

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](#).

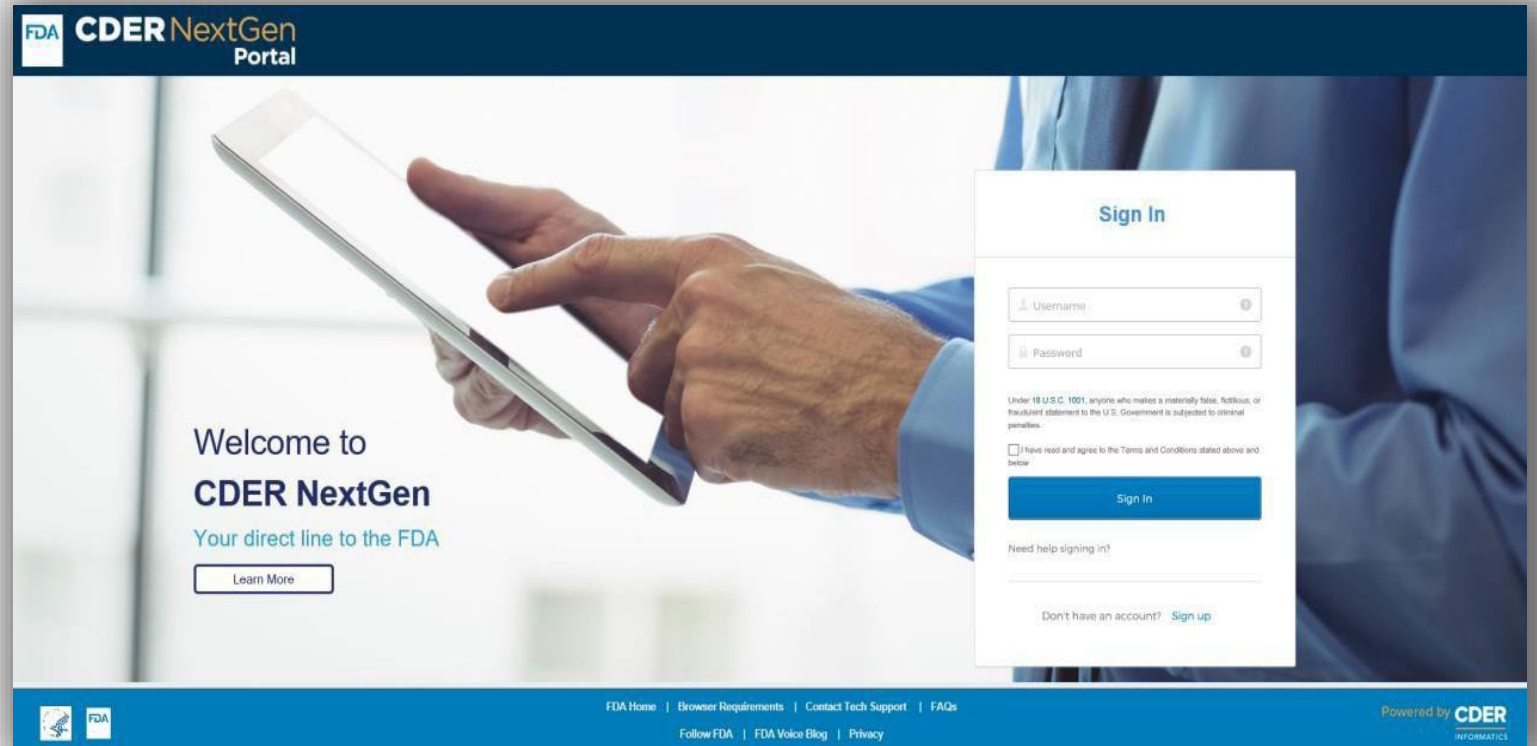
For questions on how to enter or upload data, please email the Drug Amount Reporting Team (DrugAmountReporting@fda.hhs.gov).

CSVFileUploadSubmission

CSV FileUpload – 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

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

CDERNextGen
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.

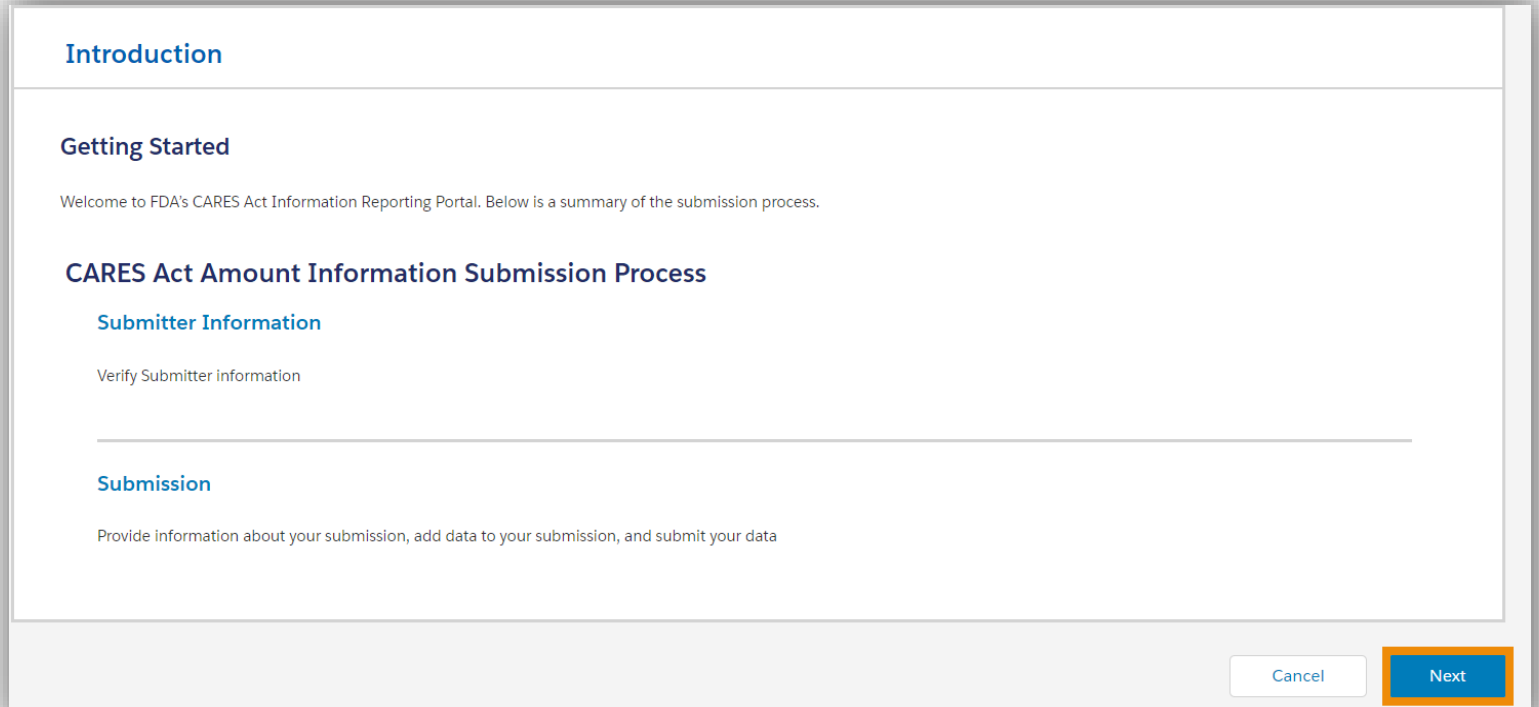
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INFORMATICS

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's CARES Act Information Reporting Portal. The page has a white background with a light blue header bar containing the title 'Introduction'. Below the header, the section 'Getting Started' is displayed, followed by a welcome message: 'Welcome to FDA's CARES Act Information Reporting Portal. Below is a summary of the submission process.' The main content area is titled 'CARES Act Amount Information Submission Process' and contains two sections: 'Submitter Information' with the instruction 'Verify Submitter information' and 'Submission' with the instruction 'Provide information about your submission, add data to your submission, and submit your data'. At the bottom right, there are two buttons: 'Cancel' and 'Next'. The 'Next' button is highlighted with an orange 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

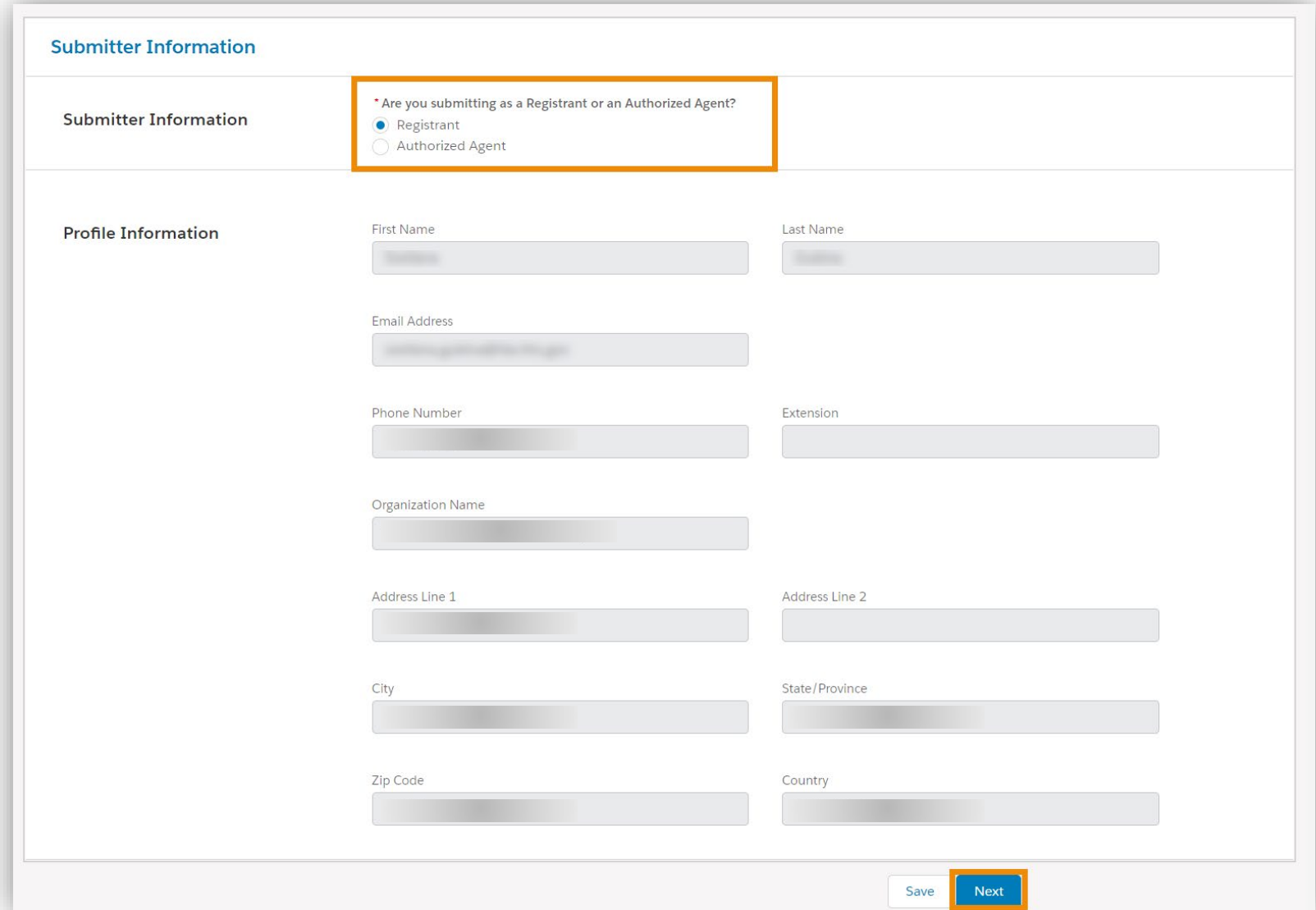
Provide information about your submission, add data to your submission, and submit your data

[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.



The screenshot shows the 'Submitter Information' form. The title 'Submitter Information' is at the top left. Below it, the 'Submitter Information' section contains a question: '*Are you submitting as a Registrant or an Authorized Agent?'. There are two radio buttons: 'Registrant' (which is selected) and 'Authorized Agent'. This section is highlighted with an orange border. Below this is the 'Profile Information' section, which contains several text input fields: 'First Name', 'Last Name', 'Email Address', 'Phone Number', 'Extension', 'Organization Name', 'Address Line 1', 'Address Line 2', 'City', 'State/Province', 'Zip Code', and 'Country'. At the bottom right of the form, there are two buttons: 'Save' and 'Next'. The 'Next' button is highlighted with an orange border.

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

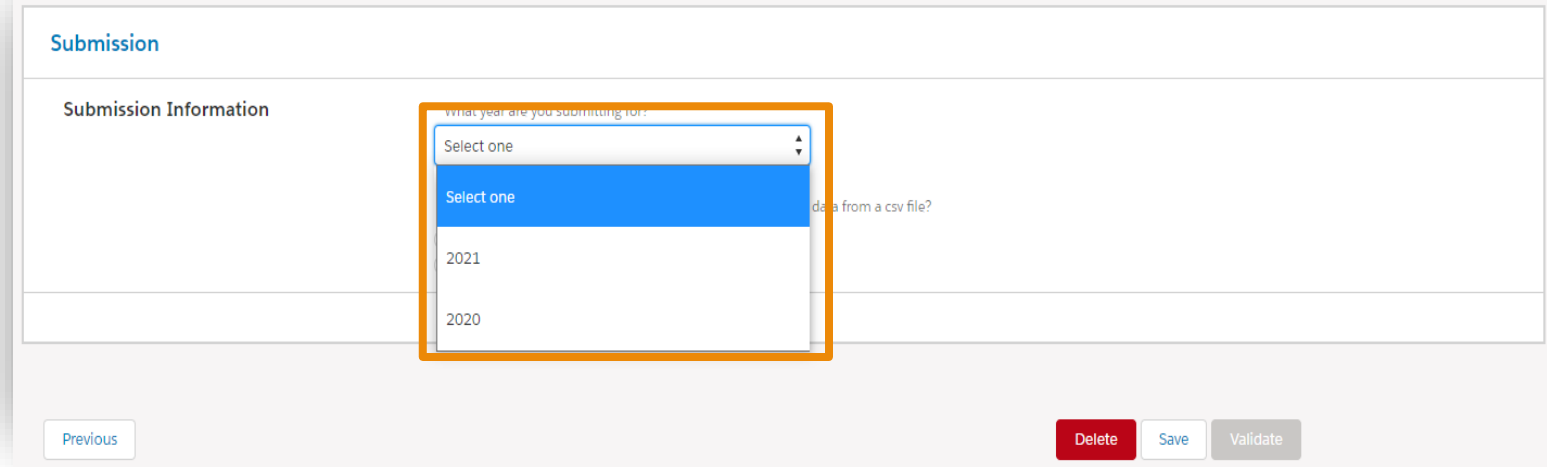
CSVFileUploadSubmission -Finished Package Form

CSV Submission – Finished Package Form

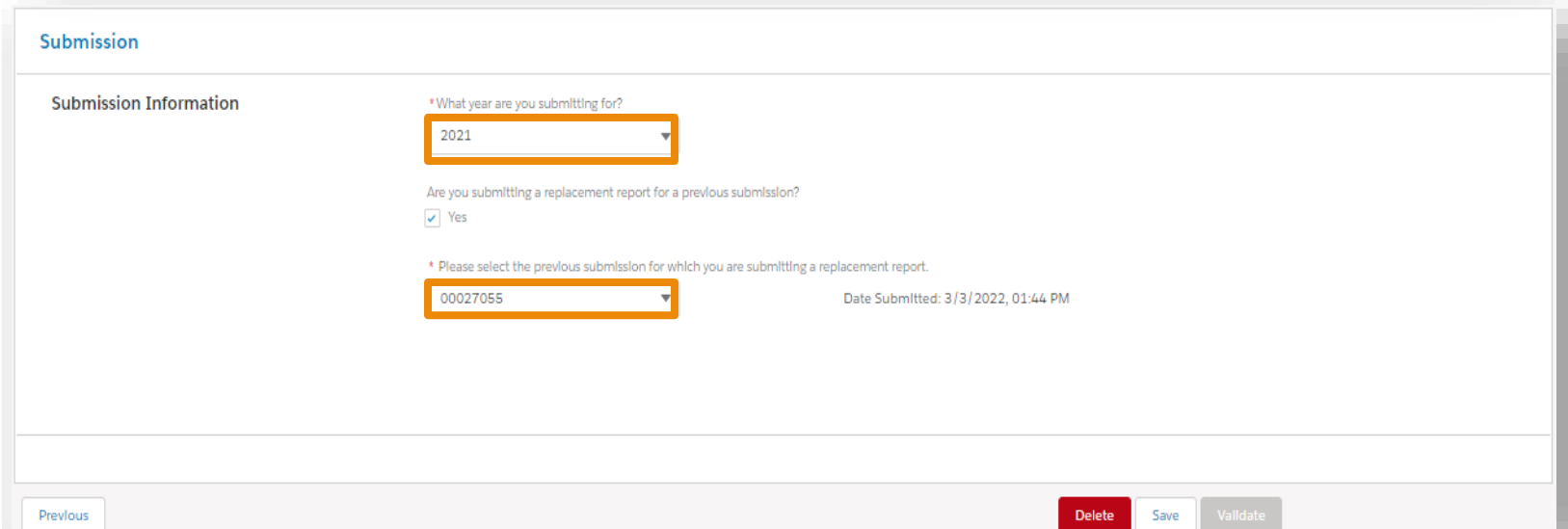
Step 8. In the **Submission** section, select the **year** (calendar year) that the report will cover.

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.



The screenshot shows the 'Submission' section of the 'Finished Package Form'. Under the 'Submission Information' heading, there is a dropdown menu labeled 'What year are you submitting for:'. The dropdown is open, showing options 'Select one', '2021', and '2020'. The '2021' option is highlighted. To the right of the dropdown, there is a checkbox labeled 'data from a csv file?'. At the bottom of the form, there are three buttons: 'Previous', 'Delete', and 'Save', followed by a 'Validate' button.



The screenshot shows the 'Submission' section of the 'Finished Package Form'. Under the 'Submission Information' heading, there is a dropdown menu labeled '* What year are you submitting for?' with '2021' selected. Below this, there is a checkbox labeled 'Are you submitting a replacement report for a previous submission?' which is checked 'Yes'. Below the checkbox, there is a dropdown menu labeled '* Please select the previous submission for which you are submitting a replacement report.' with '00027055' selected. To the right of this dropdown, there is a timestamp 'Date Submitted: 3/3/2022, 01:44 PM'. At the bottom of the form, there are three buttons: 'Previous', 'Delete', and 'Save', followed by a 'Validate' button.

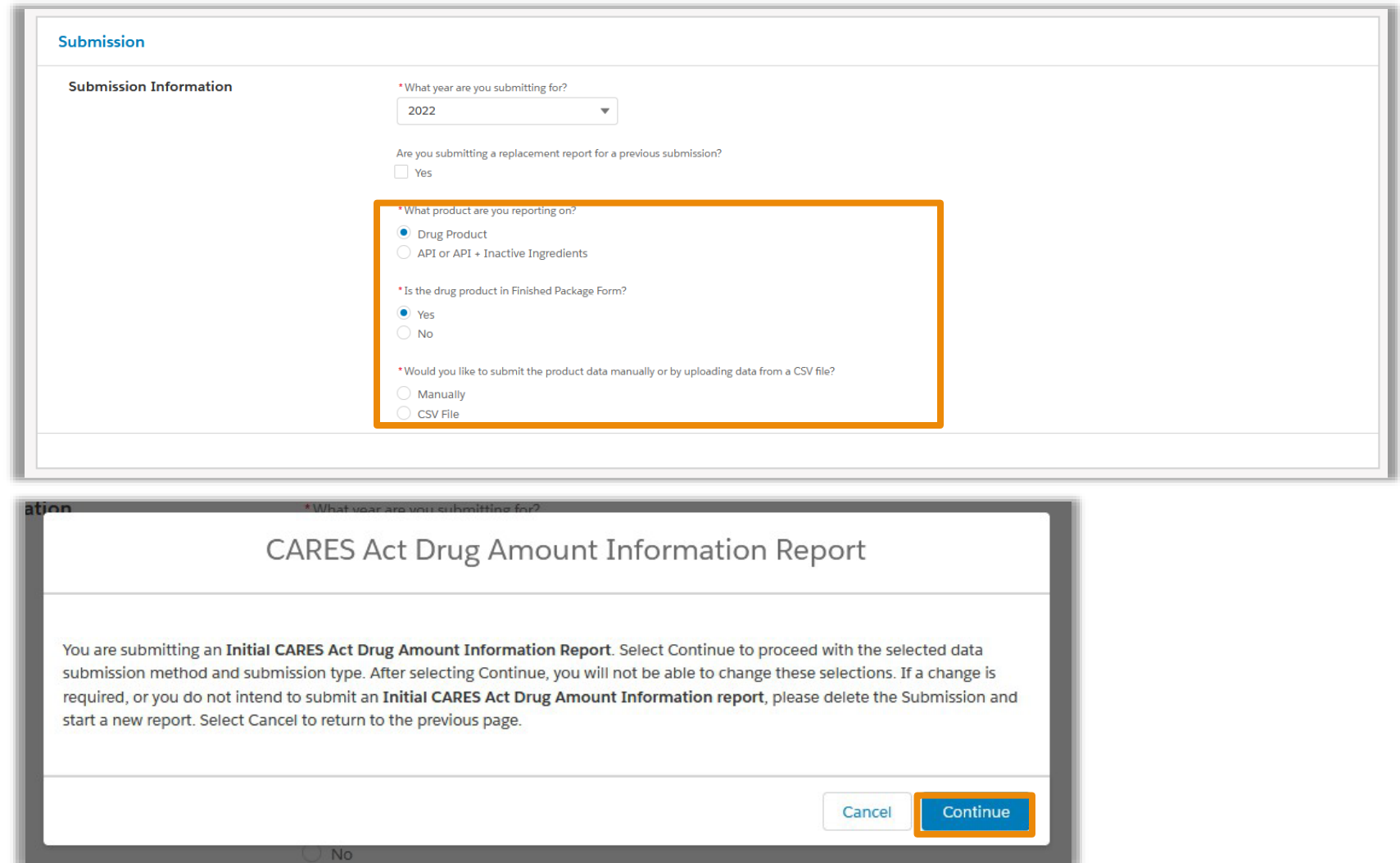
CSV Submission – Finished Package Form

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**.



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.

