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.

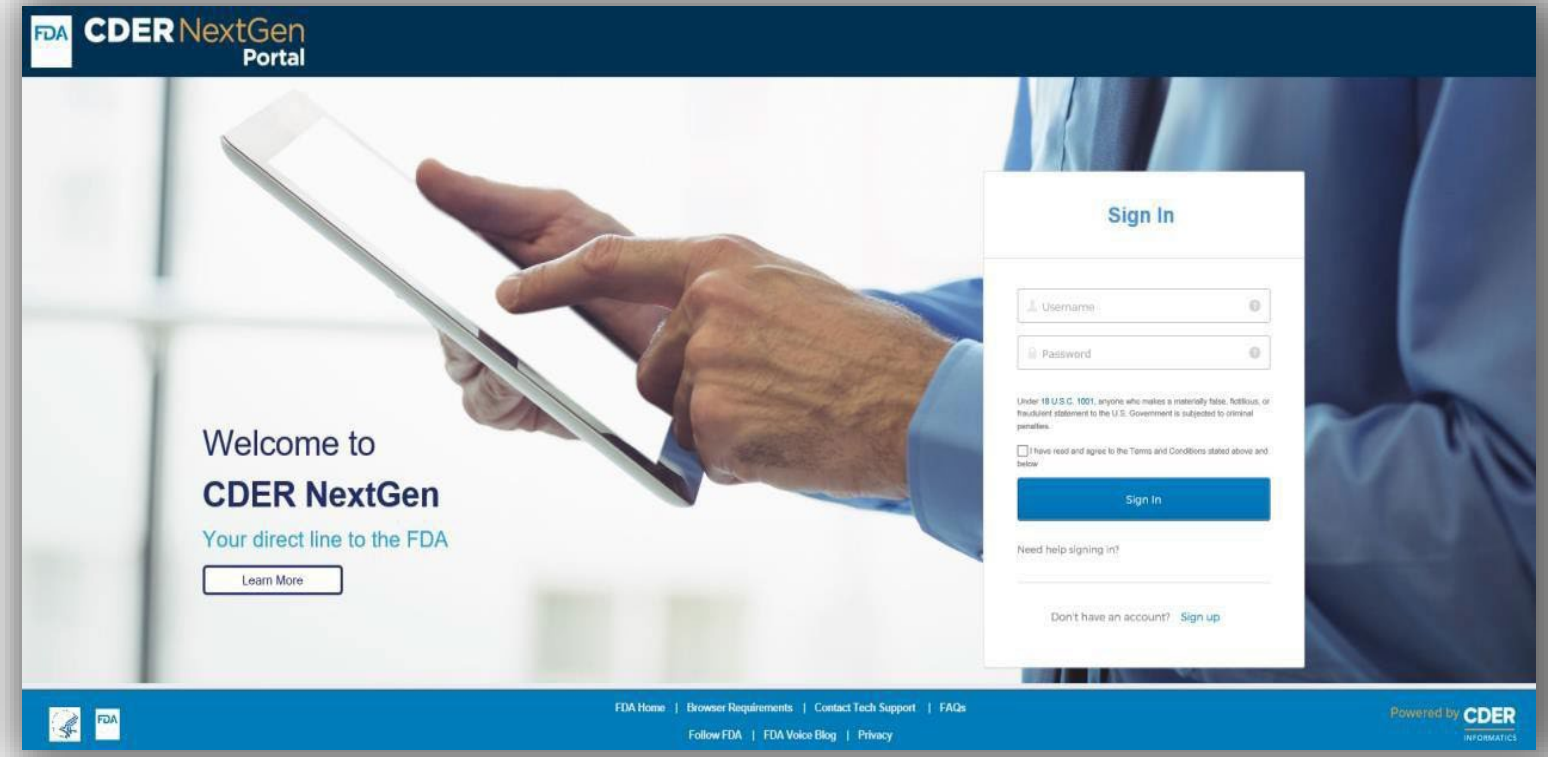
For questions on how to enter or upload data, please email the Drug Amount Reporting Team (DrugAmountReporting@fda.hhs.gov).

