'APPLICATION BUILDER' and 'Submission' tabs, and a 'Need Help?' section. The main area is titled 'Submission' and contains 'Submission Information' fields: 'What year are you submitting for?' (2022), 'Are you submitting a replacement report for a previous submission?' (Yes), 'What product are you reporting on?' (Drug Product), 'Would you like to submit the product data manually or by uploading data from a CSV file?' (Manually). At the bottom, there is a 'Submission Details' section with a DUNS number (123456789) and a 'Validation' button, which is highlighted with an orange box.

The screenshot shows a confirmation dialog box titled 'Complete & Submit CARES ACT Amount Information Report'. It contains a 'Certifications' section with a checked checkbox and a statement: '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.' Below this is a message: '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.' At the bottom are 'Cancel' and 'Submit' buttons, both highlighted with orange boxes.

Manual Submission – API or API + Inactive Ingredients

Step 25. After clicking on **Submit**,
there will be a confirmation screen
to confirm your report was
submitted to the FDA.

Click **Return Home** to log out.



The screenshot shows a confirmation page for a drug amount information report submission. The title is "CARES Act Drug Amount Information Report Submitted to the FDA". A "Congratulations!" message is displayed. A summary box shows the Report ID (00141969), Date/Time Submitted (11/16/2023, 11:38 AM), and Reporting Year (2021). The main message states: "Your CARES Act Drug Amount Information Report #00142773 has been submitted successfully. You will receive a confirmation email with your Report details. If you need to make changes to your submission, please submit a replacement Report. If you have any questions about your submission, please contact the FDA staff at (DrugAmountReporting@fda.hhs.gov) and include the Report ID." A "Return Home" button is present. The footer includes the FDA logo, links to FDA Home, Browser Requirements, Contact Tech Support, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy, and a note that the site is "Powered by CDER INFORMATICS".

Technical Support and 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.



Technical Support

For all technical support, contact visit the [NextGen Portal Help Center](#)

Learn More Information

Everything related to the portal events can be found on the [NextGen Portal Help Center](#) that provides links to the Resource Center, which includes **Reference Guides and FAQs**.

CDER NextGen Portal Video Tutorial

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