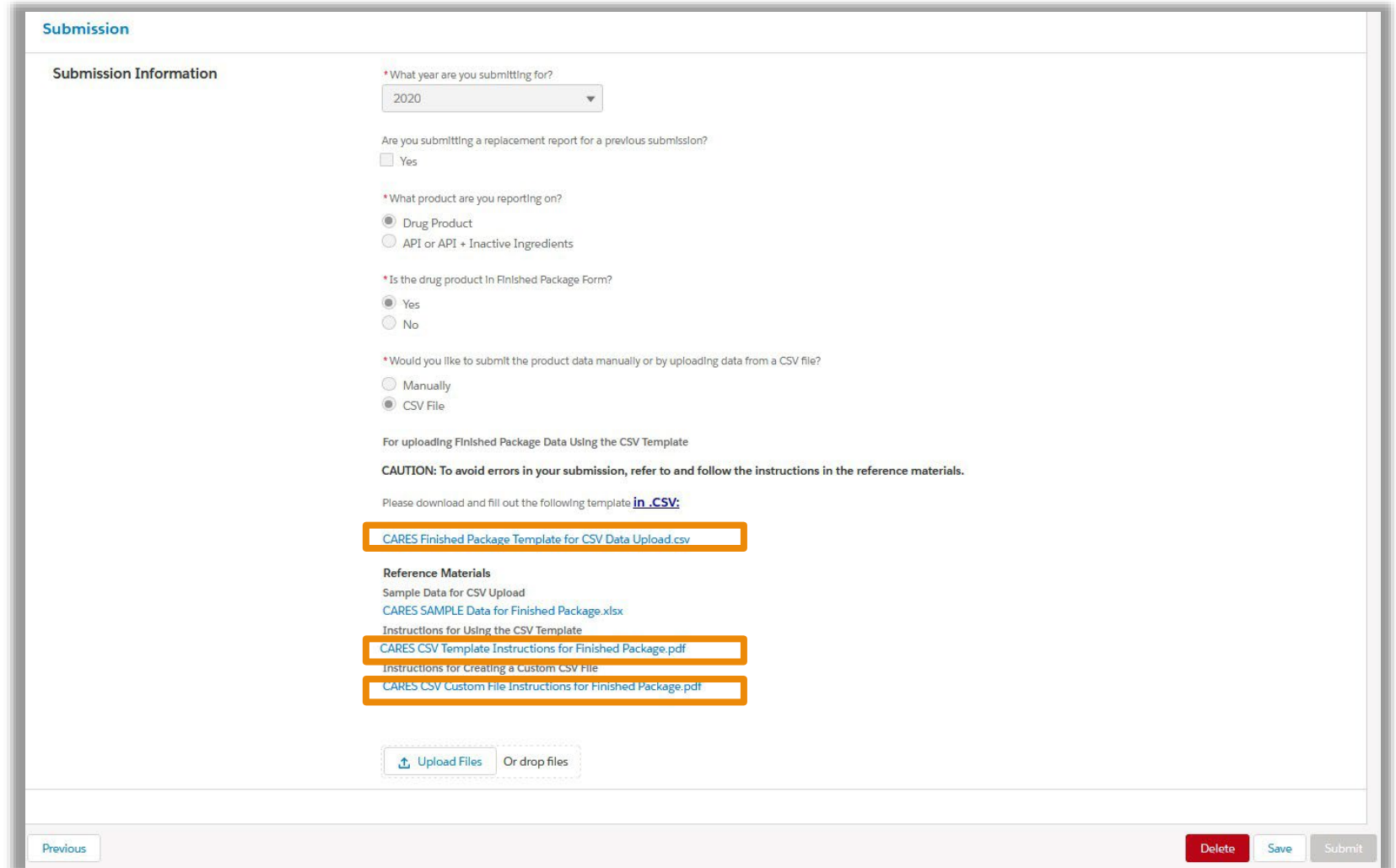
CSV Submission – Finished Package Form

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 the 'Submission Information' form for the CARES Act Amount Information Reporting. The form includes the following fields and options:

- Submission Information**
- *What year are you submitting for?** (Dropdown menu showing 2020)
- Are you submitting a replacement report for a previous submission?** (Radio button for Yes)
- *What product are you reporting on?** (Radio buttons for Drug Product and API or API + Inactive Ingredients)
- *Is the drug product in Finished Package Form?** (Radio buttons for Yes and No)
- *Would you like to submit the product data manually or by uploading data from a CSV file?** (Radio buttons for Manually and CSV File)
- For uploading Finished Package 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 Finished Package Template for CSV Data Upload.csv** (Link highlighted with an orange box)
- Reference Materials**
- Sample Data for CSV Upload**
- CARES SAMPLE Data for Finished Package.xlsx** (Link highlighted with an orange box)
- Instructions for Using the CSV Template**
- CARES CSV Template Instructions for Finished Package.pdf** (Link highlighted with an orange box)
- Instructions for Creating a Custom CSV File**
- CARES CSV Custom File Instructions for Finished Package.pdf** (Link highlighted with an orange box)
- Upload Files** (Button with an upload icon) and **Or drop files** (Text)
- Previous** (Button)
- Delete** (Button)
- Save** (Button)
- Submit** (Button)

CARES Act Amount Information Reporting

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 C	Innermost Package Type	Intended to Fulfill 21 CFR 314.81
2	111111111	Manufacture	12345-678-01		January	10.5		CASE	10	10	BLISTER PACK	No
3	111111111	Manufacture	12345-678-01		February	10		CASE	10	10	BLISTER PACK	No
4	111111111	Manufacture	12345-678-01		March	10		CASE	10	10	BLISTER PACK	No
5	111111111	Manufacture	12345-678-01		April	10		CASE	10	10	BLISTER PACK	No
6	111111111	Manufacture	12345-678-01		May	10		CASE	10.7	10	BLISTER PACK	No
7	111111111	Manufacture	12345-678-01		June	10		CASE	10	10	BLISTER PACK	No
8	111111111	Manufacture	12345-678-01		July	10		CASE	10	10	BLISTER PACK	No
9	111111111	Manufacture	12345-678-01		August	10		CASE	10	10	BLISTER PACK	No
10	111111111	Manufacture	12345-678-01		September	10		CASE	10.8	10	BLISTER PACK	No
11	111111111	Manufacture	12345-678-01		October	10		CASE	10	10	BLISTER PACK	No
12	111111111	Manufacture	12345-678-01		November	10		CASE	10	10	BLISTER PACK	No
13	111111111	Manufacture	12345-678-01		December	10		CASE	10	10	BLISTER PACK	No
14	111111111	Manufacture	12345-678-01		Annual Total	120.5		CASE	121.5	120	BLISTER PACK	No
15	111111111	Manufacture	12345-678-91		January	50	10	CASE	10	10	BLISTER PACK	Yes
16	111111111	Manufacture	12345-678-91		February	50	10	CASE	10	10	BLISTER PACK	Yes
17	111111111	Manufacture	12345-678-91		March	50	10	CASE	10	10	BLISTER PACK	Yes
18	111111111	Manufacture	12345-678-91		April	50	10	CASE	10	10	BLISTER PACK	Yes
19	111111111	Manufacture	12345-678-91		May	50	10	CASE	10	10	BLISTER PACK	Yes
20	111111111	Manufacture	12345-678-91		June	50	10	CASE	10	10	BLISTER PACK	Yes
21	111111111	Manufacture	12345-678-91		July	50	10	CASE	10	10	BLISTER PACK	Yes
22	111111111	Manufacture	12345-678-91		August	50	10	CASE	10	10	BLISTER PACK	Yes
23	111111111	Manufacture	12345-678-91		September	50	10	CASE	10	10	BLISTER PACK	Yes
24	111111111	Manufacture	12345-678-91		October	50	10	CASE	10	10	BLISTER PACK	Yes
25	111111111	Manufacture	12345-678-91		November	0	10	CASE	10	10	BLISTER PACK	Yes
26	111111111	Manufacture	12345-678-91		December	0	0	CASE	10	10	BLISTER PACK	Yes
27	111111111	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 screenshot shows the 'Submission Information' form. The 'What year are you submitting for?' dropdown is set to 2020. The 'Are you submitting a replacement report for a previous submission?' checkbox is unchecked. The 'What product are you reporting on?' radio buttons are set to 'Drug Product'. The 'Is the drug product in Finished Package Form?' radio buttons are set to 'Yes'. The 'Would you like to submit the product data manually or by uploading data from a CSV file?' radio buttons are set to 'CSV File'. Below these fields, there is a section for uploading the CSV file, including a 'CAUTION' note and a link to the 'CARES Finished Package Template for CSV Data Upload.csv'. At the bottom of the form, the 'Upload Files' button is highlighted with an orange box, along with the 'Or drop files' text.

The screenshot shows the 'Upload Files' dialog box. It displays a progress bar for the file 'CSVFileForTemplate (1).csv'. At the bottom right, there is a 'Done' button highlighted with an orange box.

The screenshot shows the 'Submission Information' form with a green 'Success' message at the top: 'File Uploaded Successfully'. The form fields are the same as in the previous screenshot. At the bottom of the form, there is a status bar that reads: '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.'

The screenshot shows the 'Save CARES Act Amount Information Report' dialog box. It contains the text: '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.' At the bottom, there are three buttons: 'Cancel', 'Save', and 'Save & Close', with 'Save & Close' highlighted with an orange box.

CARES Act Amount Information Reporting

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. ****

CARES Act Amount Information Reporting

+ New Report

Search Submissions

Search



[00027123](#)

Draft

Last Modified: 03/04/2022, 12:47 PM

Reporting Year: 2021

Correction to Report: 00026981

✎ Unsubmitted Draft

Submission

Submission Information

* What year are you submitting for?

2021

Are you submitting a replacement report to a previous submission?

☒ Yes

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

00026981

Date Submitted: 3/2/2022, 12:29 PM

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

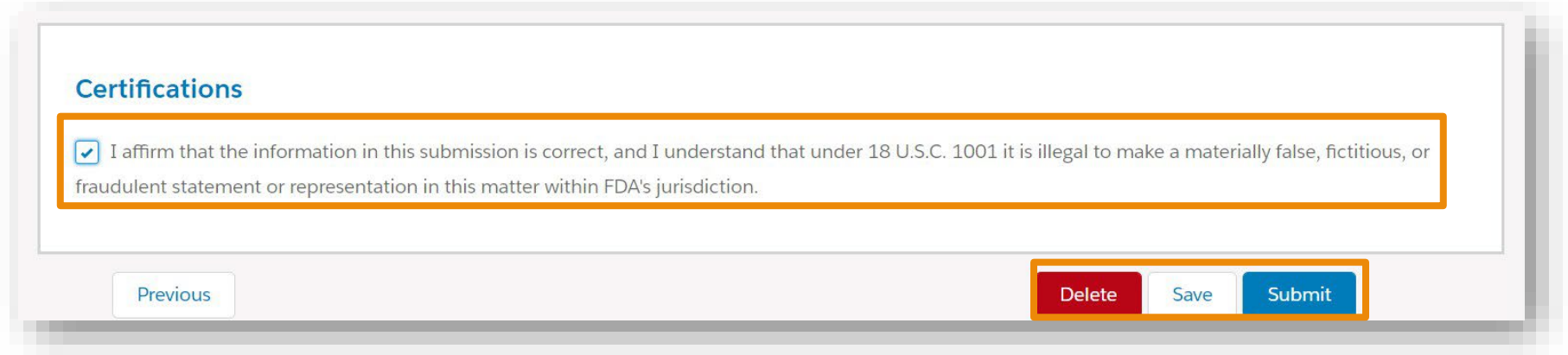
☐ Manually

☒ CSV File

✎ SuccessfulUpload.csv

Your file has successfully processed. You may proceed by certifying your submission and selecting Submit.

CSV Submission – Finished Package Form



Certifications

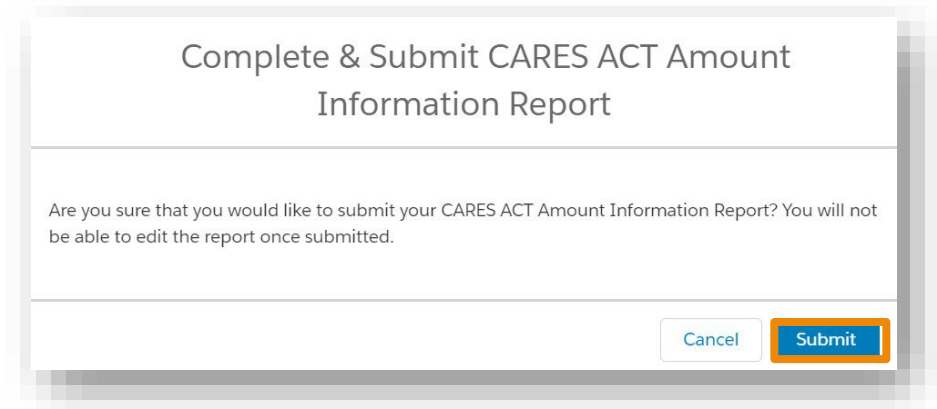
☒ I affirm that the information in this submission is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent statement or representation in this matter within FDA's jurisdiction.

[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.



Complete & Submit CARES ACT Amount
Information Report

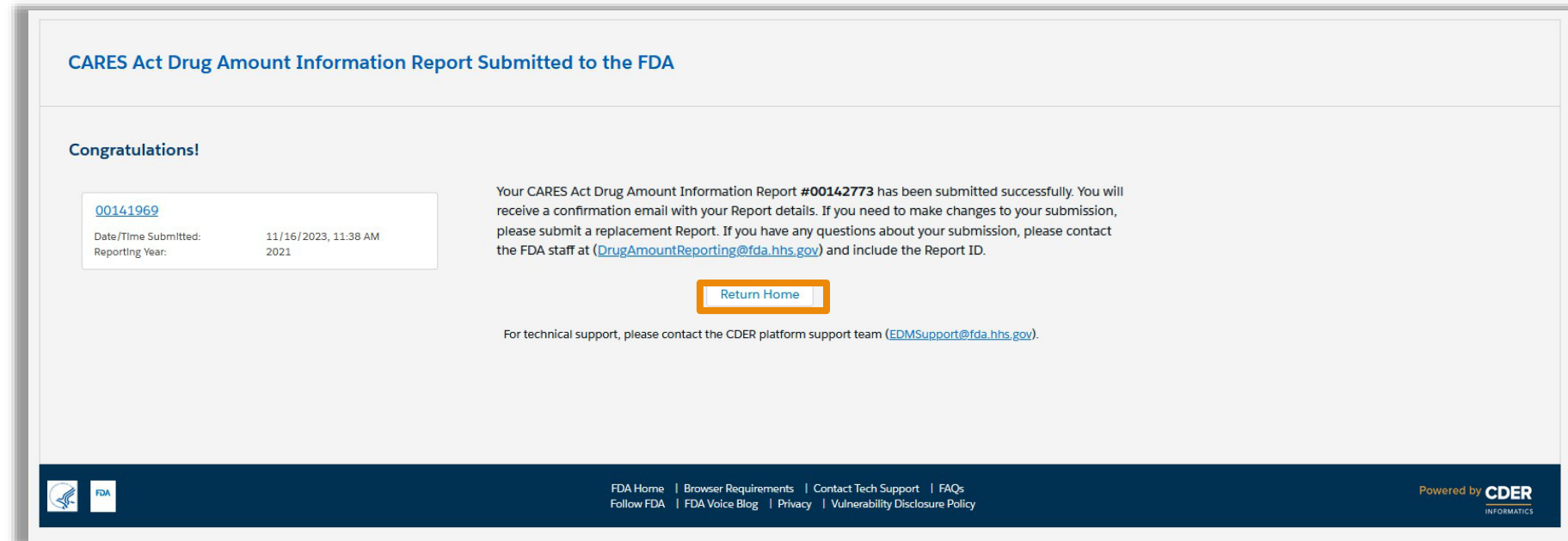
Are you sure that you would like to submit your CARES ACT Amount Information Report? You will not be able to edit the report once submitted.

[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.



The screenshot shows a confirmation page titled "CARES Act Drug Amount Information Report Submitted to the FDA". It features a "Congratulations!" message and a box containing the Report ID "00141969", the submission date "11/16/2023, 11:38 AM", and the reporting year "2021". A "Return Home" button is prominently displayed. The page also includes instructions on how to handle a replacement report and contact information for technical support. The footer contains links to FDA resources and is powered by CDER Informatics.

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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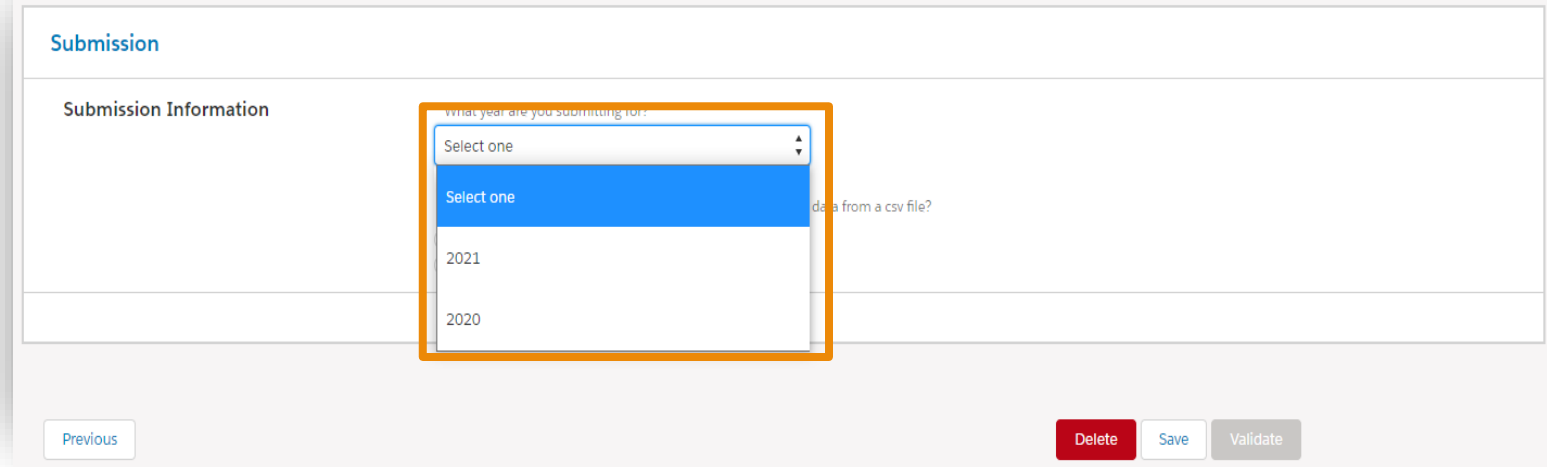
Powered by CDER
INFORMATICS

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

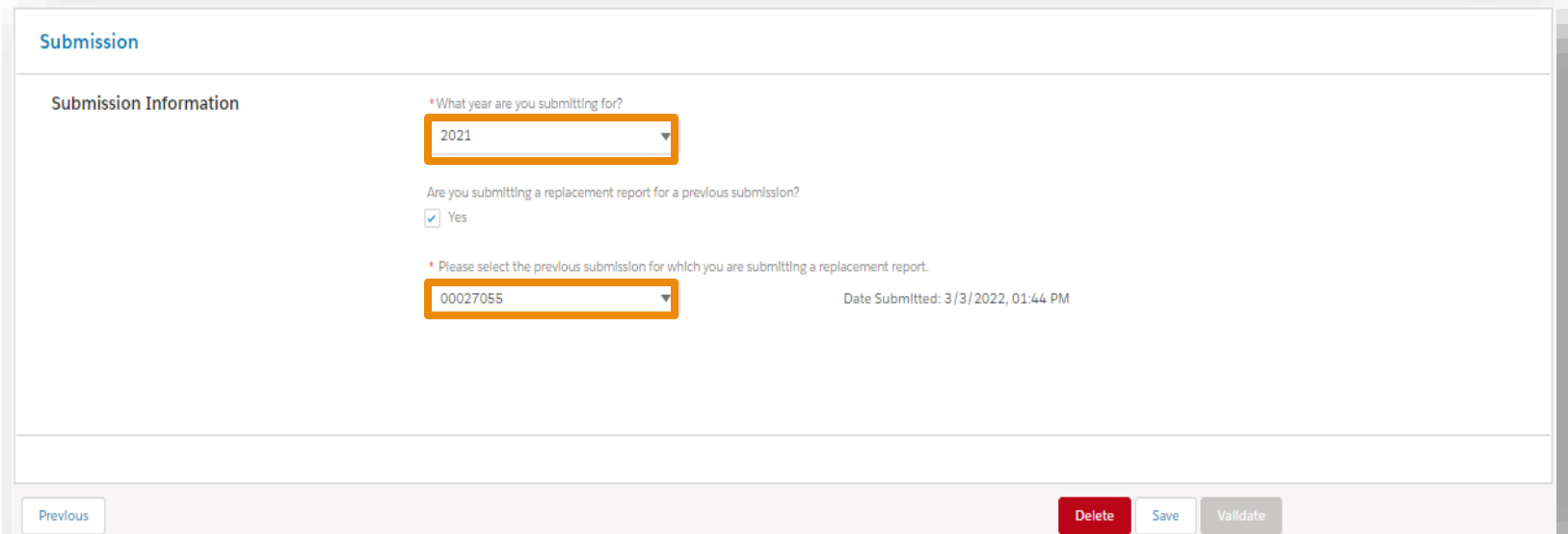
Select one

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

CARES Act Amount Information Reporting

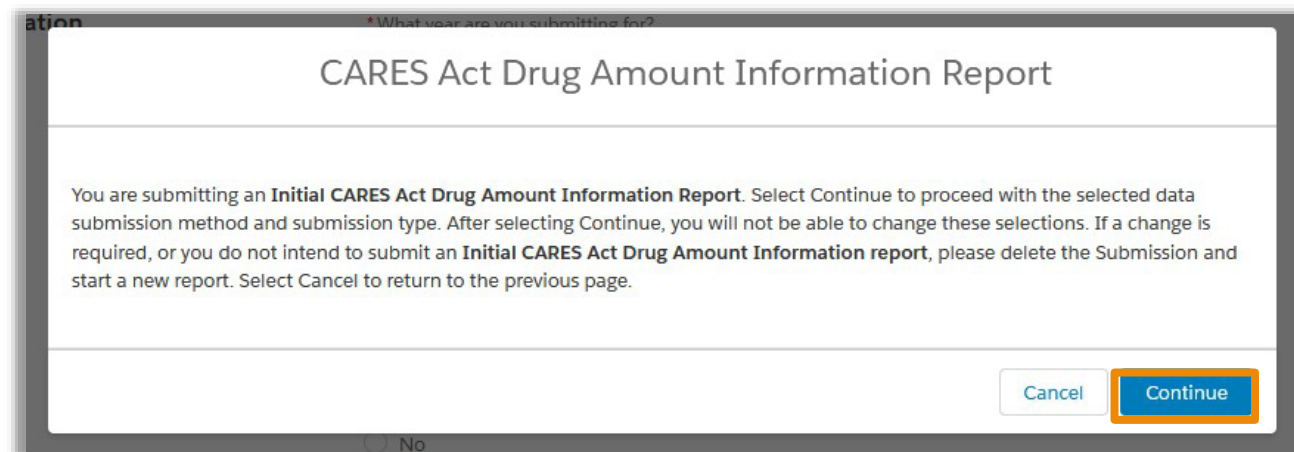
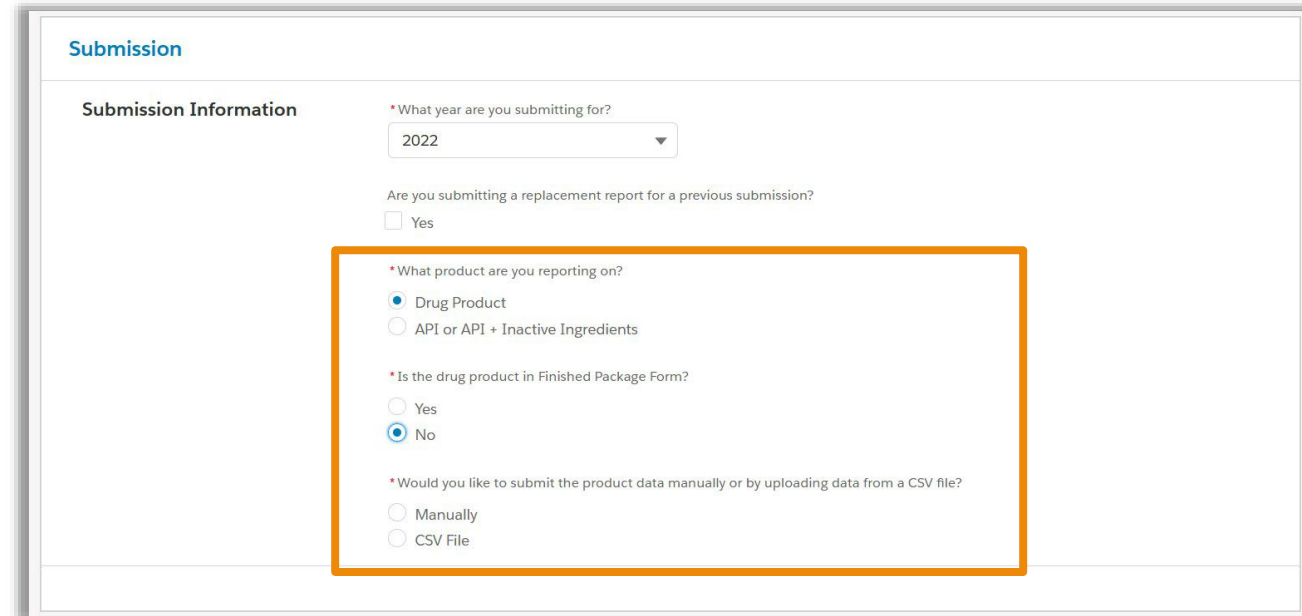
CSV Submission – Not in Finished Package Form

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**.