CSVFileUploadSubmission

CSV FileUpload – CreatingaNewReportandEnteringSubmitterDetails

CDER NextGen Portal Homepage

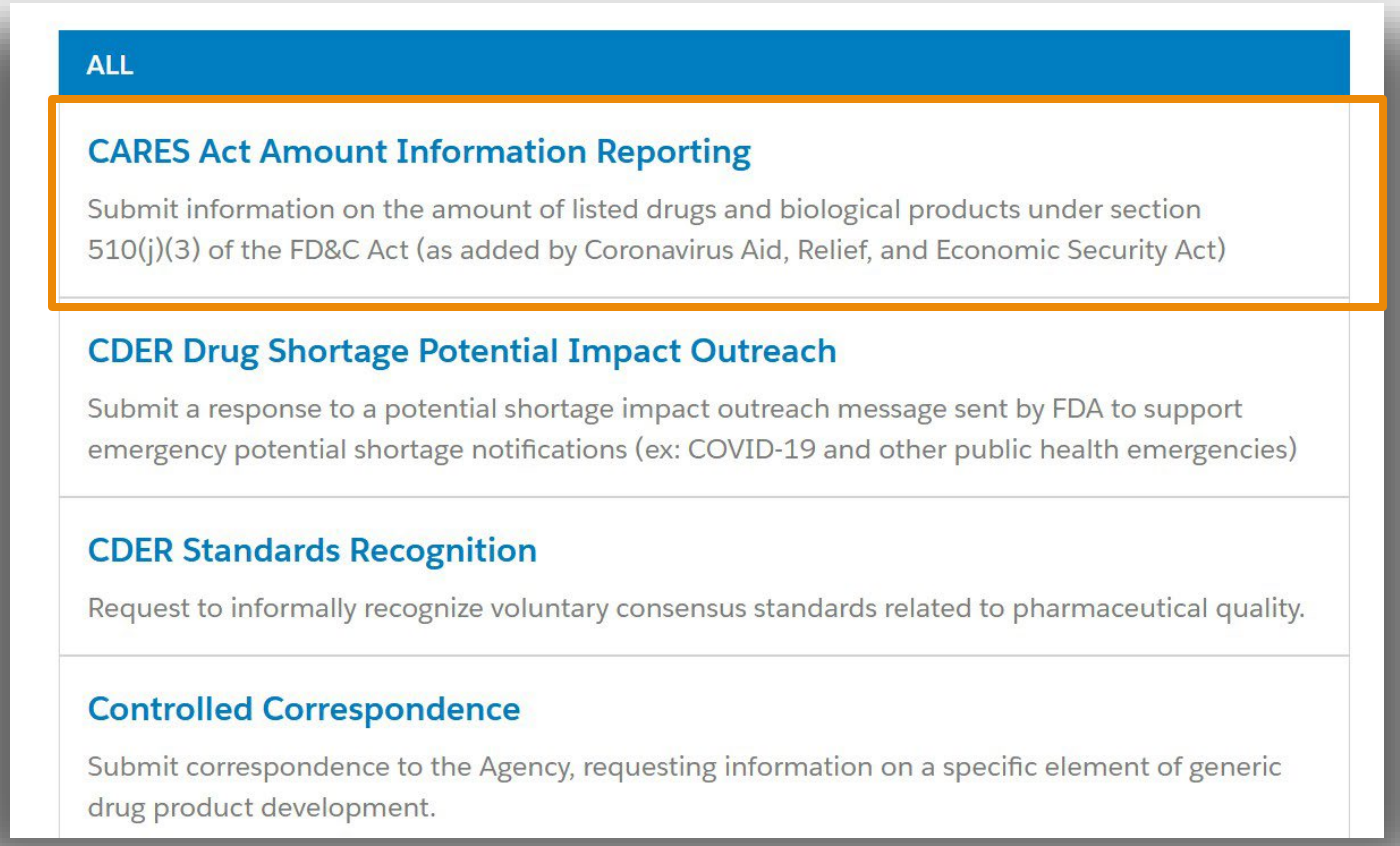
Step 1. First, sign in on the CDER NextGen Portal homepage.