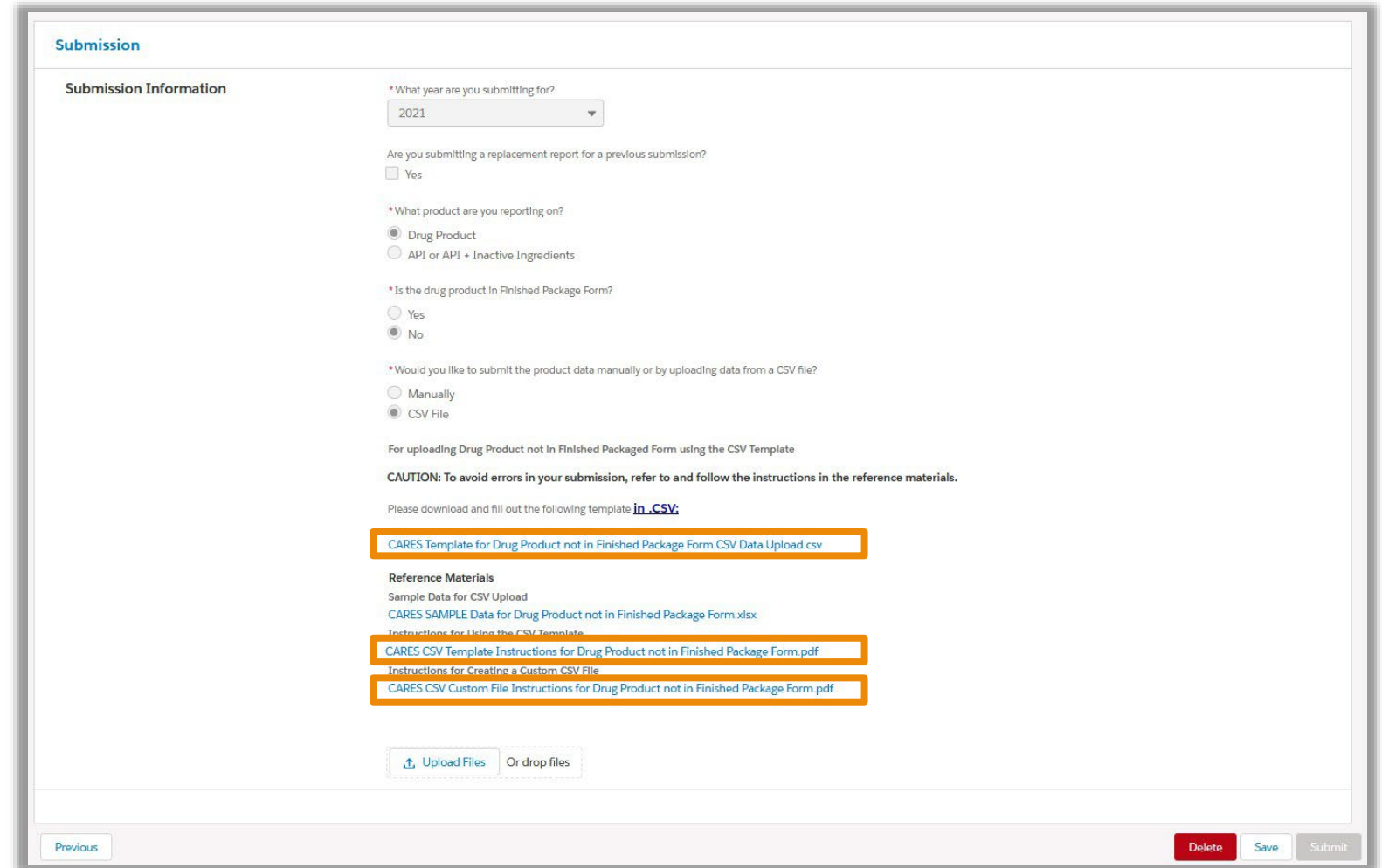
CSV Submission – Not in Finished Package Form

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 Information' form for the CARES Act Amount Information Reporting. The form includes the following fields and options:

- Submission Information**
- * What year are you submitting for?**: A dropdown menu with '2021' selected.
- 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' and 'No' (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' (selected).
- For uploading Drug Product not in Finished Packaged Form 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 Template for Drug Product not in Finished Package Form CSV Data Upload.csv** (highlighted with an orange box)
- Reference Materials**
- Sample Data for CSV Upload**
- CARES SAMPLE Data for Drug Product not in Finished Package Form.xlsx**
- Instructions for Using the CSV Template**
- CARES CSV Template Instructions for Drug Product not in Finished Package Form.pdf** (highlighted with an orange box)
- Instructions for Creating a Custom CSV File**
- CARES CSV Custom File Instructions for Drug Product not in Finished Package Form.pdf** (highlighted with an orange box)
- Upload Files** (button) or **drop files** (text)
- Previous** (button)
- Delete** (button)
- Save** (button)
- Submit** (button)

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
1	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
2	111111111	Manufacture	12345-678-91		January	100	50	TABLET	Yes
3	111111111	Manufacture	12345-678-91		February	100	50	TABLET	Yes
4	111111111	Manufacture	12345-678-91		March	100	50	TABLET	Yes
5	111111111	Manufacture	12345-678-91		April	100	50	TABLET	Yes
6	111111111	Manufacture	12345-678-91		May	100	50	TABLET	Yes
7	111111111	Manufacture	12345-678-91		June	150	50	TABLET	Yes
8	111111111	Manufacture	12345-678-91		July	151	51	TABLET	Yes
9	111111111	Manufacture	12345-678-91		August	150.25	50.25	TABLET	Yes
10	111111111	Manufacture	12345-678-91		September	150	50	TABLET	Yes
11	111111111	Manufacture	12345-678-91		October	150	50	TABLET	Yes
12	111111111	Manufacture	12345-678-91		November	0	50	TABLET	Yes
13	111111111	Manufacture	12345-678-91		December	0	0	TABLET	Yes
14	111111111	Manufacture	12345-678-91		Annual Total	1250.25	550.25	TABLET	Yes
15	222222222	Transfill	12345-678-01		January	600		CAPSULE	No
16	222222222	Transfill	12345-678-01		February	0		CAPSULE	No
17	222222222	Transfill	12345-678-01		March	0		CAPSULE	No
18	222222222	Transfill	12345-678-01		April	0		CAPSULE	No
19	222222222	Transfill	12345-678-01		May	100		CAPSULE	No
20	222222222	Transfill	12345-678-01		June	0		CAPSULE	No
21	222222222	Transfill	12345-678-01		July	0		CAPSULE	No
22	222222222	Transfill	12345-678-01		August	0		CAPSULE	No
23	222222222	Transfill	12345-678-01		September	700		CAPSULE	No
24	222222222	Transfill	12345-678-01		October	0		CAPSULE	No
25	222222222	Transfill	12345-678-01		November	0		CAPSULE	No
26	222222222	Transfill	12345-678-01		December	900		CAPSULE	No
27	222222222	Transfill	12345-678-01		Annual Total	2300		CAPSULE	No

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”

CARES Act Amount Information Reporting

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 shows the 'Submission Information' form. At the bottom, the 'Upload Files' button is highlighted with an orange rectangle. The form includes fields for 'What year are you submitting for?' (set to 2021), 'Are you submitting a replacement report for a previous submission?' (Yes/No), 'What product are you reporting on?' (Drug Product, API or API + Inactive Ingredients), 'Is the drug product in Finished Package Form?' (Yes/No), and 'Would you like to submit the product data manually or by uploading data from a CSV file?' (Manually, CSV File). Below these are links for 'Reference Materials' and a 'CAUTION' note.

The screenshot shows the 'Upload Files' dialog box. It displays a progress bar for 'CSVFileForTemplate (1).csv' and a 'Done' button at the bottom right.

The screenshot shows the 'Submission' page with a green 'Success' message: 'File Uploaded Successfully'. At the bottom, the 'Save & Close' button is highlighted with an orange rectangle. The form content is identical to the previous screenshot.

The screenshot shows the 'Save CARES Act Amount Information Report' dialog box. It contains instructions: 'Select "Save" to save your progress and stay on the page or select "Save and Close" to save your progress and leave the page. Select "Cancel" to return to the current page.' At the bottom are 'Cancel', 'Save', and 'Save & Close' buttons.

CARES Act Amount Information Reporting

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. ****

CARES Act Amount Information Reporting

+ New Report

Search Submissions

Search



[00027123](#)

Draft

Last Modified: 03/04/2022, 12:47 PM

Reporting Year: 2021

Correction to Report: 00026981

✎ Unsubmitted Draft

Submission

Submission Information

* What year are you submitting for?

2021

Are you submitting a replacement report to a previous submission?

☒ Yes

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

00026981

Date Submitted: 3/2/2022, 12:29 PM

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

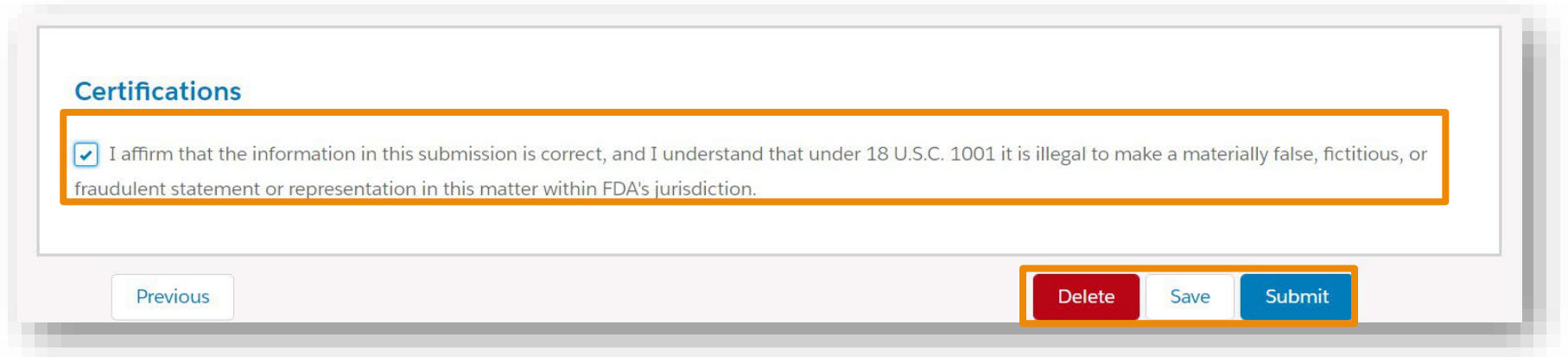
☐ Manually

☒ CSV File

✎ SuccessfulUpload.csv

Your file has successfully processed. You may proceed by certifying your submission and selecting Submit.

CSV Submission – Not In Finished Package Form

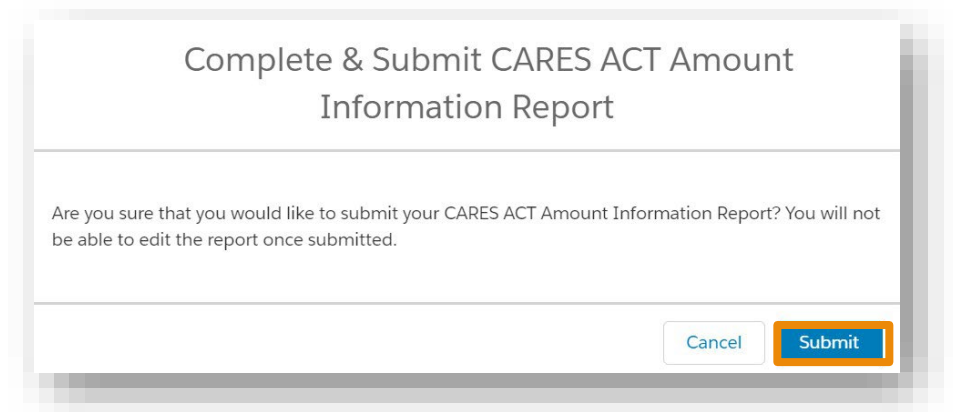


The screenshot shows a web form titled "Certifications". Inside the form, there is a checkbox that is checked, followed by the text: "I affirm that the information in this submission is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent statement or representation in this matter within FDA's jurisdiction." Below the text area, there are three buttons: "Previous", "Delete", and "Submit". The "Delete" and "Submit" buttons are highlighted with orange borders.

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.

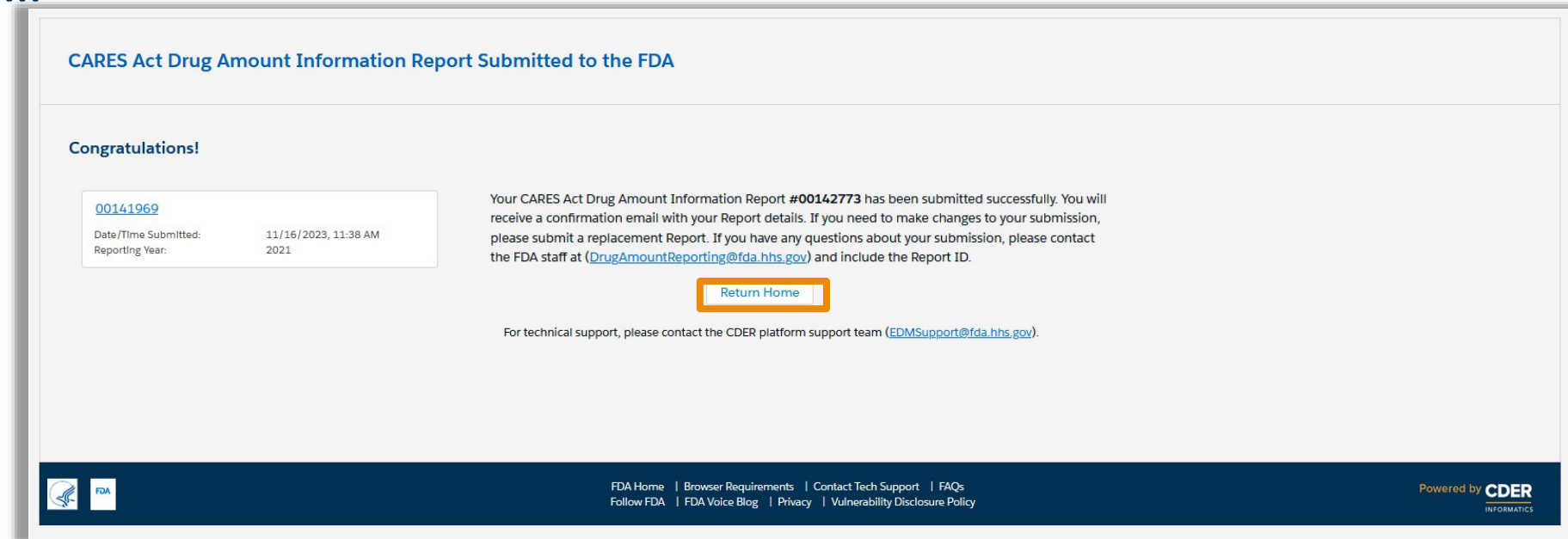


The screenshot shows a confirmation screen titled "Complete & Submit CARES ACT Amount Information Report". Below the title, there is a text box containing the question: "Are you sure that you would like to submit your CARES ACT Amount Information Report? You will not be able to edit the report once submitted." At the bottom right of the screen, there are two buttons: "Cancel" and "Submit". The "Submit" button is 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.



The screenshot shows a confirmation page titled "CARES Act Drug Amount Information Report Submitted to the FDA". It features a "Congratulations!" message and a box containing the Report ID [00141969](#), the submission date/time (11/16/2023, 11:38 AM), and the reporting year (2021). A message states that the report #00142773 was submitted successfully and provides instructions for replacements and contact information. A "Return Home" button is highlighted with an orange border. Technical support contact information is also provided at the bottom of the main content area.

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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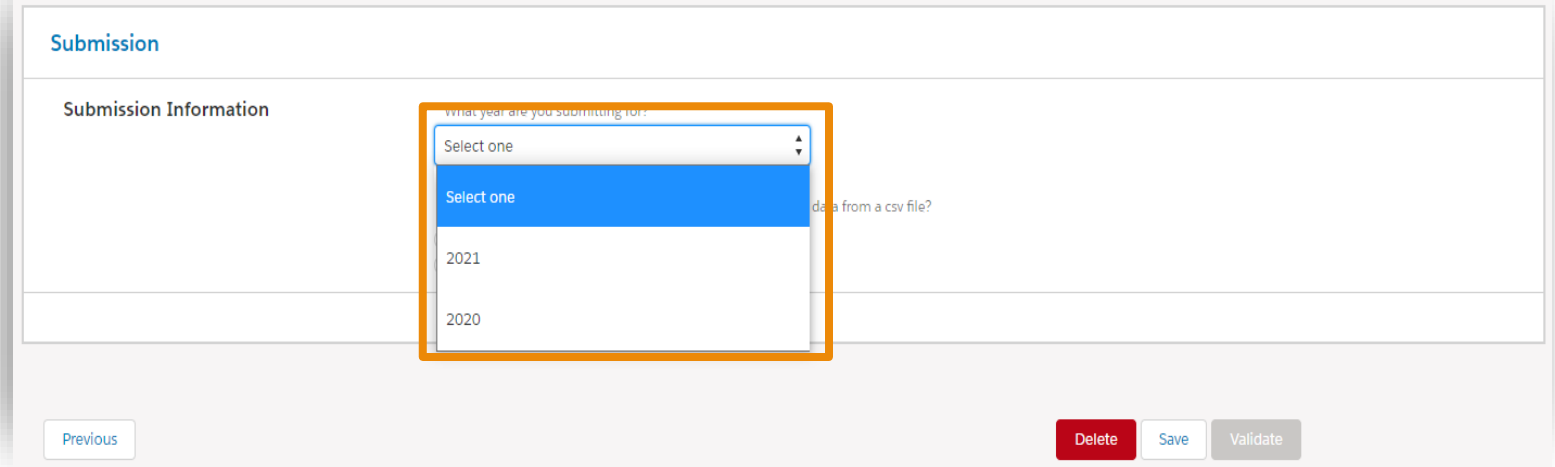
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INFORMATICS

CSVFileUploadSubmission - APIorAPI+InactiveIngredients

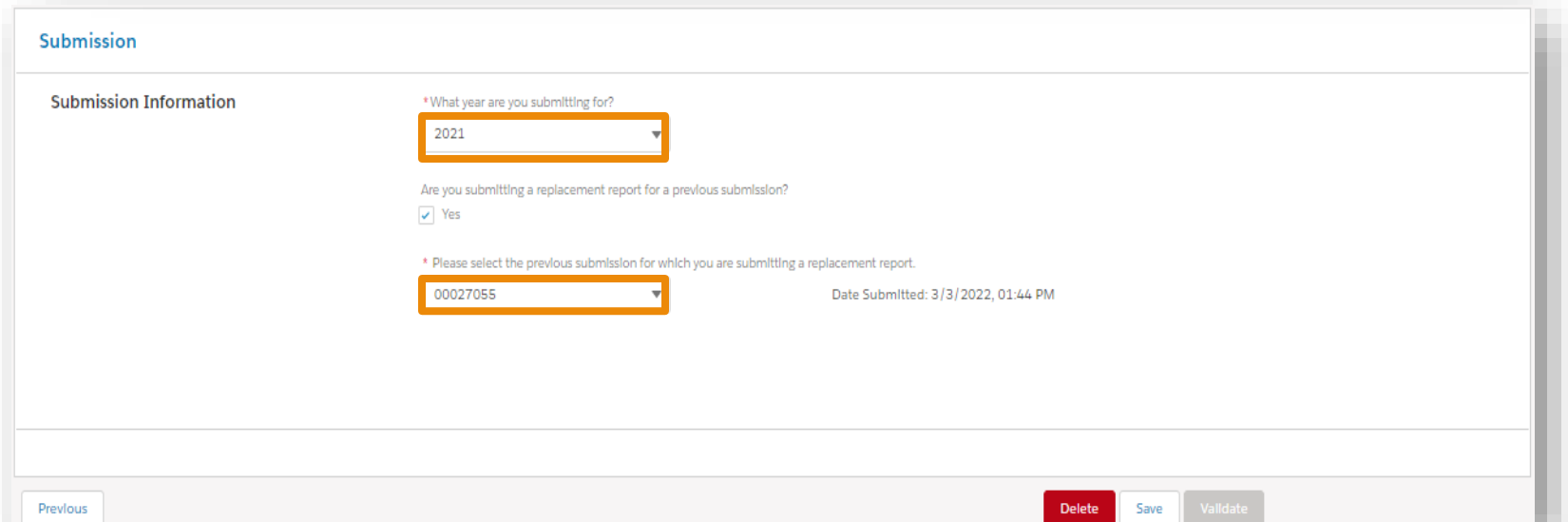
CSV Submission – API or API + Inactive Ingredients

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.



The screenshot shows the 'Submission' form with the 'Submission Information' section. A dropdown menu is open for the question 'What year are you submitting for:'. The menu shows 'Select one' at the top, followed by '2021' and '2020'. The '2021' option is highlighted in blue. Below the dropdown, there is a checkbox for 'Are you submitting a replacement report for a previous submission?' and a 'Previous' button. At the bottom right, there are 'Delete', 'Save', and 'Validate' buttons.



The screenshot shows the 'Submission' form with the 'Submission Information' section. The 'What year are you submitting for:' dropdown is now closed and shows '2021'. Below it, the checkbox for 'Are you submitting a replacement report for a previous submission?' is checked. Below that, a dropdown menu is open for the question 'Please select the previous submission for which you are submitting a replacement report.', showing '00027055'. To the right of this dropdown, the text 'Date Submitted: 3/3/2022, 01:44 PM' is displayed. At the bottom right, there are 'Delete', 'Save', and 'Validate' buttons.

CARES Act Amount Information Reporting

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**.

The screenshot shows the 'Submission' form with the following fields and selections:

- Submission Information**
 - * What year are you submitting for?
 - 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

The section containing the product type, finished package form, and submission method questions is highlighted with an orange border.

The screenshot shows the confirmation screen titled 'CARES Act Drug Amount Information Report'. The text reads:

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.

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

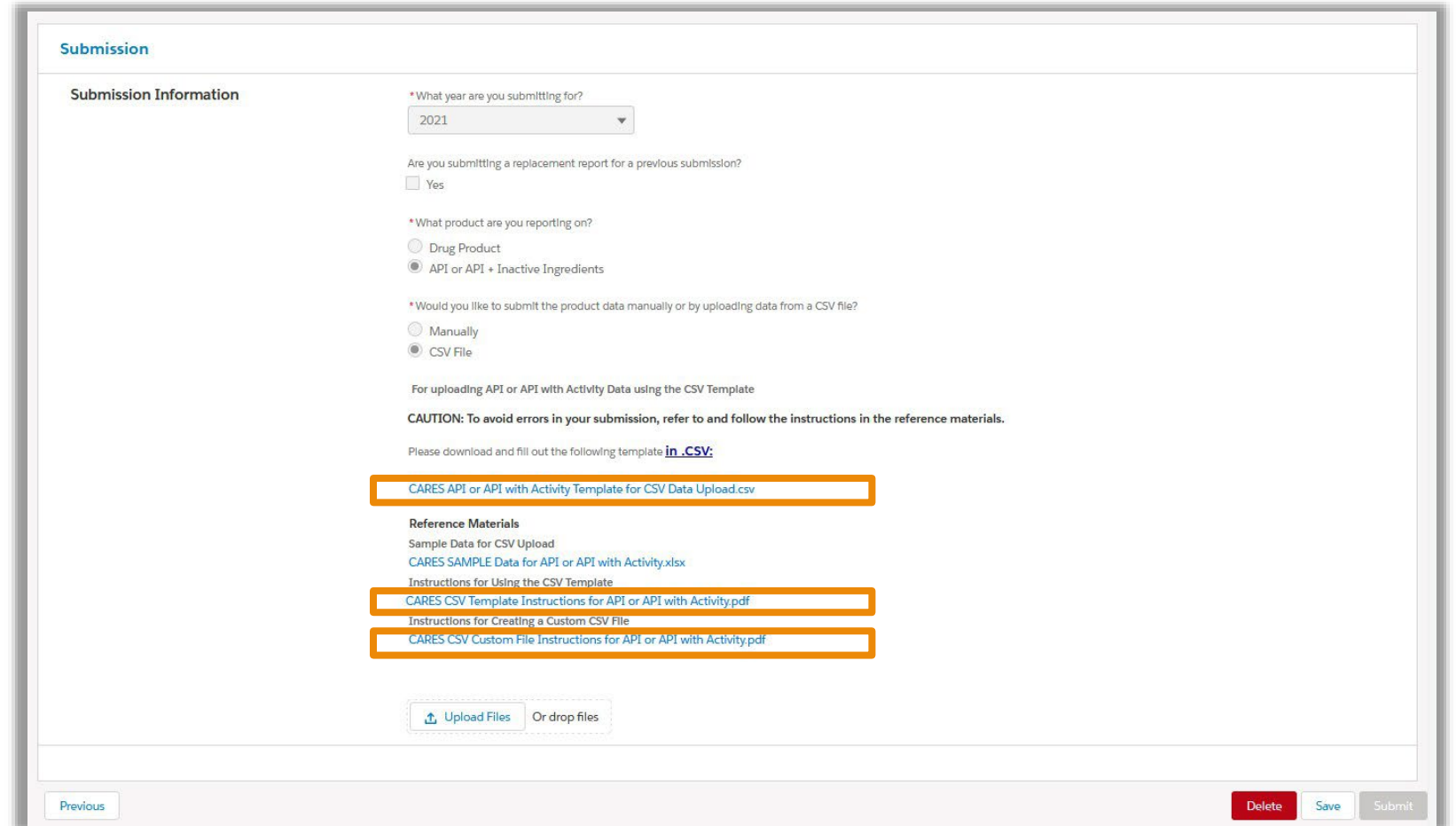
CSV Submission – API or API + Inactive Ingredients

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](#)

CARES Act Amount Information Reporting



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	111111111	API Manufacture	12345-678-01	June	100	kg	u/mg	190	190
8	111111111	API Manufacture	12345-678-01	July	100	kg	u/mg	190	190
9	111111111	API Manufacture	12345-678-01	August	100	kg	u/mg	190	190
10	111111111	API Manufacture	12345-678-01	September	100	kg	u/mg	190	190
11	111111111	API Manufacture	12345-678-01	October	100	kg	u/mg	190	190
12	111111111	API Manufacture	12345-678-01	November	100	kg	u/mg	190	190
13	111111111	API Manufacture	12345-678-01	December	100	kg	u/mg	190	190
14	111111111	API Manufacture	12345-678-01	Annual Total	1510	kg	u/mg	192	190
15	222222222	Manufacture	12345-678-91	January	300	mg	USP'U/mg	140	100
16	222222222	Manufacture	12345-678-91	February	150	mg	USP'U/mg	80	100
17	222222222	Manufacture	12345-678-91	March	150	mg	USP'U/mg	80	100
18	222222222	Manufacture	12345-678-91	April	260	mg	USP'U/mg	120	80
19	222222222	Manufacture	12345-678-91	May	150	mg	USP'U/mg	120	80
20	222222222	Manufacture	12345-678-91	June	150	mg	USP'U/mg	80	100
21	222222222	Manufacture	12345-678-91	July	150	mg	USP'U/mg	100	100
22	222222222	Manufacture	12345-678-91	August	150	mg	USP'U/mg	100	100
23	222222222	Manufacture	12345-678-91	September	150	mg	USP'U/mg	80	100
24	222222222	Manufacture	12345-678-91	October	220	mg	USP'U/mg	100	80
25	222222222	Manufacture	12345-678-91	November	150	mg	USP'U/mg	100	100
26	222222222	Manufacture	12345-678-91	December	150	mg	USP'U/mg	100	100
27	222222222	Manufacture	12345-678-91	Annual Total	2130	mg	USP'U/mg	100	80

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 screenshot shows the 'Submission Information' form. The 'What year are you submitting for?' dropdown is set to '2021'. The 'Are you submitting a replacement report for a previous submission?' checkbox is unchecked. The 'What product are you reporting on?' radio buttons have 'API or API + Inactive Ingredients' selected. The 'Would you like to submit the product data manually or by uploading data from a CSV file?' radio buttons have 'CSV File' selected. Below the form, there is a section for 'Reference Materials' with links to sample data, instructions for using the CSV template, and instructions for creating a custom CSV file. At the bottom of the form, the 'Upload Files' button is highlighted with an orange box, and the 'Or drop files' text is also visible.

The screenshot shows the 'Submission Information' form with a green success message overlay: 'Success File Uploaded Successfully'. The form content is the same as the previous screenshot, but the 'Upload Files' button is no longer highlighted. At the bottom of the form, there is a status bar that reads: 'Your file is currently being processed and you will receive an email notification once processing is complete. You may exit the application by selecting Save and Save & Close.'

The screenshot shows the 'Upload Files' dialog box. It displays a progress bar for the file 'CSVFileForTemplate (1).csv'. At the bottom right, there is a 'Done' button highlighted with an orange box.

The screenshot shows the 'Save CARES Act Amount Information Report' dialog box. It contains the text: '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.' At the bottom, there are three buttons: 'Cancel', 'Save', and 'Save & Close', with 'Save & Close' highlighted with an orange box.

CARES Act Amount Information Reporting

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.

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. ****

CARES Act Amount Information Reporting

+ New Report

Search Submissions

Search



[00027123](#)

Draft

Last Modified: 03/04/2022, 12:47 PM

Reporting Year: 2021

Correction to Report: 00026981

✎ Unsubmitted Draft

Submission

Submission Information

* What year are you submitting for?

2021

Are you submitting a replacement report to a previous submission?

☒ Yes

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

00026981

Date Submitted: 3/2/2022, 12:29 PM

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

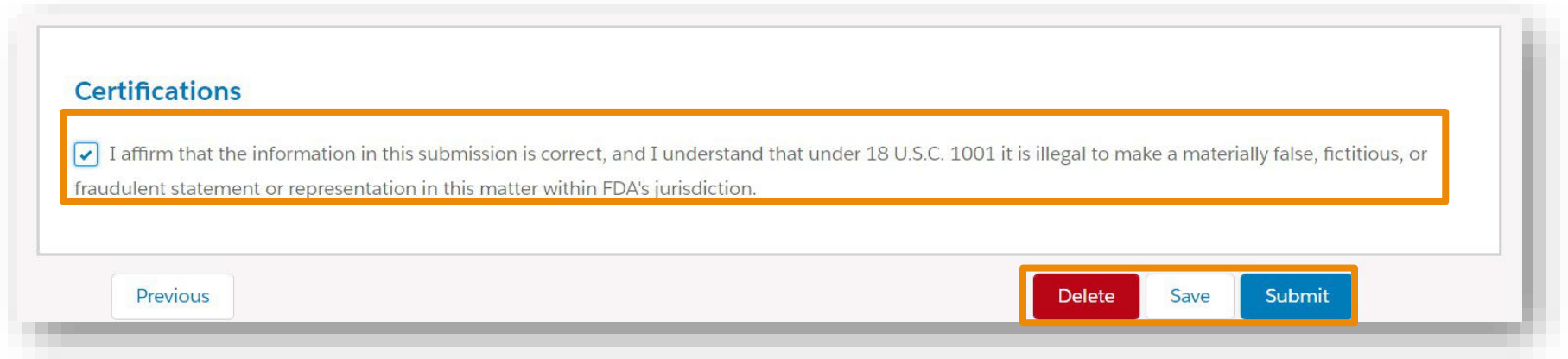
☐ Manually

☒ CSV File

✎ SuccessfulUpload.csv

Your file has successfully processed. You may proceed by certifying your submission and selecting Submit.

CSV Submission – API or API + Inactive Ingredients

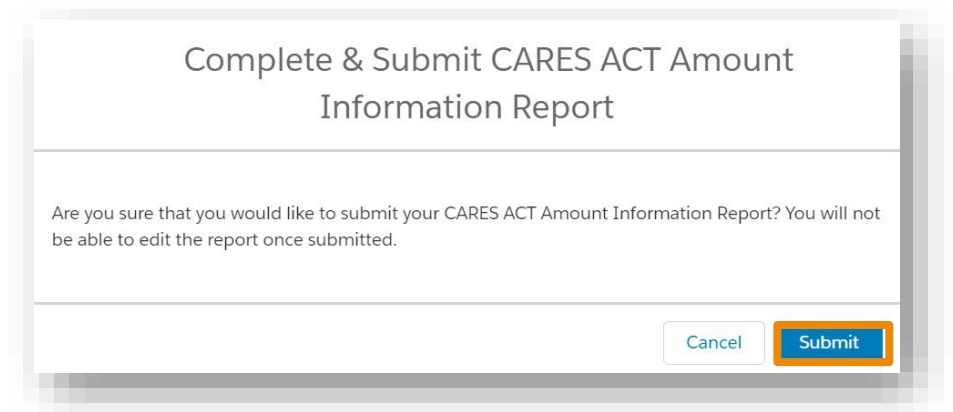


The screenshot shows a web form titled "Certifications". Inside the form, there is a checkbox that is checked, followed by the text: "I affirm that the information in this submission is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent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

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 screen titled "Complete & Submit CARES ACT Amount Information Report". The text on the screen asks: "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 right, there are two buttons: "Cancel" (disabled) and "Submit" (blue). The "Submit" button is highlighted with an orange border.

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.

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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CSVFileSubmissionErrors

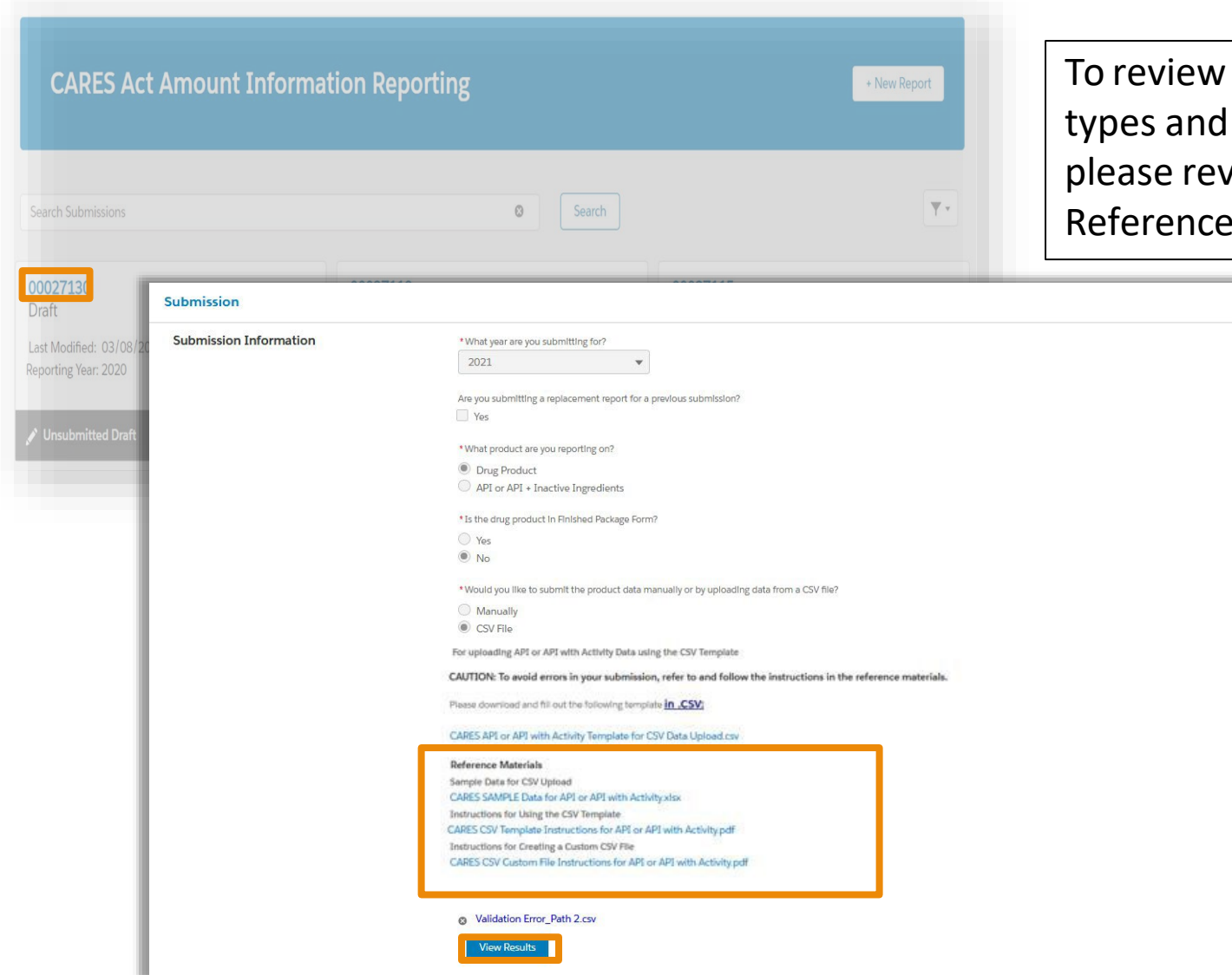
Submission Errors

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.

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



The screenshot displays the 'CARES Act Amount Information Reporting' web application. At the top, there's a blue header with the title and a '+ New Report' button. Below the header is a search bar labeled 'Search Submissions' and a 'Search' button. A list of submissions is shown below, with one entry highlighted: '00027130 Draft'. To the left of this entry is a status indicator 'Unsubmitted Draft'. The main content area shows the 'Submission Information' form for the selected submission. The form includes fields for 'What year are you submitting for?' (set to 2021), '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?' (No), and 'Would you like to submit the product data manually or by uploading data from a CSV file?' (CSV File). Below these fields, there's a 'CAUTION' message and a link to download a CSV template. A 'Reference Materials' section is highlighted with an orange box, containing links to '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', and 'CARES CSV Custom File Instructions for API or API with Activity.pdf'. At the bottom of the form, there's a 'Validation Error_Path 2.csv' message and a 'View Results' button.

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

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.

Report ID: 00140508

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

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.

Report ID: 00141764

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, 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

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**

Report ID: 00141977

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.

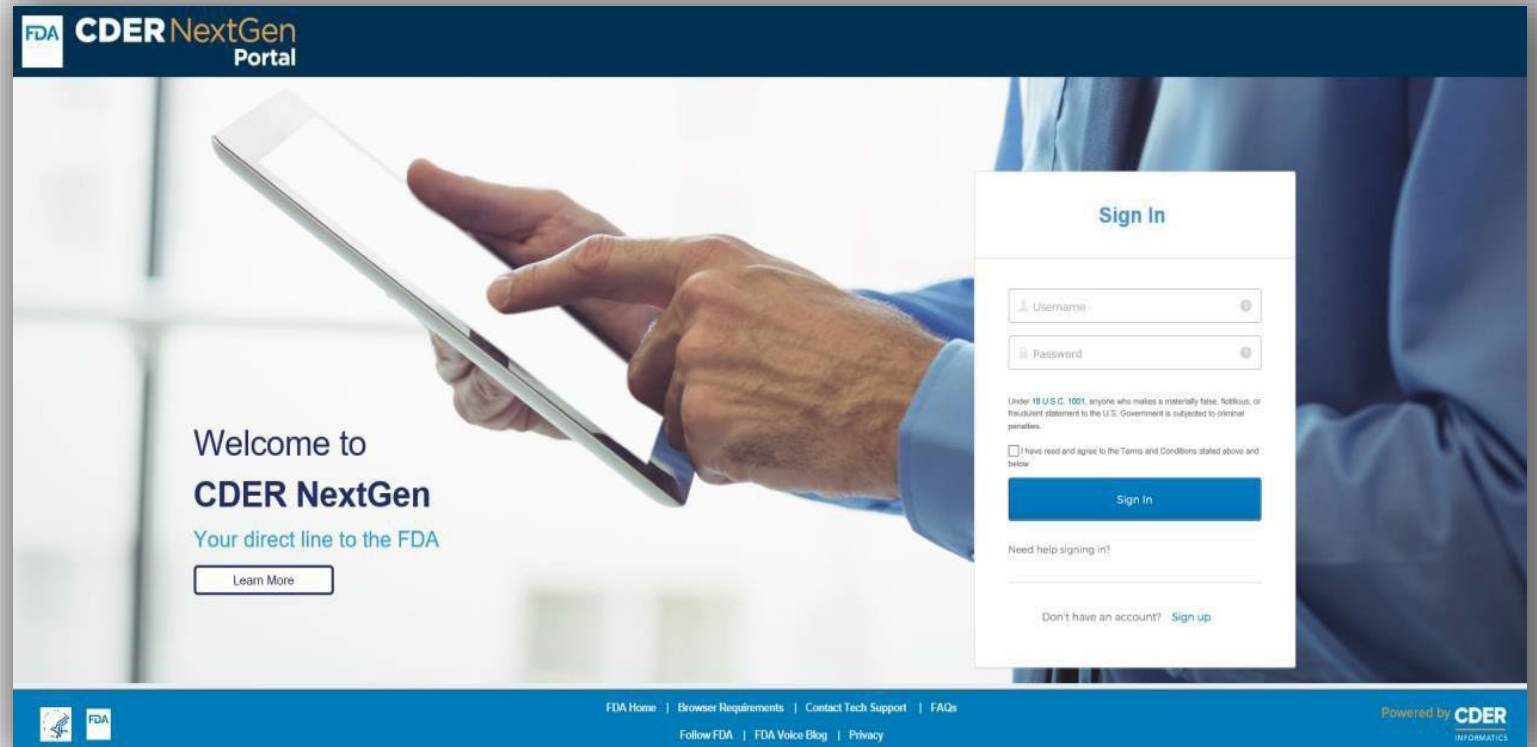
In the case you encounter any issues, please contact EDM Support at EDMSupport@fda.hhs.gov

Manual Submission

Manual Submission – 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

[00020506](#)
Draft
Last Modified: 11/29/2021, 04:48 PM
Reporting Year: 2020

[00020357](#)
Draft
Last Modified: 11/29/2021, 04:48 PM
Reporting Year: 2021

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.