CARES Act Amount Information Reporting

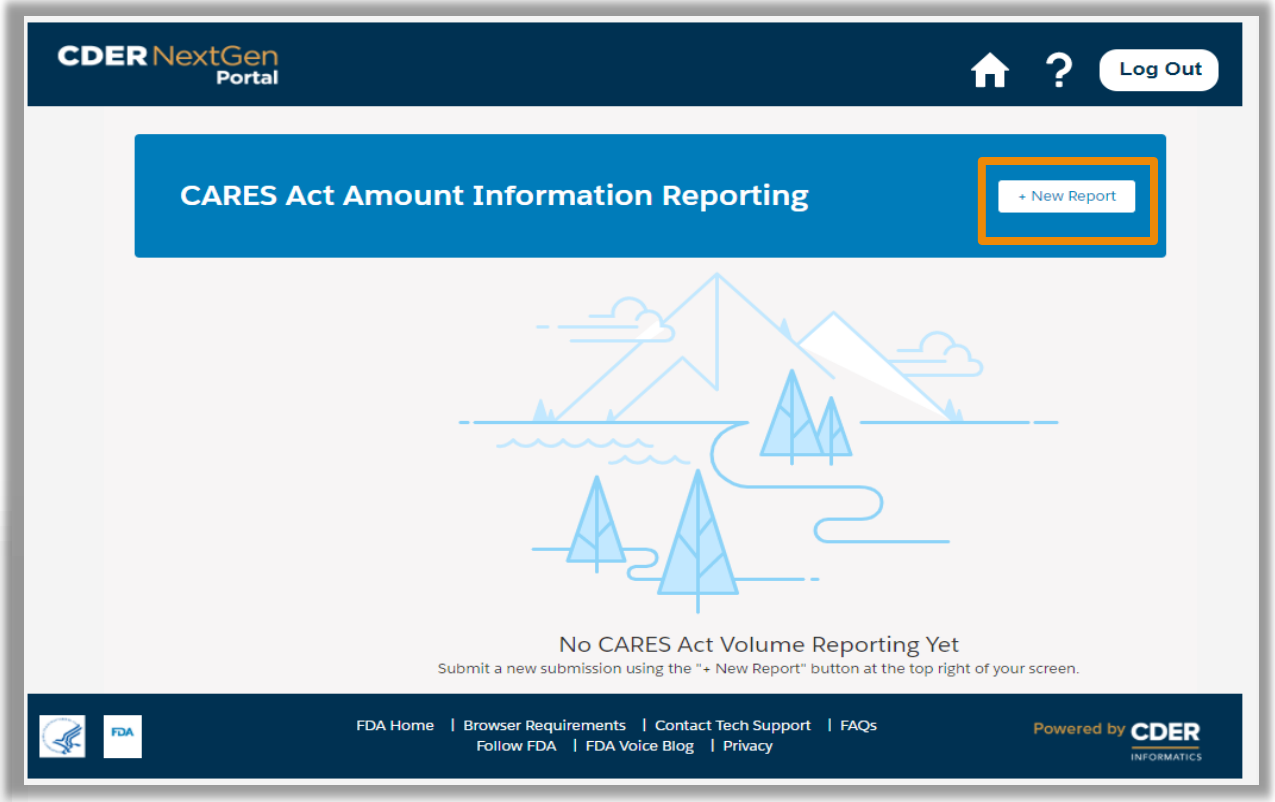
CDER NextGen Portal Homepage

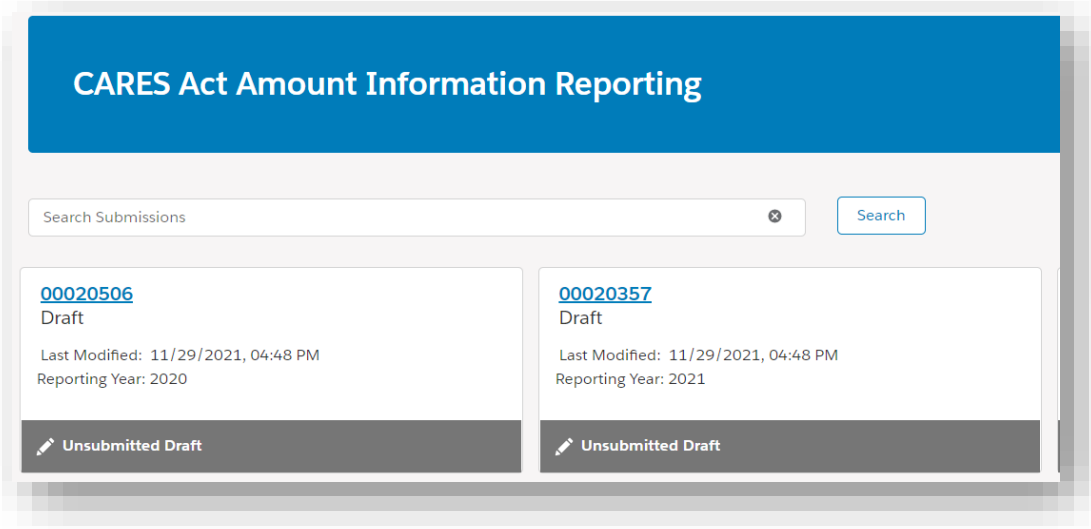
Step 2. From the main menu, click **CARES Act Amount Information Reporting.**



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.