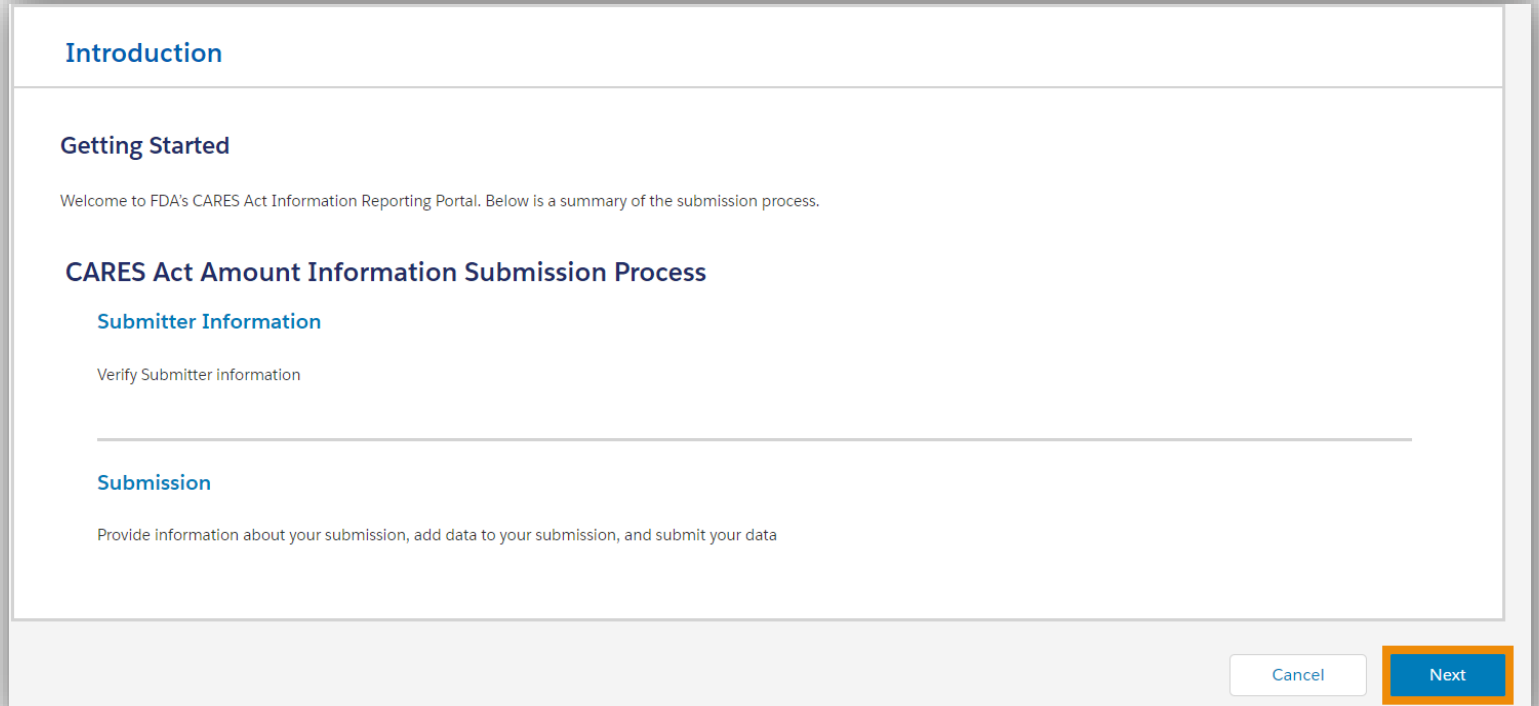
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Powered by

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's CARES Act Information Reporting Portal. The page has a white background with a light blue header bar containing the word 'Introduction'. Below the header, the section 'Getting Started' is displayed, followed by a welcome message: 'Welcome to FDA's CARES Act Information Reporting Portal. Below is a summary of the submission process.' The main heading is 'CARES Act Amount Information Submission Process'. Under this heading, there are two sections: 'Submitter Information' with the instruction 'Verify Submitter information' and 'Submission' with the instruction 'Provide information about your submission, add data to your submission, and submit your data'. At the bottom right of the screen, there are two buttons: 'Cancel' and 'Next'. The 'Next' button is highlighted with an orange border.

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

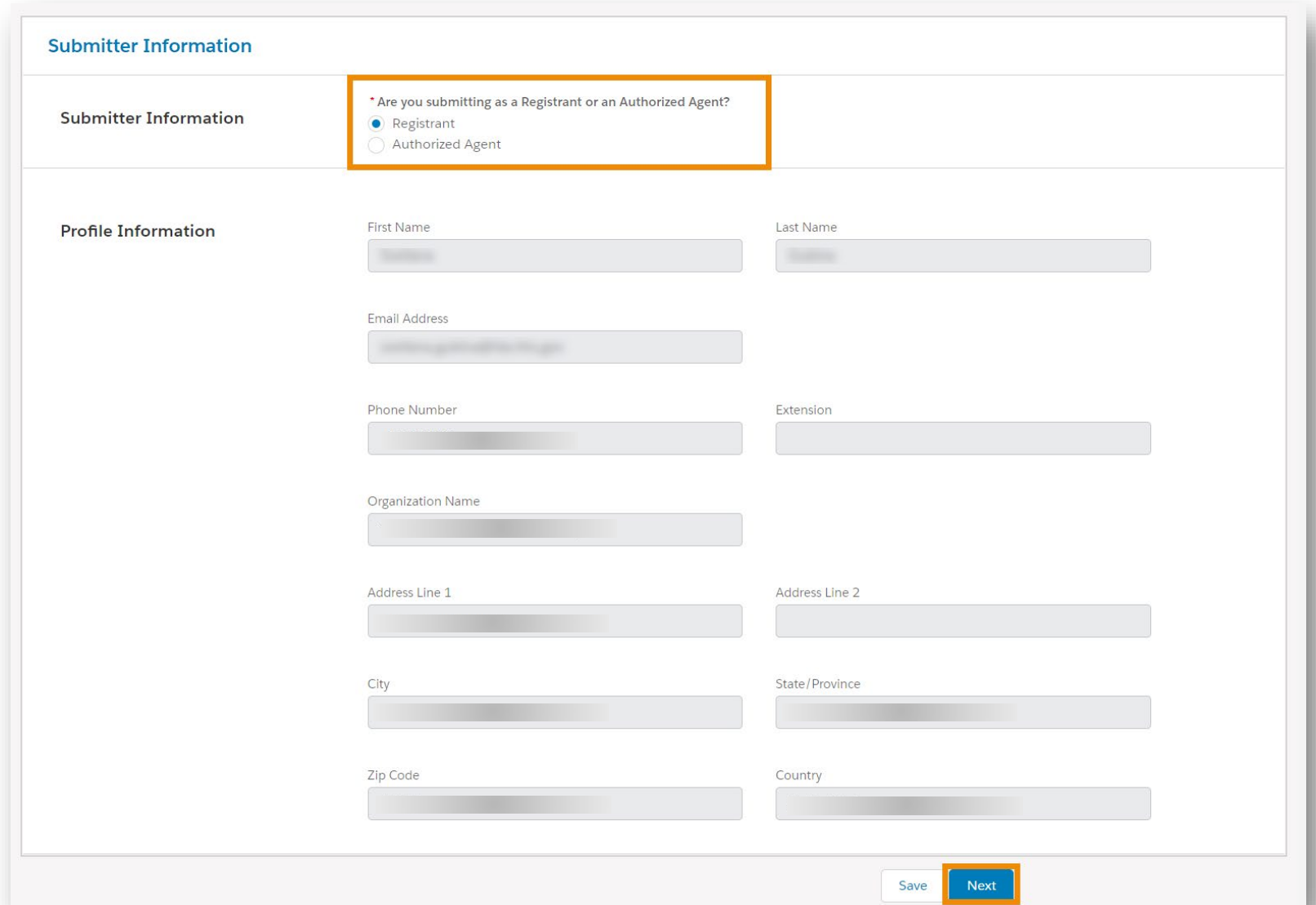
Provide information about your submission, add data to your submission, and submit your data

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.



The screenshot shows a web form titled "Submitter Information". At the top, there is a section with the heading "Submitter Information" containing a question: "*Are you submitting as a Registrant or an Authorized Agent?". Below this question are two radio button options: "Registrant" (which is selected) and "Authorized Agent". This section is highlighted with an orange border. Below this is a section titled "Profile Information" which contains several text input fields: "First Name", "Last Name", "Email Address", "Phone Number", "Extension", "Organization Name", "Address Line 1", "Address Line 2", "City", "State/Province", "Zip Code", and "Country". At the bottom right of the form, there are two buttons: "Save" and "Next". The "Next" button is highlighted with an orange border.

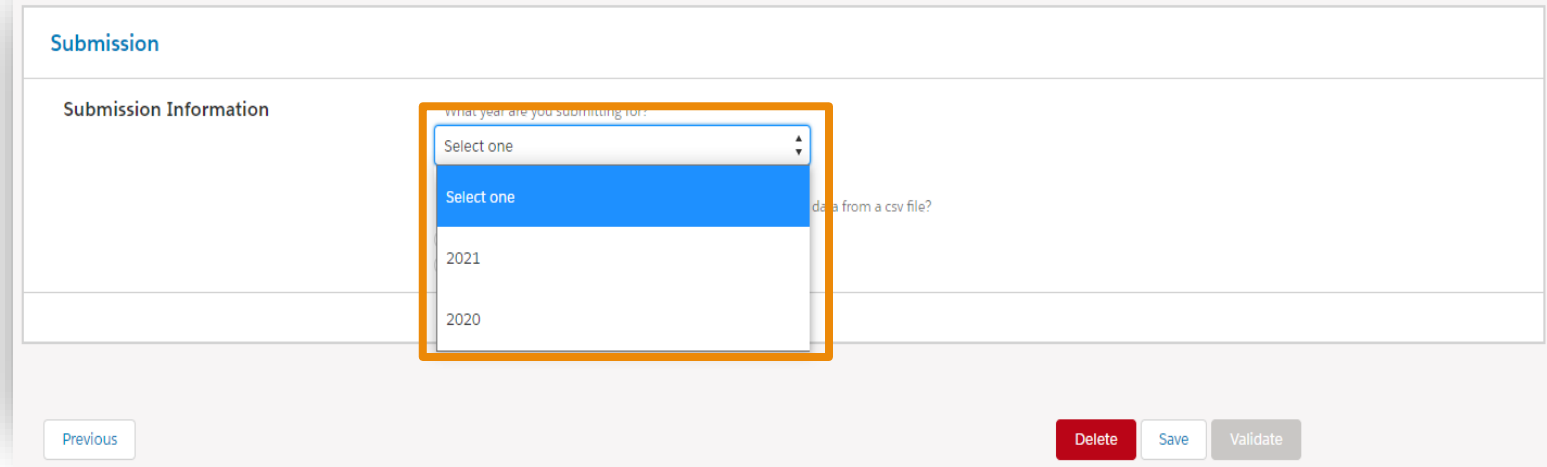
ManualSubmission-Finished Package Form

Manual Submission – Finished Package Form

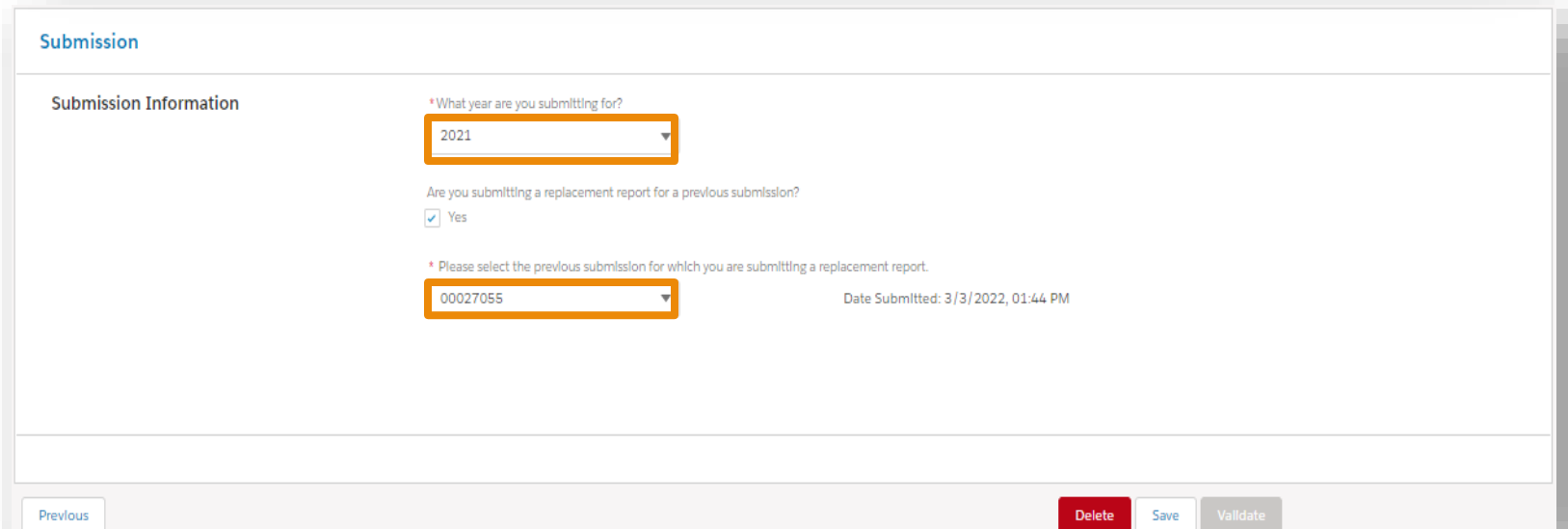
Step 8. In the **Submission** section, select the **year** (calendar year) that the report will cover.

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.



The screenshot shows the 'Submission' section of the form. Under 'Submission Information', there is a dropdown menu labeled 'What year are you submitting for:'. The dropdown is open, showing options 'Select one', '2021', and '2020'. The '2021' option is highlighted. To the right of the dropdown, there is a text input field with the placeholder 'data from a csv file?'. At the bottom of the form, there are three buttons: 'Previous', 'Delete', and 'Save', and a 'Validate' button.



The screenshot shows the 'Submission' section of the form. Under 'Submission Information', there is a dropdown menu labeled '* What year are you submitting for?' with '2021' selected. Below this, there is a checkbox labeled 'Are you submitting a replacement report for a previous submission?' which is checked. Below the checkbox, there is a dropdown menu labeled '* Please select the previous submission for which you are submitting a replacement report.' with '00027055' selected. To the right of the dropdown, there is a text input field with the placeholder 'Date Submitted: 3/3/2022, 01:44 PM'. At the bottom of the form, there are three buttons: 'Previous', 'Delete', and 'Save', and a 'Validate' button.

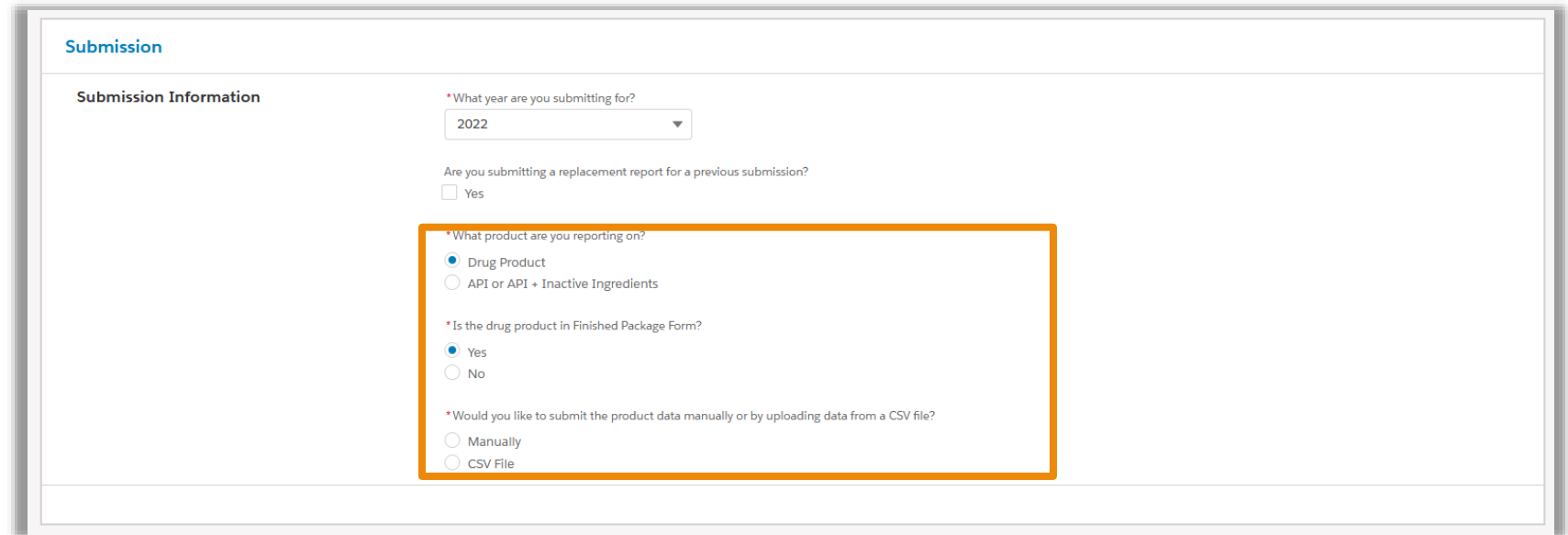
Manual Submission – Finished Package Form

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

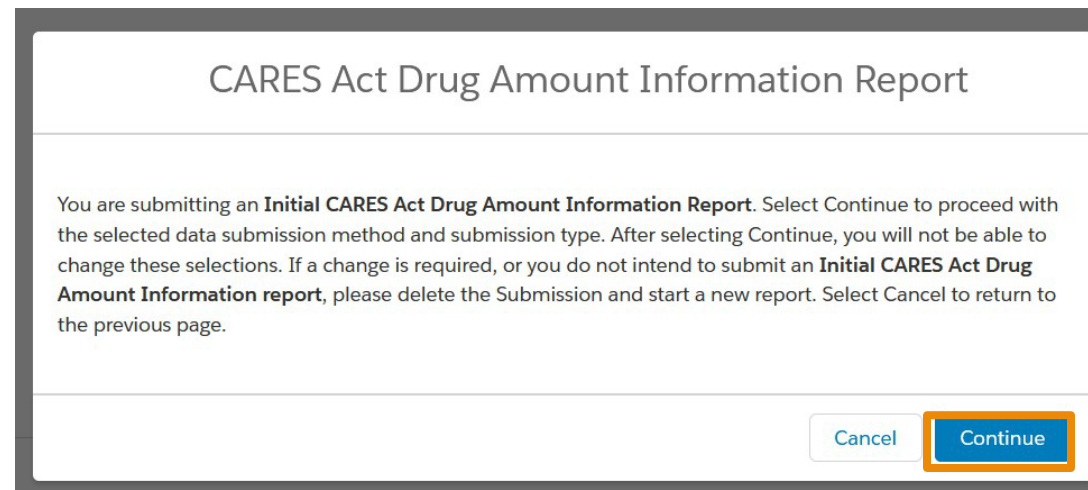
* What year are you submitting for?
2022

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

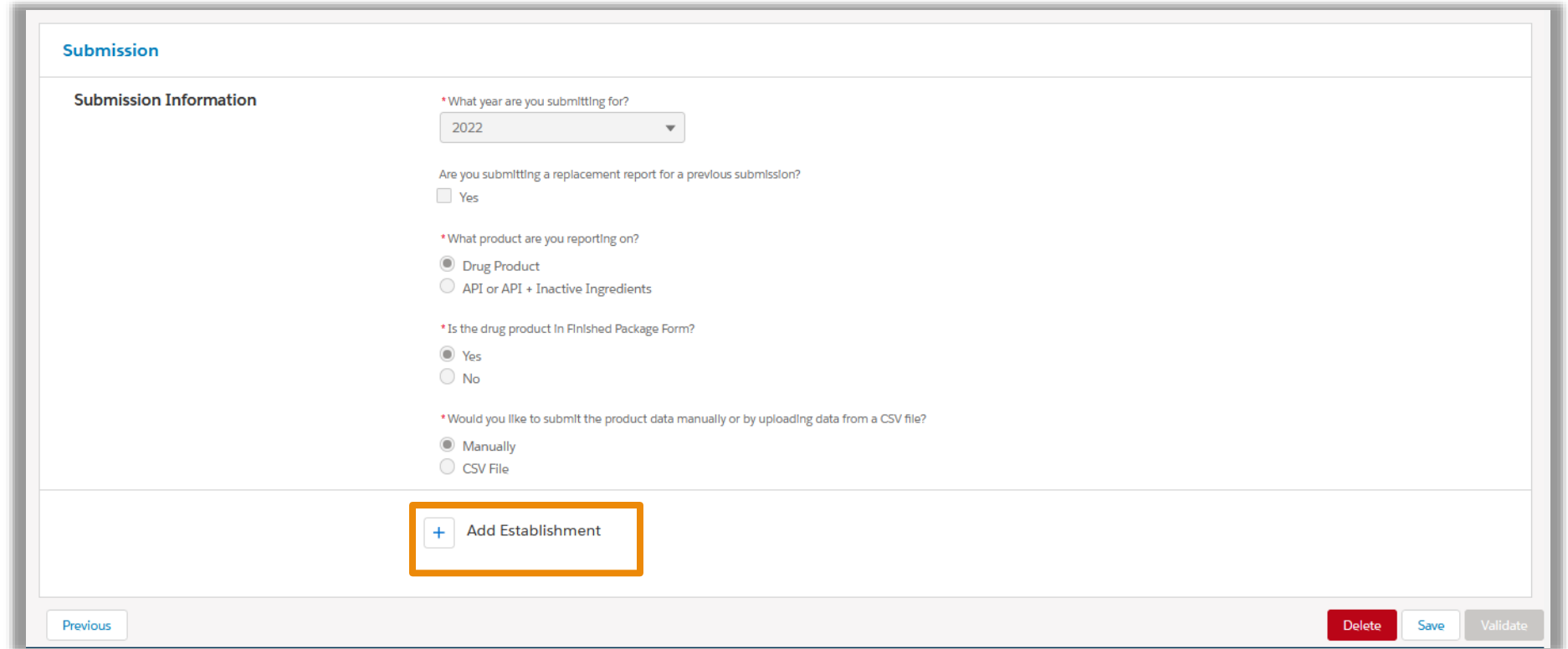


CARES Act Drug Amount Information Report

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.

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 web form titled "Submission" with a section for "Submission Information". The form contains several fields and options:

- 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" which is currently unchecked.
- What product are you reporting on?**: Two radio button options: "Drug Product" (selected) and "API or API + Inactive Ingredients".
- Is the drug product In Finished Package Form?**: Two radio button options: "Yes" (selected) and "No".
- Would you like to submit the product data manually or by uploading data from a CSV file?**: Two radio button options: "Manually" (selected) and "CSV File".

At the bottom of the form, there is a button labeled "+ Add Establishment" which is highlighted with an orange border. Below the form, there are three buttons: "Previous", "Delete", and "Save", followed by a "Validate" button.

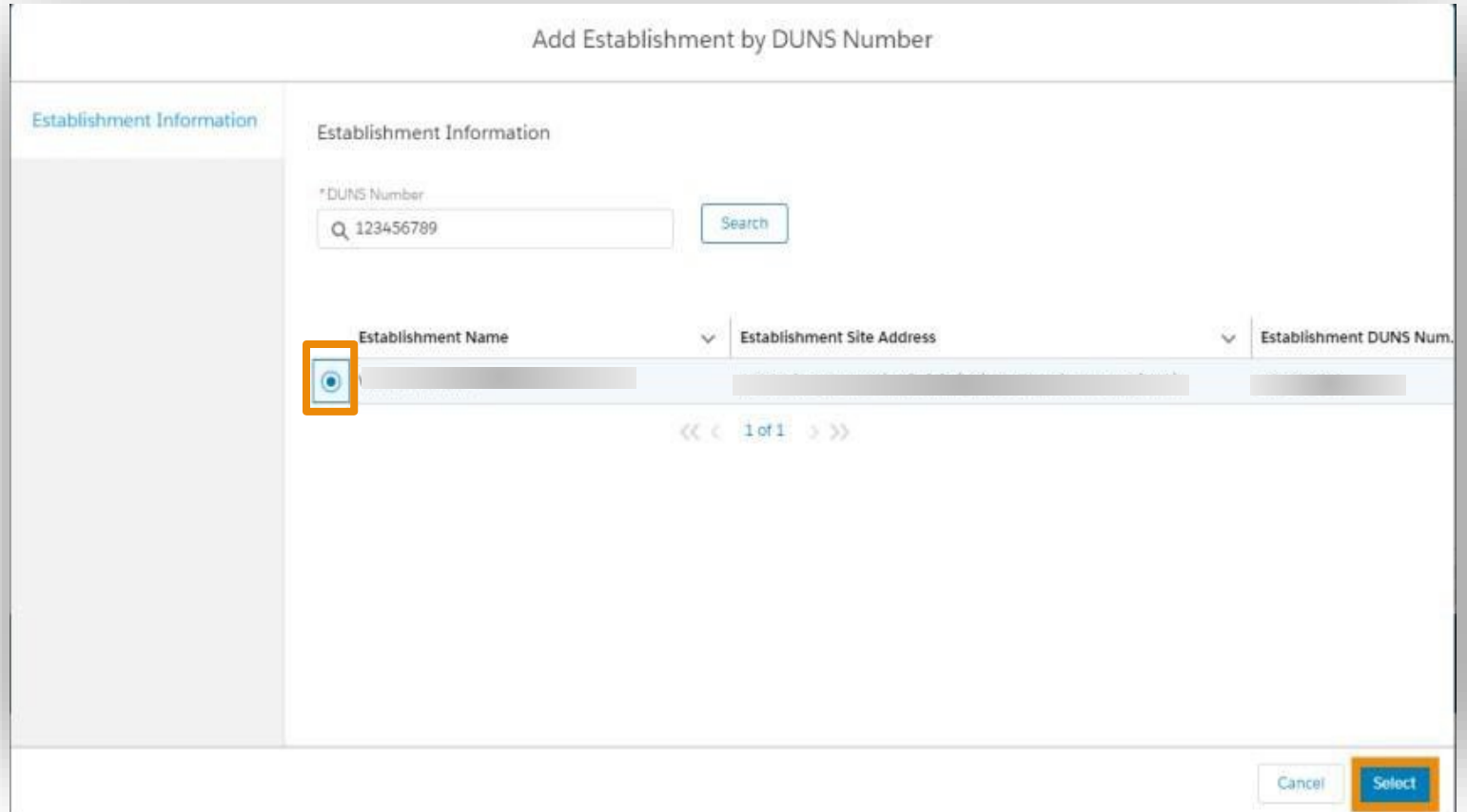
Manual Submission – Finished Package Form

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.



CARES Act Amount Information Reporting

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.

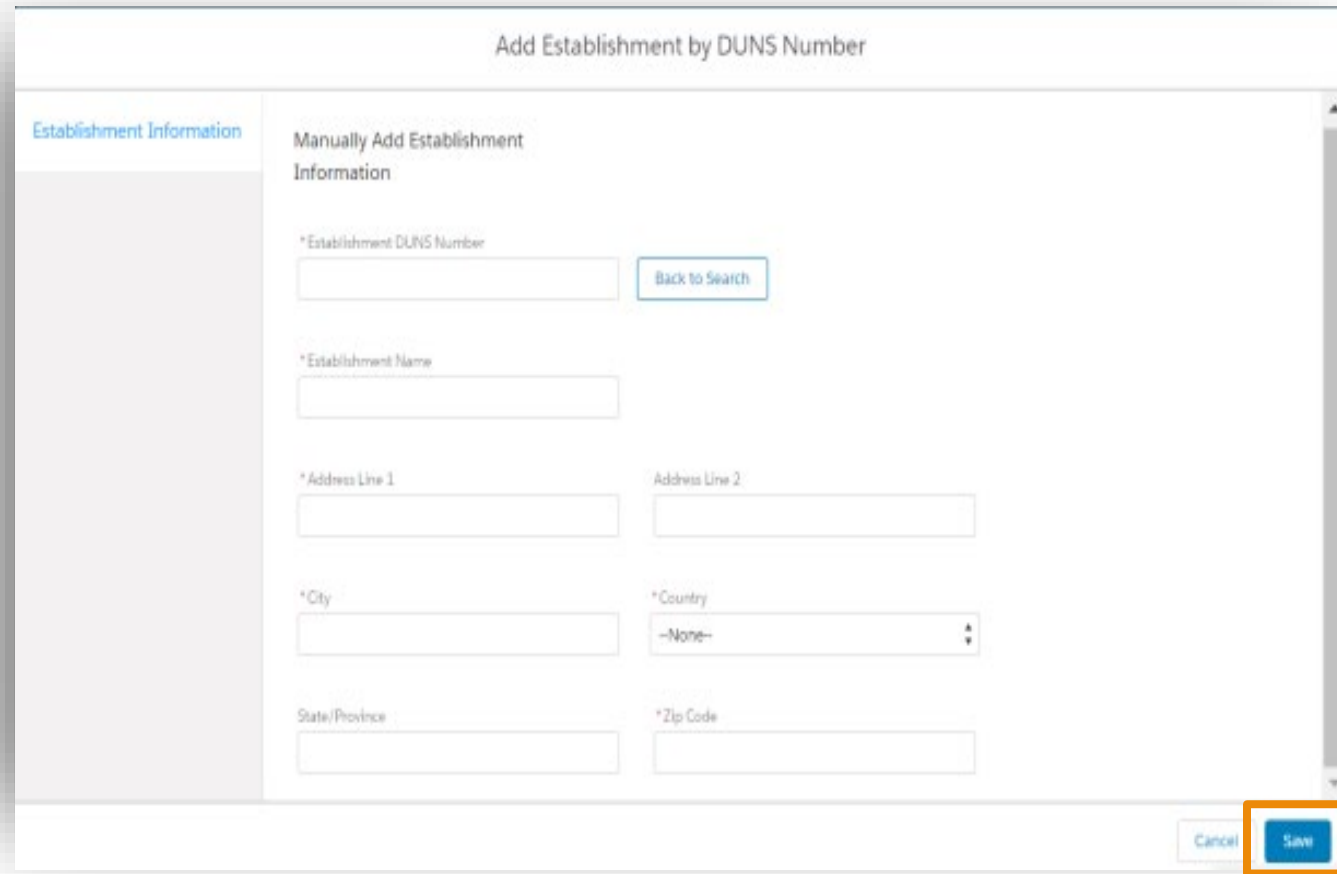
The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the heading "Establishment Information". The main content area also has the heading "Establishment Information". It contains a search field labeled "* DUNS Number" with the text "111111111" entered. To the right of the search field is a "Search" button, which is highlighted with an orange box. Below the search field, a red error message reads: "DUNS Not found. Please search a different DUNS or add manually." Below this message is a button labeled "+ Add Manually", which is also highlighted with an orange box. At the bottom right of the form are "Cancel" and "Select" buttons.

CARES Act Amount Information Reporting

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**.



The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the link "Establishment Information". The main content area is titled "Manually Add Establishment Information". It contains several input fields: "* Establishment DUNS Number" with a "Back to Search" button; "* Establishment Name"; "* Address Line 1" and "Address Line 2"; "* City" and "* Country" (a dropdown menu showing "--None--"); and "State/Province" and "* Zip Code". At the bottom right, there are "Cancel" and "Save" buttons. The "Save" button is highlighted with an orange square.

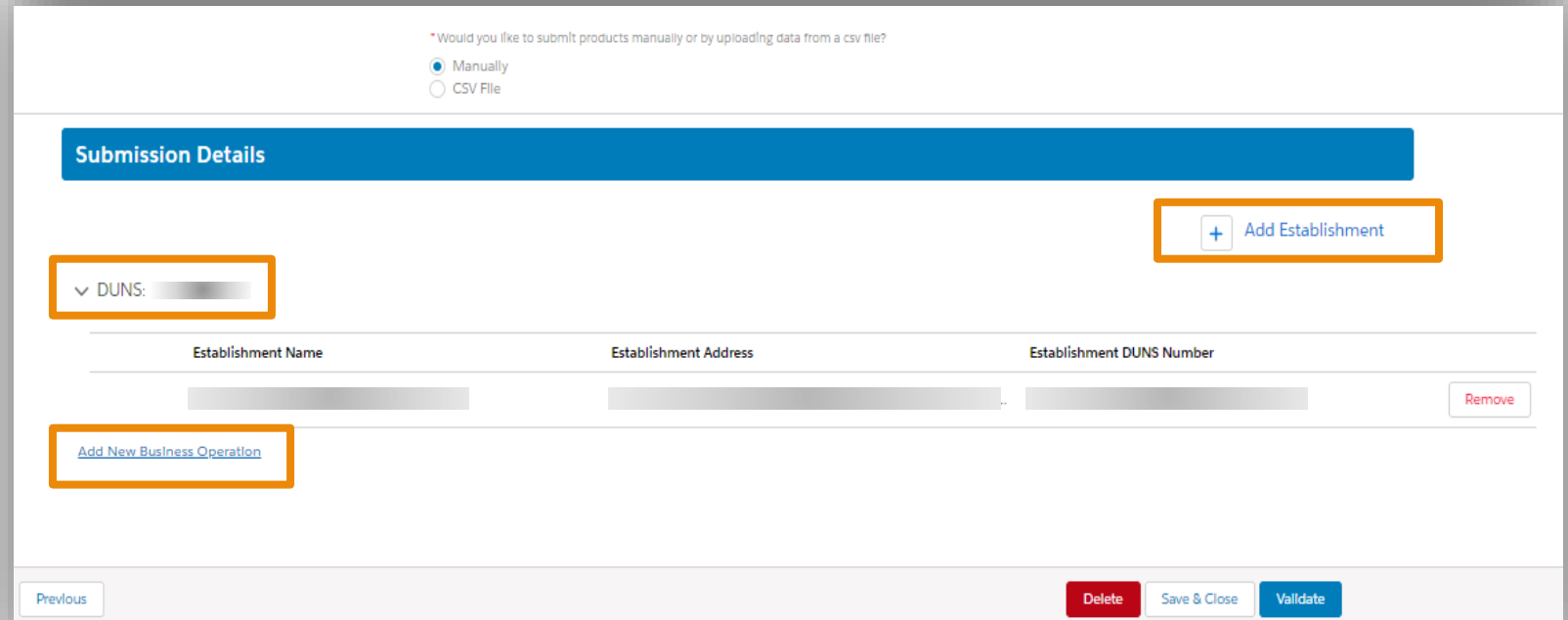
Manual Submission – Finished Package Form

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.

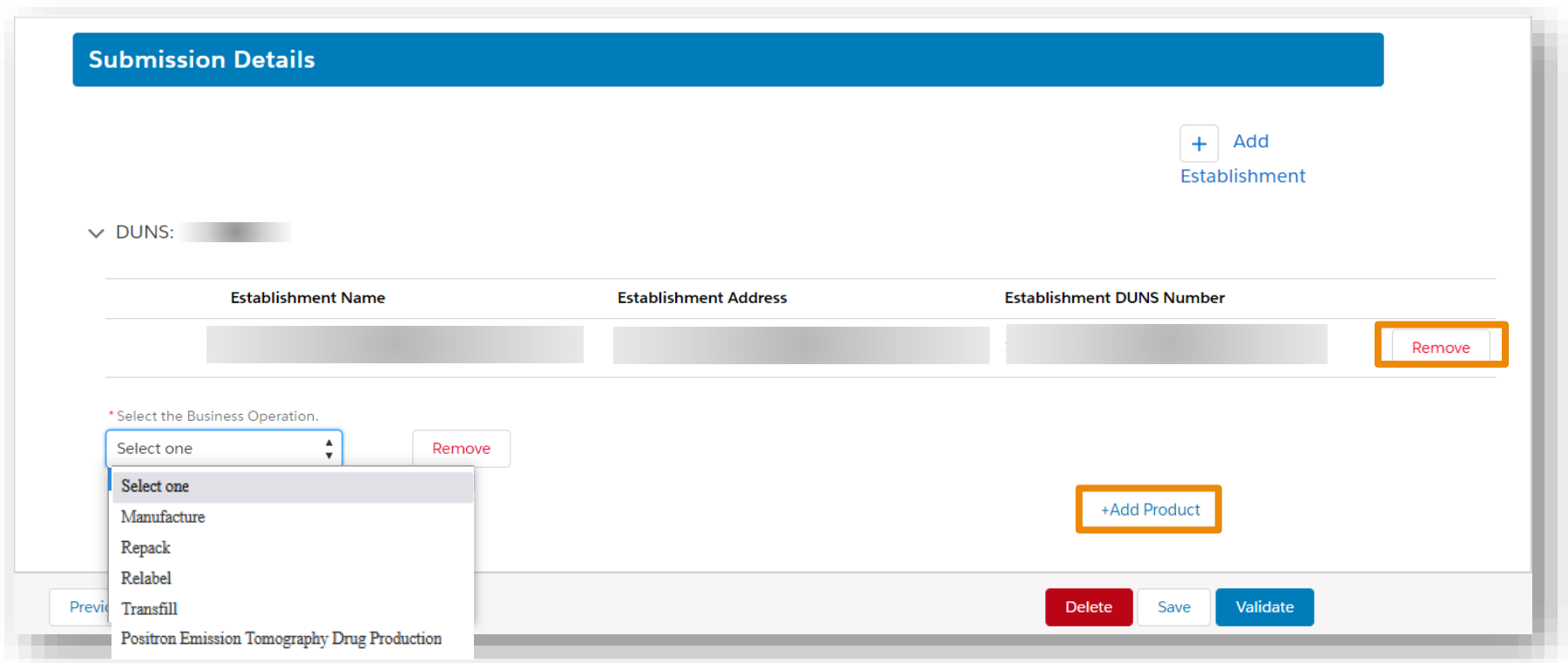


The screenshot shows the 'Submission Details' screen. At the top, there is a question: 'Would you like to submit products manually or by uploading data from a csv file?'. Below this, there are two radio buttons: 'Manually' (selected) and 'CSV File'. The main section is titled 'Submission Details'. On the right side, there is a button labeled '+ Add Establishment'. On the left side, there is a dropdown menu labeled 'DUNS:'. Below this, there is a table with three columns: 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. The table has one row with empty input fields. To the right of the table, there is a 'Remove' button. Below the table, there is a button labeled 'Add New Business Operation'. At the bottom of the screen, there are three buttons: 'Previous', 'Delete', and 'Save & Close', followed by a 'Validate' button.

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 displays the 'Submission Details' form. At the top right is a '+ Add Establishment' button. Below it is a 'DUNS:' label with a dropdown arrow. A table with three columns—'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'—contains one row with greyed-out input fields and a 'Remove' button. Below the table, a label '* Select the Business Operation.' is followed by a dropdown menu showing options: 'Select one', 'Manufacture', 'Repack', 'Relabel', 'Transfill', and 'Positron Emission Tomography Drug Production'. A 'Remove' button is next to the dropdown. To the right of the dropdown is a '+Add Product' button. At the bottom are 'Delete', 'Save', and 'Validate' buttons. A 'Previous' button is partially visible on the left.

CARES Act Amount Information Reporting

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 Manually

Add Drug or Biological Product by NDC

NDC

Cancel Select

CARES Act Amount Information Reporting

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

Back to Search

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

Cancel Add Product

Manual Submission – Finished Package Form

Outermost Package					Innermost Package				Intended to Fulfill 21 CFR 314.81	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"/> <i>Annual Total</i>	<input type="text"/> <i>Annual Total</i>		<input type="text"/> <i>Annual Total</i>	<input type="text"/> <i>Annual Total</i>		<input 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
- 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				Intended to Fulfill 21 CFR 314.81	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" value="142.00"/> <small>Annual Total</small>	<input type="text" value="40.00"/> <small>Annual Total</small>		<input type="text" value="30"/> <small>Annual Total</small>	<input type="text" value="95"/> <small>Annual Total</small>		<input type="checkbox"/>	
January		<input type="text" value="12.00"/>	<input type="text" value="10.00"/>		<input type="text" value="2"/>	<input type="text" value="10"/>			
February		<input type="text" value="15.00"/>	<input type="text" value="15.00"/>		<input type="text" value="16"/>	<input type="text" value="17"/>			
March		<input type="text" value="115.00"/>	<input type="text" value="15.00"/>		<input type="text" value="12"/>	<input type="text" value="68"/>			

CARES Act Amount Information Reporting

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.

CARES Act Drug Amount Information Reporting

Validated Successfully !

APPLICATION BUILDER

- Submitter Information
- Submission

Need Help?

The [Help Center](#) is available to answer questions on creating and submitting a CARES Act Drug Amount Information Reporting submission to the FDA.

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

Submission Details

+ Add Establishment

> DUNS: 123456789

Previous Delete Save **Validate**

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

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.

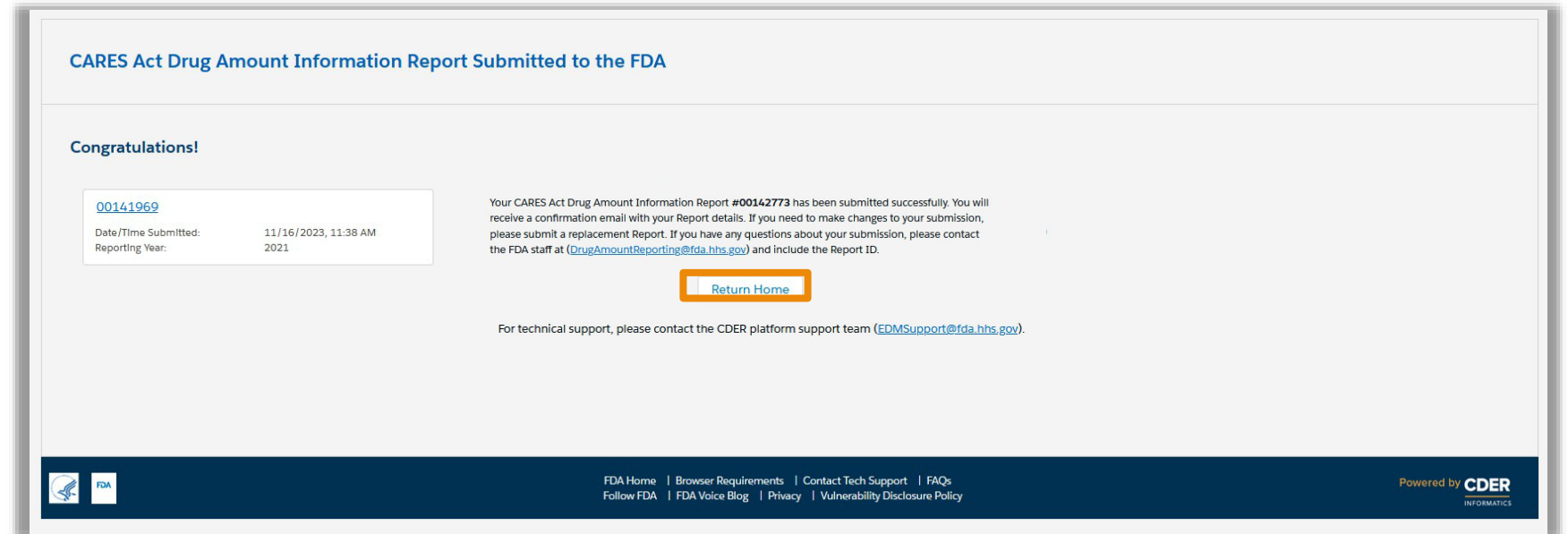
Cancel Submit

Delete Save **Submit**

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 titled "CARES Act Drug Amount Information Report Submitted to the FDA". It includes a "Congratulations!" message and a box containing the Report ID "00141969", the submission date "11/16/2023, 11:38 AM", and the reporting year "2021". A message states that the report #00142773 has been submitted successfully and provides instructions for replacement reports and contact information. A "Return Home" button is highlighted with an orange border. The footer contains links for FDA Home, Browser Requirements, Contact Tech Support, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy, along with the text "Powered by CDER INFORMATICS".

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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INFORMATICS

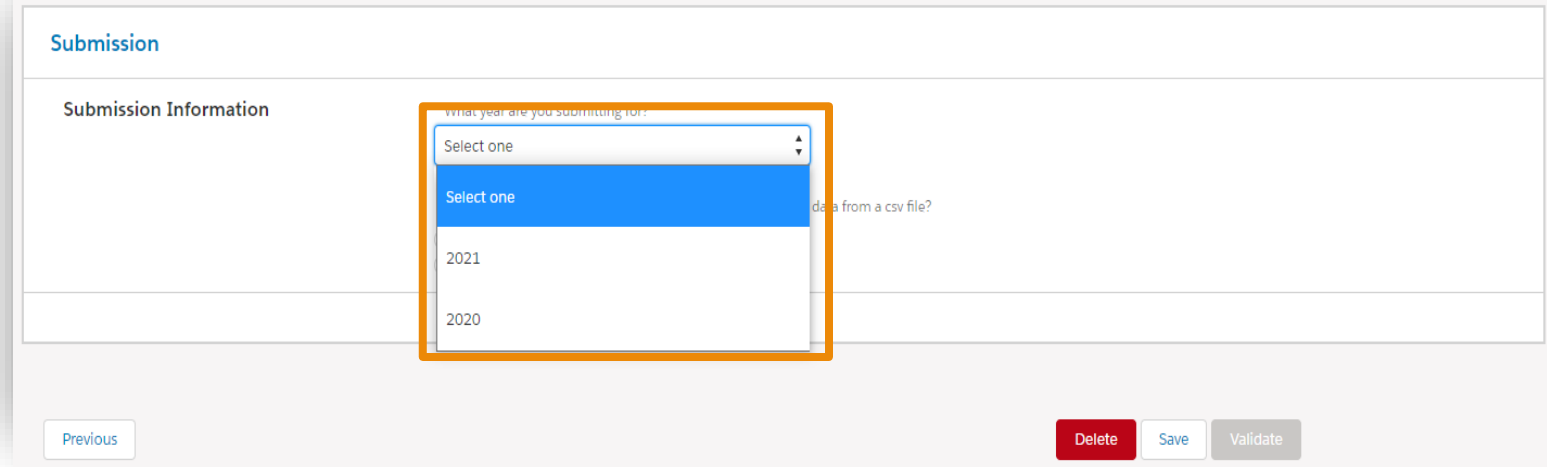
ManualSubmission - NotinFinished Package Form

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

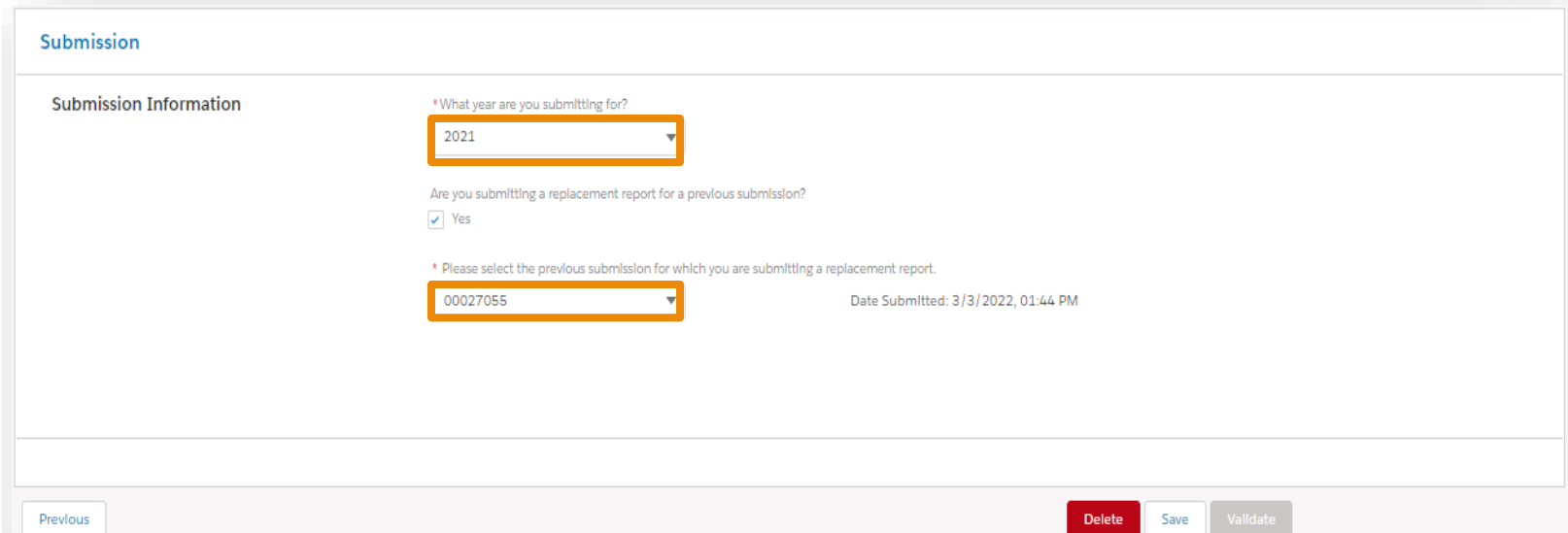
Select one

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

CARES Act Amount Information Reporting

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**.

The screenshot shows the '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
- Product Information** (highlighted with an orange box)
 - * 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

The screenshot shows the 'CARES Act Drug Amount Information Report' confirmation screen. The text reads: "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." At the bottom right, there are two buttons: 'Cancel' and 'Continue'. The 'Continue' button is highlighted with an orange box.

CARES Act Amount Information Reporting

Manual Submission – Not in Finished Package Form

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

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

+ Add Establishment

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

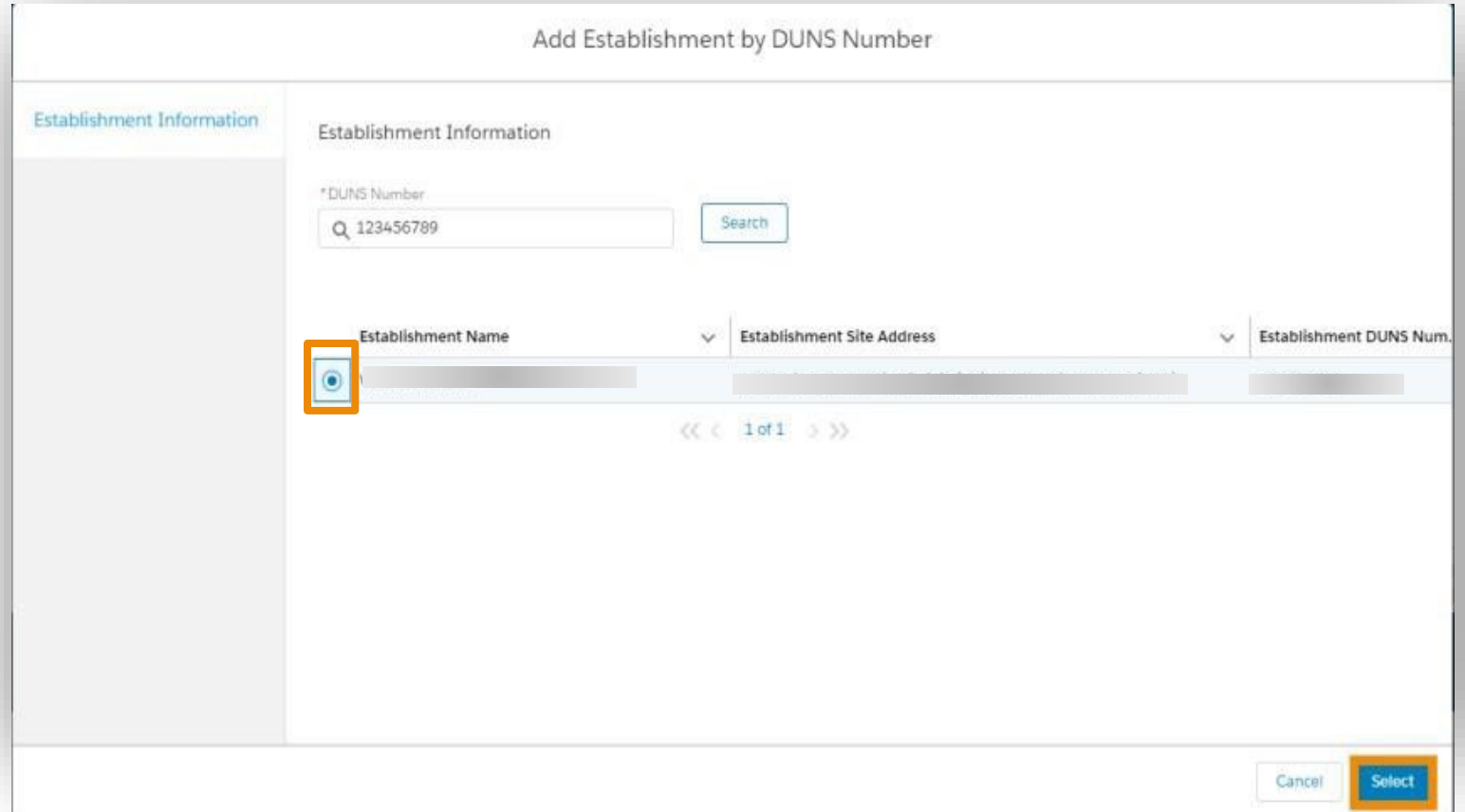
Manual Submission – Not in Finished Package Form

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
Q 123456789 Search

Establishment Name	Establishment Site Address	Establishment DUNS Num.
<input checked="" type="radio"/>		

<< < 1 of 1 > >>

Cancel Select

CARES Act Amount Information Reporting

Manual Submission – Not in Finished Package Form

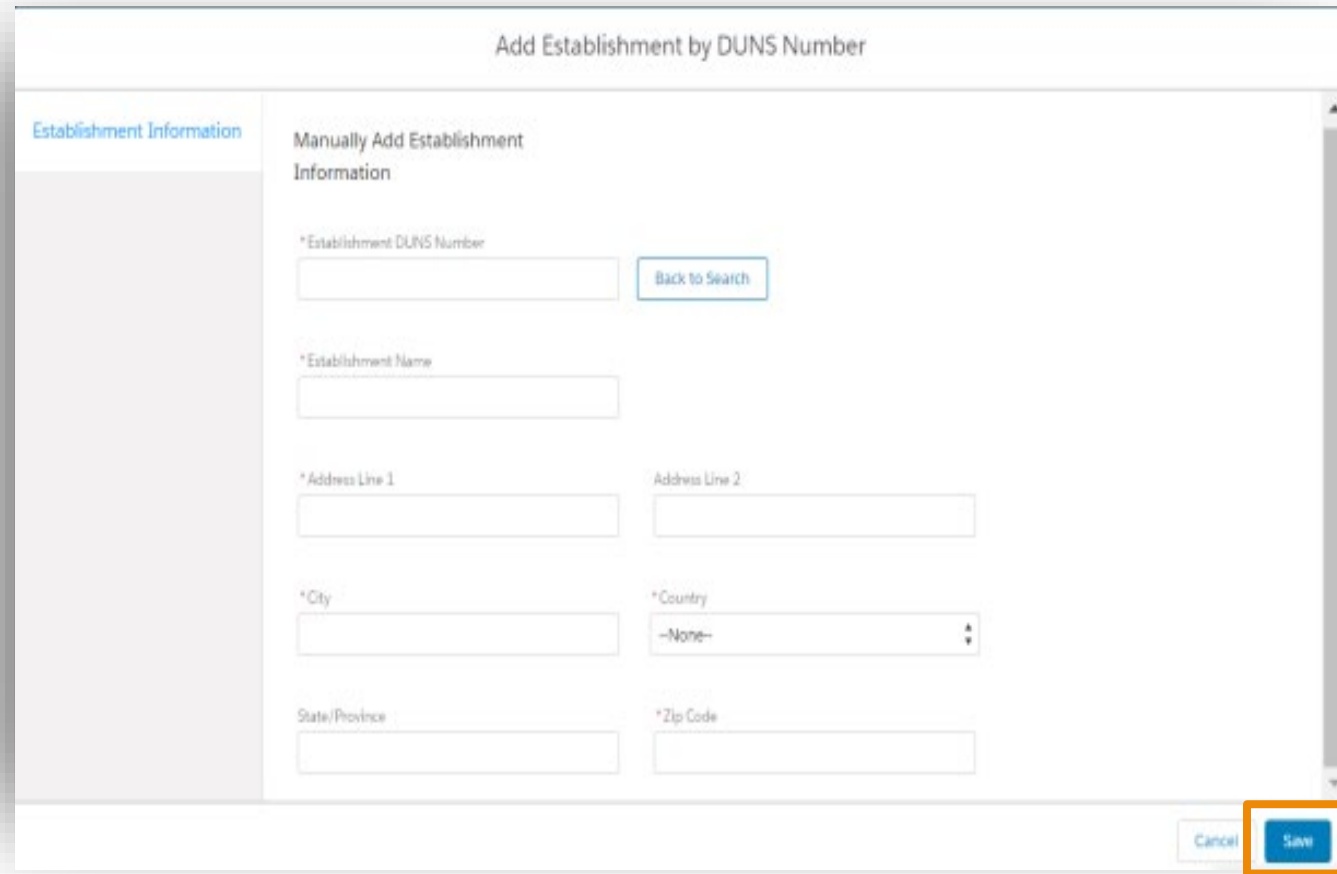
Step 16. If the search for a DUNS number fails, an error message and an **+Add Manually** button will appear. Click the button to enter establishment information.

The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the heading "Establishment Information". The main content area also has the heading "Establishment Information". It contains a search field labeled "* DUNS Number" with the text "111111111" entered. To the right of the search field is a "Search" button. Below the search field, a red error message reads: "DUNS Not found. Please search a different DUNS or add manually." Below this message is a button labeled "+ Add Manually". At the bottom right of the form are "Cancel" and "Select" buttons. Orange boxes highlight the "Search" button and the "+ Add Manually" button.

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**.



The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the link "Establishment Information". The main content area is titled "Manually Add Establishment Information". It contains several input fields: "* Establishment DUNS Number" with a "Back to Search" button; "* Establishment Name"; "* Address Line 1" and "Address Line 2"; "* City" and "* Country" (a dropdown menu showing "--None--"); and "State/Province" and "* Zip Code". At the bottom right, there are "Cancel" and "Save" buttons. The "Save" button is highlighted with an orange rectangle.

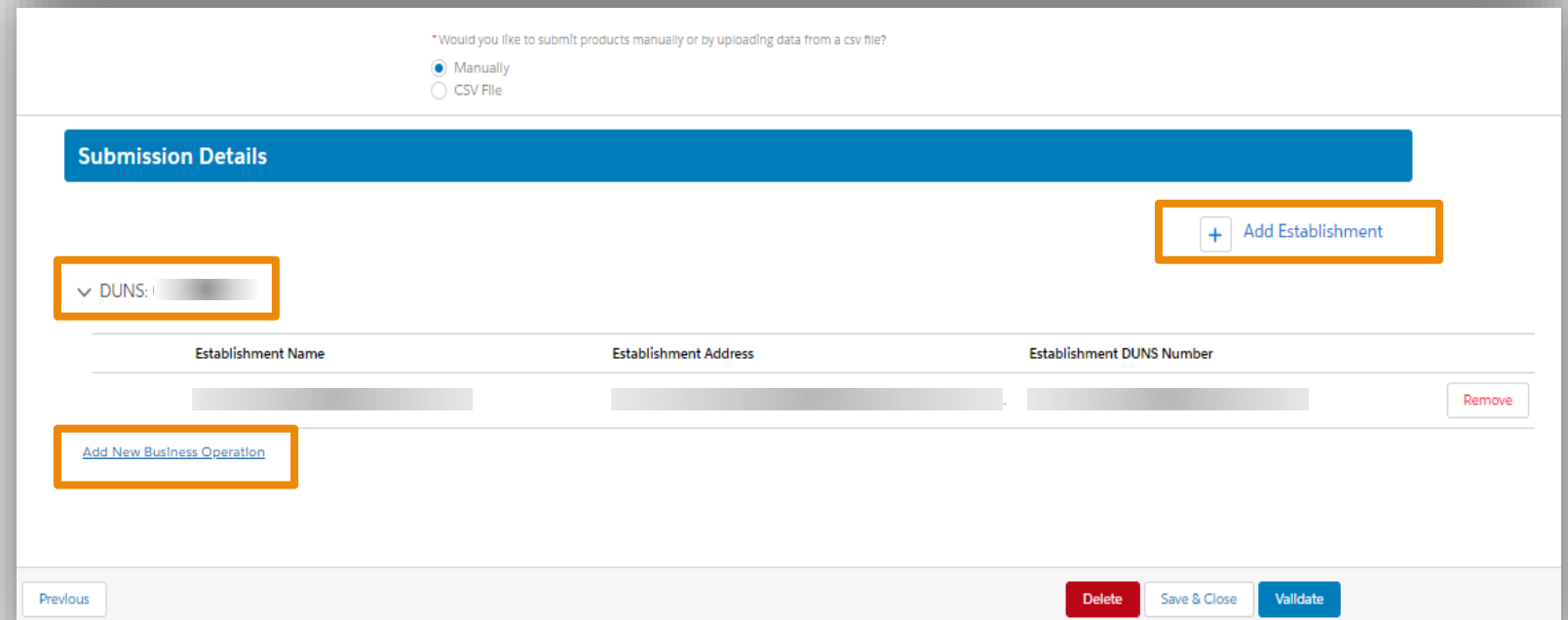
Manual Submission – Not in Finished Package Form

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.



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

☒ Manually
☐ CSV File

Submission Details

[+ Add Establishment](#)

▼ DUNS: [redacted]

Establishment Name	Establishment Address	Establishment DUNS Number	
[redacted]	[redacted]	[redacted]	Remove

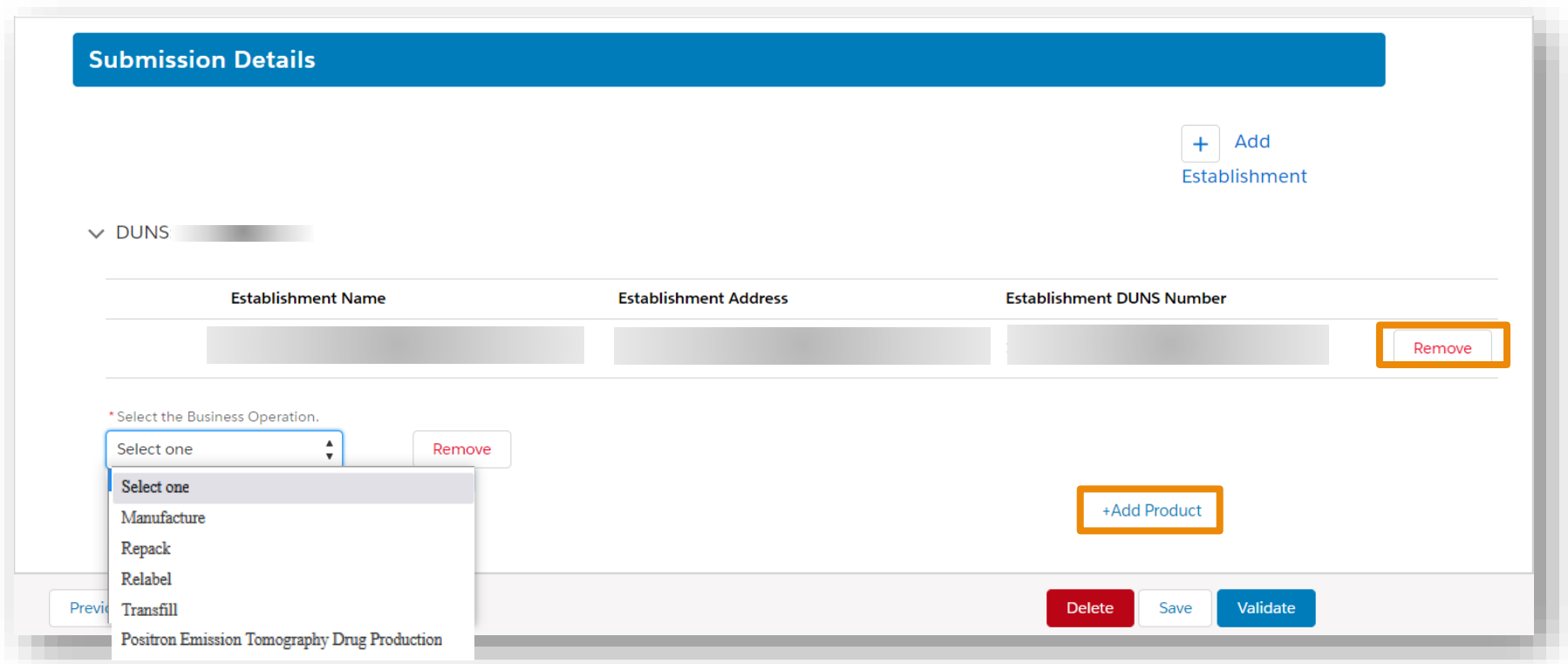
[Add New Business Operation](#)

[Previous](#) [Delete](#) [Save & Close](#) [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' form. At the top right is a '+ Add Establishment' button. Below it is a 'DUNS' section with a table. The table has three columns: 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. There is a 'Remove' button next to the DUNS number column. Below the table is a '* Select the Business Operation.' section with a dropdown menu. The dropdown menu is open, showing options: 'Select one', 'Manufacture', 'Repack', 'Relabel', 'Transfill', and 'Positron Emission Tomography Drug Production'. There is a 'Remove' button next to the dropdown. At the bottom right is a '+Add Product' button. At the bottom are 'Delete', 'Save', and 'Validate' buttons.

Establishment Name	Establishment Address	Establishment DUNS Number

* Select the Business Operation.

Select one

- Select one
- Manufacture
- Repack
- Relabel
- Transfill
- Positron Emission Tomography Drug Production

+Add Product

Delete Save Validate

CARES Act Amount Information Reporting

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**.

SEARCH RESULTS

NDC

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

Search

+ Add Manually

Add Drug or Biological Product by NDC

NDC

Cancel Select

CARES Act Amount Information Reporting

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.

The screenshot shows a web form titled "Add Drug or Biological Product Manually". It features a text input field labeled "* NDC" containing the value "1234-1234-12". Below the input field, a note states: "Allowable formats are: 1234-1234-12, 12345-123-12 and 12345-1234-1". To the right of the input field is a button labeled "Back to Search". At the bottom right of the form, there are two buttons: "Cancel" and "Add Product". The "Add Product" button is highlighted with an orange border.

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"/>	<div>12.00 <i>Annual Total</i></div>	<div>35.00 <i>Annual Total</i></div>	<div>LITER: L</div>	<input checked="" type="checkbox"/>	<div></div>

+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]	<input type="text" value="40.00"/> <small>Annual Total</small>	<input type="text" value="40.00"/> <small>Annual Total</small>	LITER: L	<input checked="" type="checkbox"/>	<input type="button" value="▲"/>
January	<input type="text" value="10.00"/>	<input type="text" value="10.00"/>			
February	<input type="text" value="20.00"/>	<input type="text" value="20.00"/>			
March	<input type="text" value="10.00"/>	<input type="text" value="10.00"/>			

CARES Act Amount Information Reporting

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**.

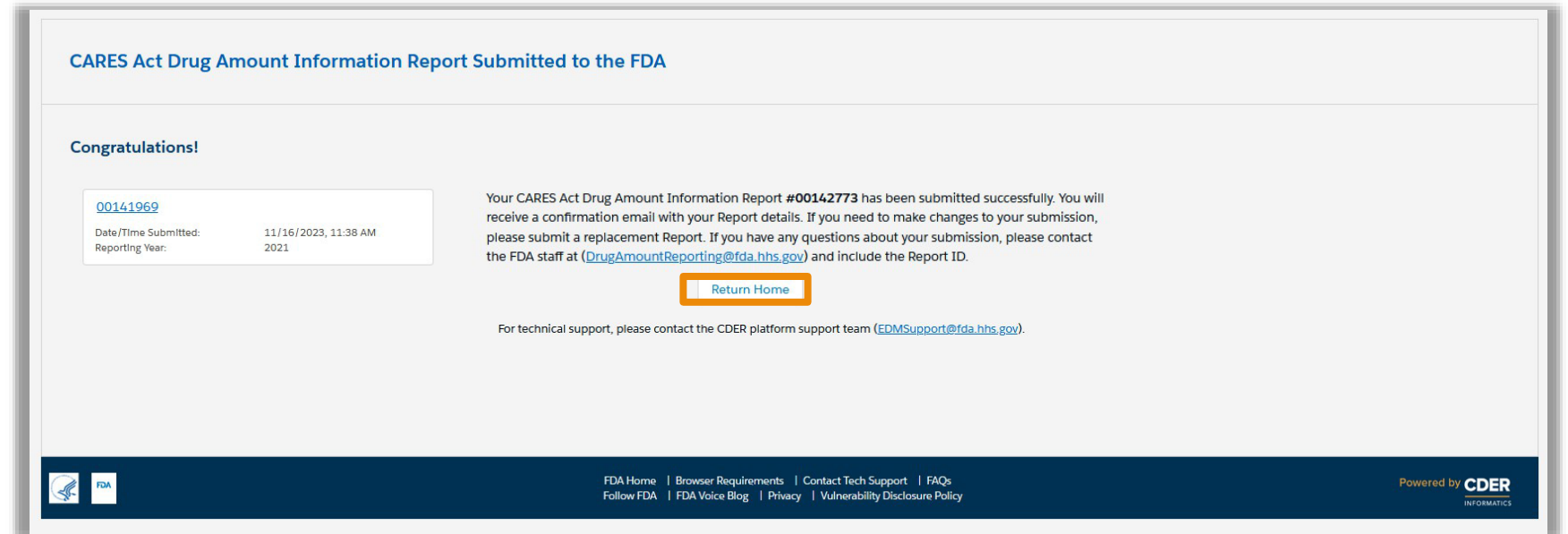
Click **Save** to keep the report for later or click **Delete** to remove the submission.

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

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 titled "CARES Act Drug Amount Information Report Submitted to the FDA". It features a "Congratulations!" message and a box containing the report ID "00141969", the submission date "11/16/2023, 11:38 AM", and the reporting year "2021". A "Return Home" button is highlighted with an orange border. The page also includes instructions on how to contact FDA staff for technical support and a footer with navigation links and the CDER Informatics logo.

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).

  FDA

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INFORMATICS

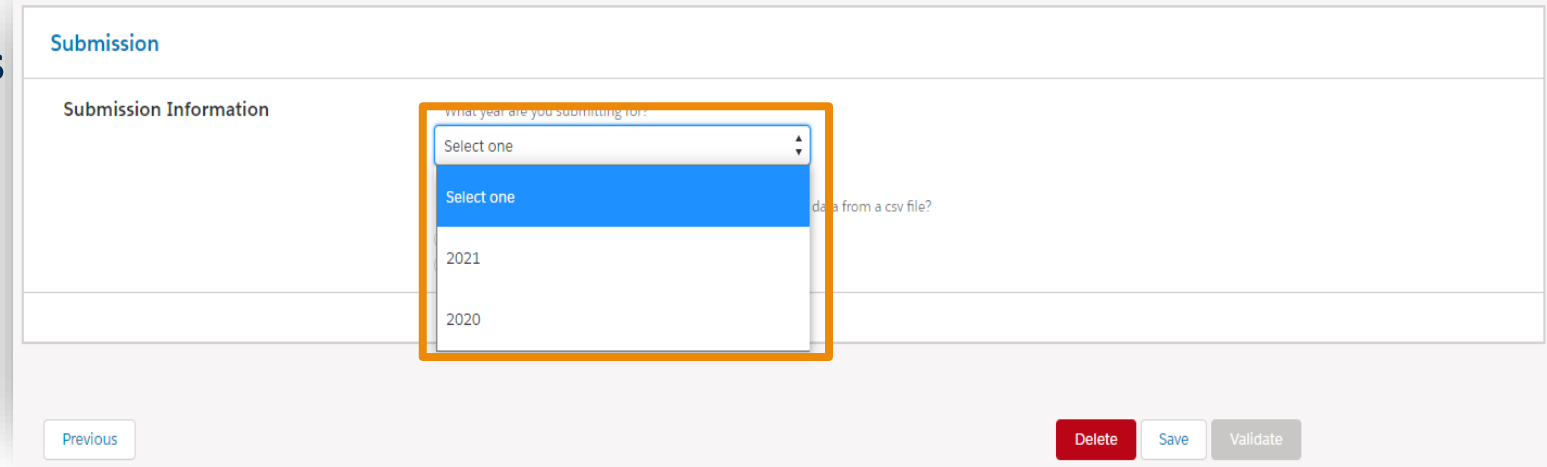
ManualSubmission - API or API+Inactive Ingredients

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

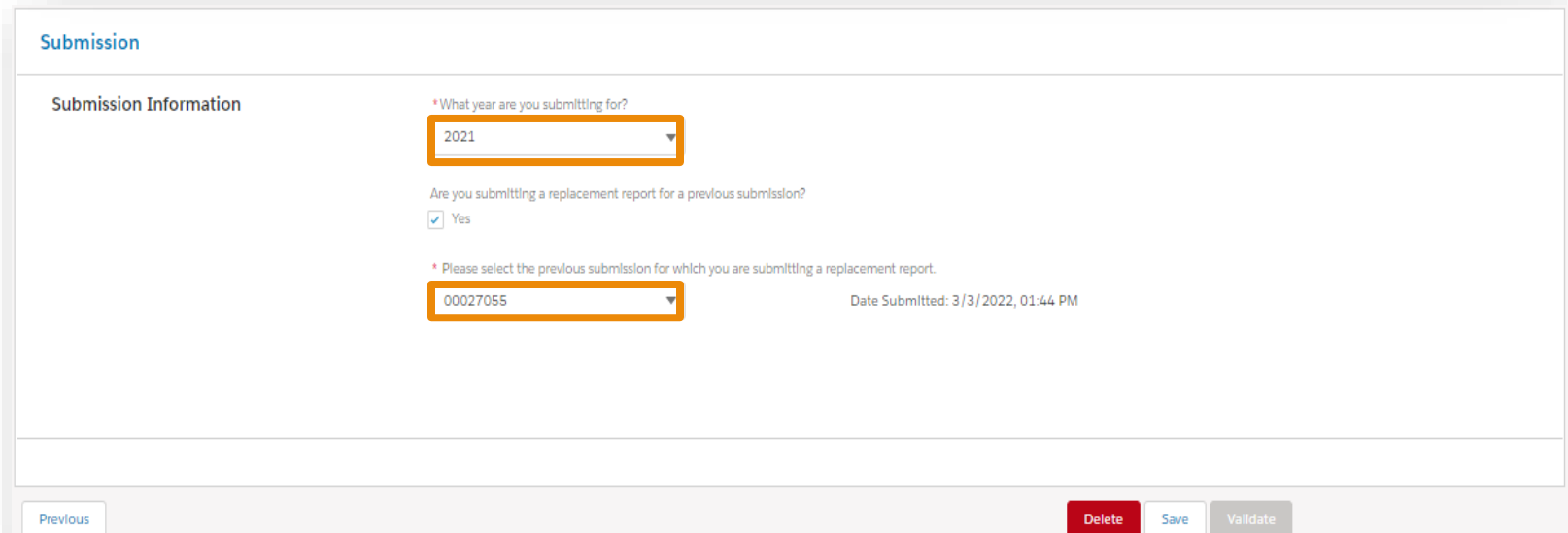
Select one

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

CARES Act Amount Information Reporting

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**.

The screenshot shows the 'Submission Information' form. At the top, there is a dropdown menu for 'What year are you submitting for?' set to '2021'. Below this is a checkbox for 'Are you submitting a replacement report for a previous submission?' which is unchecked. An orange rectangular box highlights the following section: 'What product are you reporting on?' with two radio button options, 'Drug Product' (unchecked) and 'API or API + Inactive Ingredients' (checked); and 'Would you like to submit the product data manually or by uploading data from a CSV file?' with two radio button options, 'Manually' (checked) and 'CSV File' (unchecked). Below the orange box is a '+ Add Establishment' button. At the bottom of the form are three buttons: 'Previous', 'Delete', and 'Save', with a 'Validate' button partially visible on the right.

The screenshot shows the 'CARES Act Drug Amount Information Report' confirmation screen. The title is centered at the top. Below the title is a paragraph of text: '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.' At the bottom right of the screen are two buttons: 'Cancel' and 'Continue'. The 'Continue' button is highlighted with an orange rectangular box.

CARES Act Amount Information Reporting

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

+ Add Establishment

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

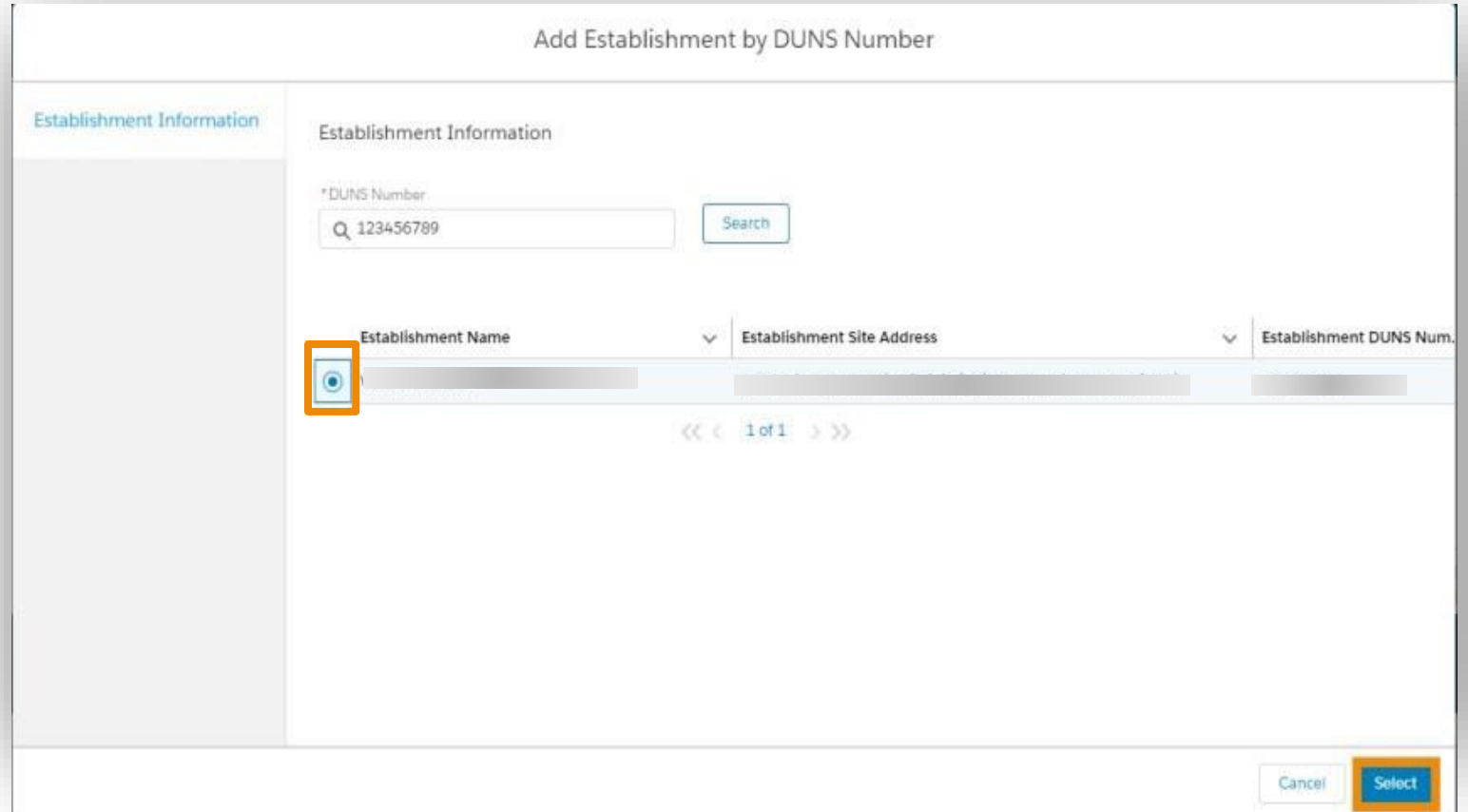
Manual Submission – API or API + Inactive Ingredients

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

*DUNS Number
Q 123456789 Search

Establishment Name	Establishment Site Address	Establishment DUNS Num.
<input checked="" type="radio"/>		

<< < 1 of 1 > >>

Cancel Select

CARES Act Amount Information Reporting

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.

The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the heading "Establishment Information". The main content area also has the heading "Establishment Information". It contains a search field labeled "* DUNS Number" with the text "111111111" entered. To the right of the search field is a "Search" button. Below the search field, a red error message reads: "DUNS Not found. Please search a different DUNS or add manually." Below this message is a button labeled "+ Add Manually". At the bottom right of the form are "Cancel" and "Select" buttons. Orange boxes highlight the "Search" button and the "+ Add Manually" button.

CARES Act Amount Information Reporting

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**.

The screenshot shows a web form titled "Add Establishment by DUNS Number". On the left is a sidebar with the link "Establishment Information". The main content area is titled "Manually Add Establishment Information". It contains several input fields: "* Establishment DUNS Number" with a "Back to Search" button; "* Establishment Name"; "* Address Line 1" and "Address Line 2"; "* City" and "* Country" (a dropdown menu showing "--None--"); and "State/Province" and "* Zip Code". At the bottom right, there are "Cancel" and "Save" buttons. The "Save" button is highlighted with an orange rectangle.

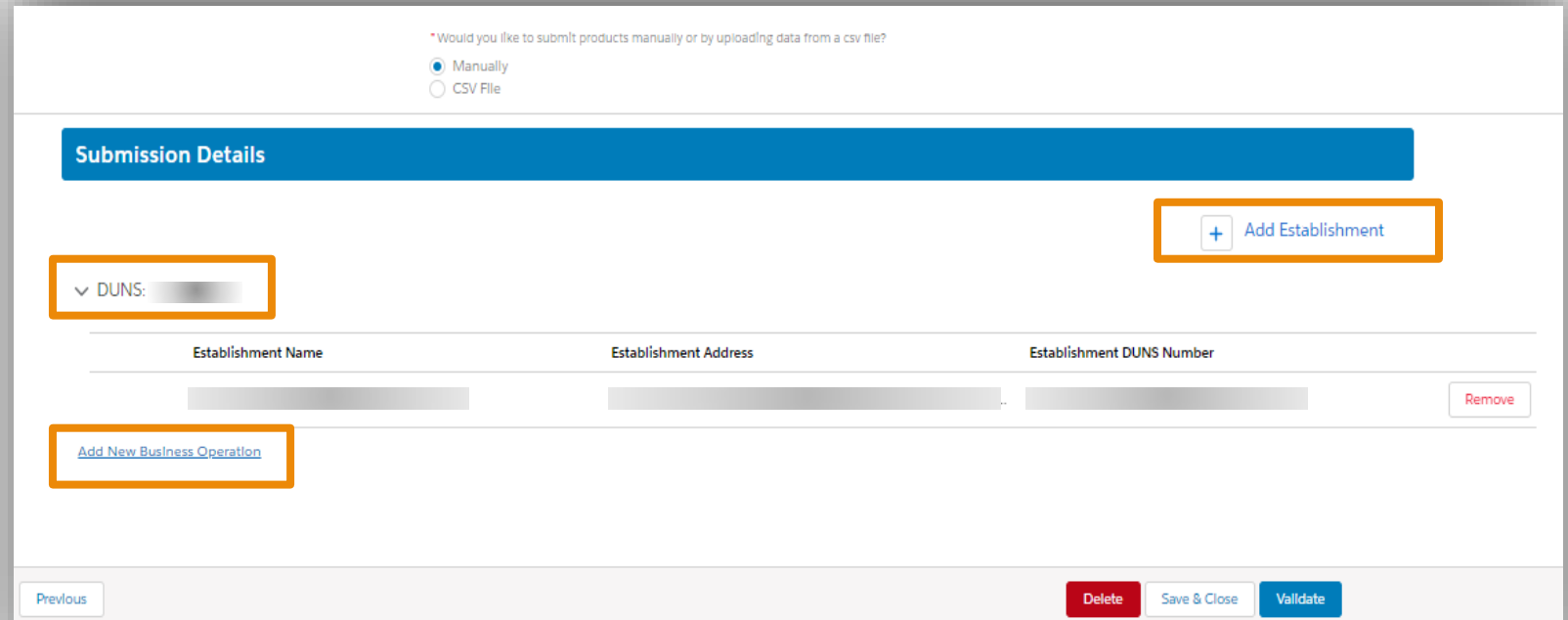
Manual Submission – API or API + Inactive Ingredients

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.



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

☒ Manually
☐ CSV File

Submission Details

[+ Add Establishment](#)

▼ DUNS: [redacted]

Establishment Name	Establishment Address	Establishment DUNS Number	
[redacted]	[redacted]	[redacted]	Remove

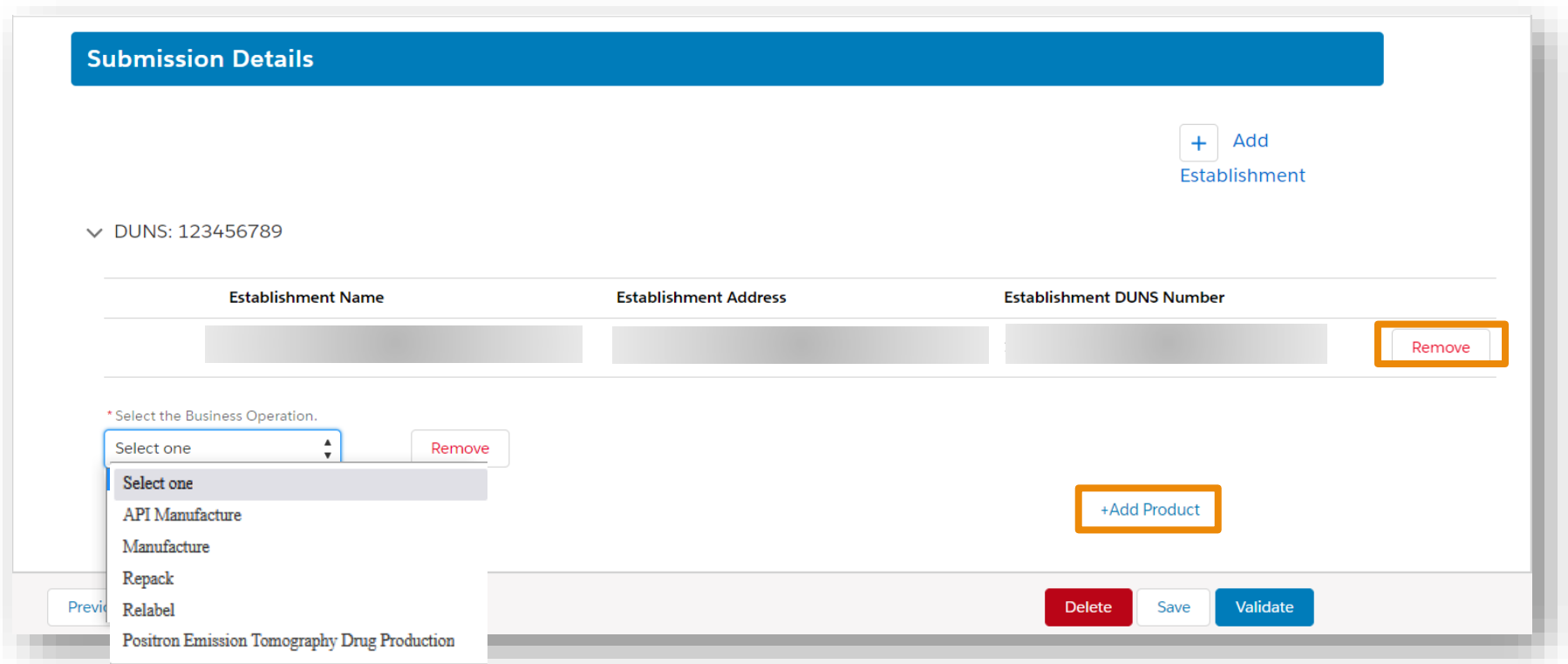
[Add New Business Operation](#)

[Previous](#) [Delete](#) [Save & Close](#) [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 displays the 'Submission Details' form. At the top right is a '+ Add Establishment' button. Below it, a collapsed section 'DUNS: 123456789' is shown. A table with three columns—'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'—contains one row with greyed-out input fields and a 'Remove' button. Below the table, a label '* Select the Business Operation.' is followed by a dropdown menu currently showing 'Select one'. The dropdown list includes 'API Manufacture', 'Manufacture', 'Repack', 'Relabel', and 'Positron Emission Tomography Drug Production'. A 'Remove' button is next to the dropdown. To the right of the dropdown is a '+Add Product' button. At the bottom left is a 'Previous' button, and at the bottom right are 'Delete', 'Save', and 'Validate' buttons.

CARES Act Amount Information Reporting

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 Manually

Add Drug or Biological Product by NDC

NDC

Cancel Select

CARES Act Amount Information Reporting

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

Back to Search

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

Cancel Add Product

Manual Submission – API or API + Inactive Ingredients

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

[+Add Product](#) [Remove Product](#)

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
<input type="checkbox"/>	60.00 <i>Annual Total</i>	L		11.33 <i>Annual Average</i>	3.00 <i>Annual Minimum</i>	▲
January	10.00			20.00	5.00	
February	20.00			10.00	3.00	
March	30.00			4.00	10.00	

CARES Act Amount Information Reporting

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.

CARES Act Drug Amount Information Reporting

Validated Successfully !

APPLICATION BUILDER

- Submitter Information
- Submission

Need Help?

The [Help Center](#) is available to answer questions on creating and submitting a CARES Act Drug Amount Information Reporting submission to the FDA.

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

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

Submission Details

+ Add Establishment

> DUNS: 123456789

Previous

Delete Save **Validate**

Certifications

☒ 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

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.

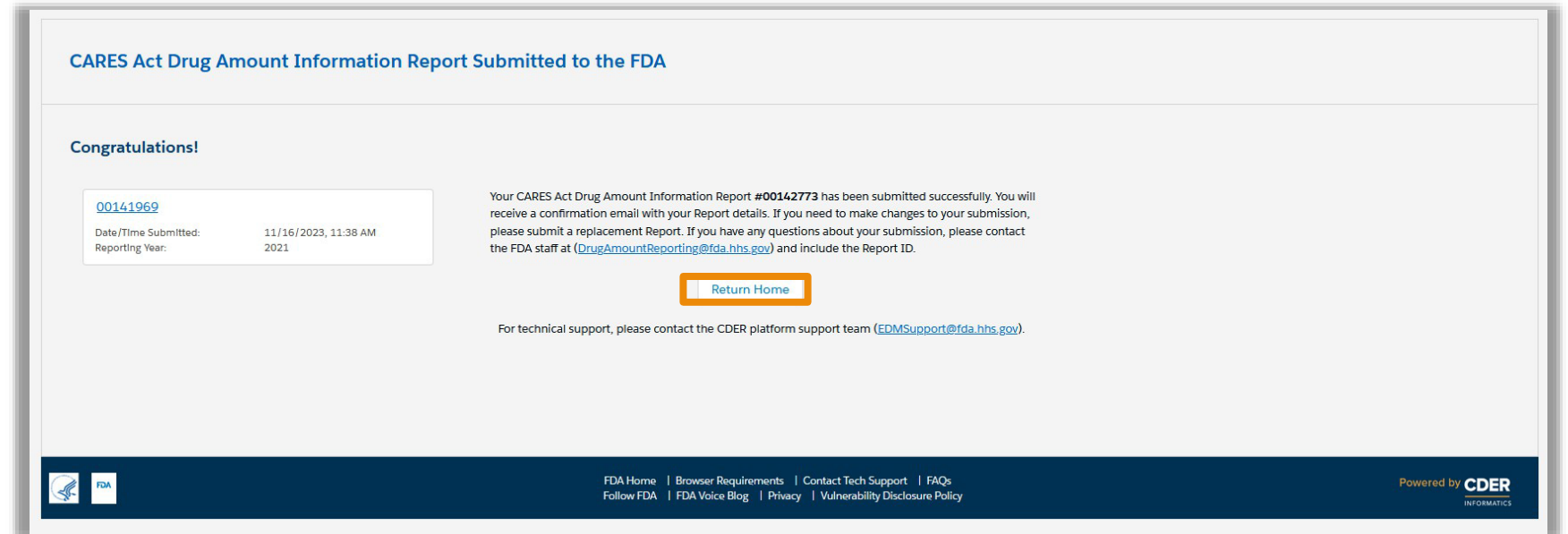
Cancel Submit

Delete Save **Submit**

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.



Technical Support and Resources

CDER NextGen Portal Support & Resources

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

CDER NextGen Portal Announcements

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

Learn More Information

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

Technical Support

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

CDER NextGen Portal Video Tutorial

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