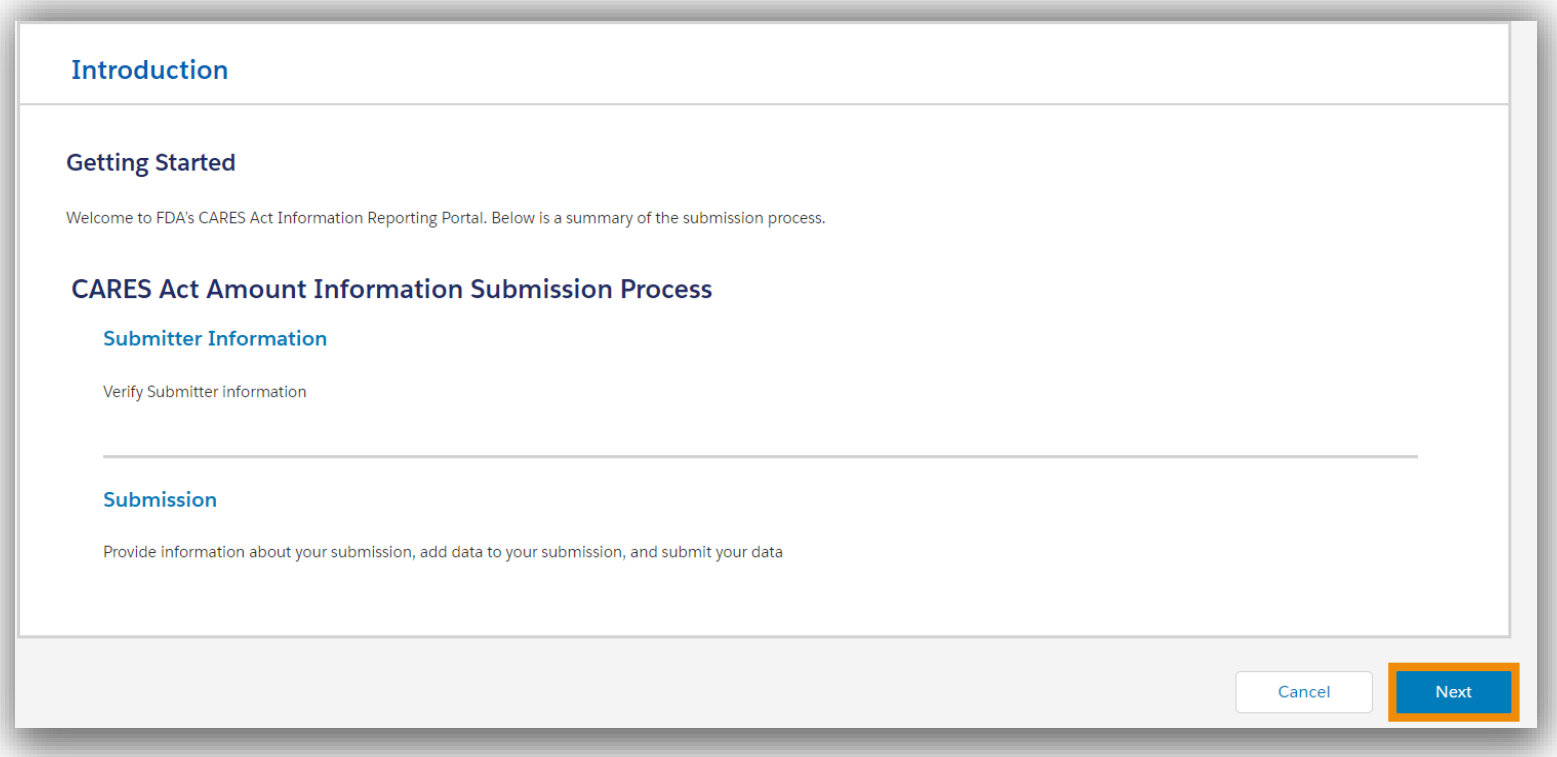




CARES Act Amount Information Report

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.**

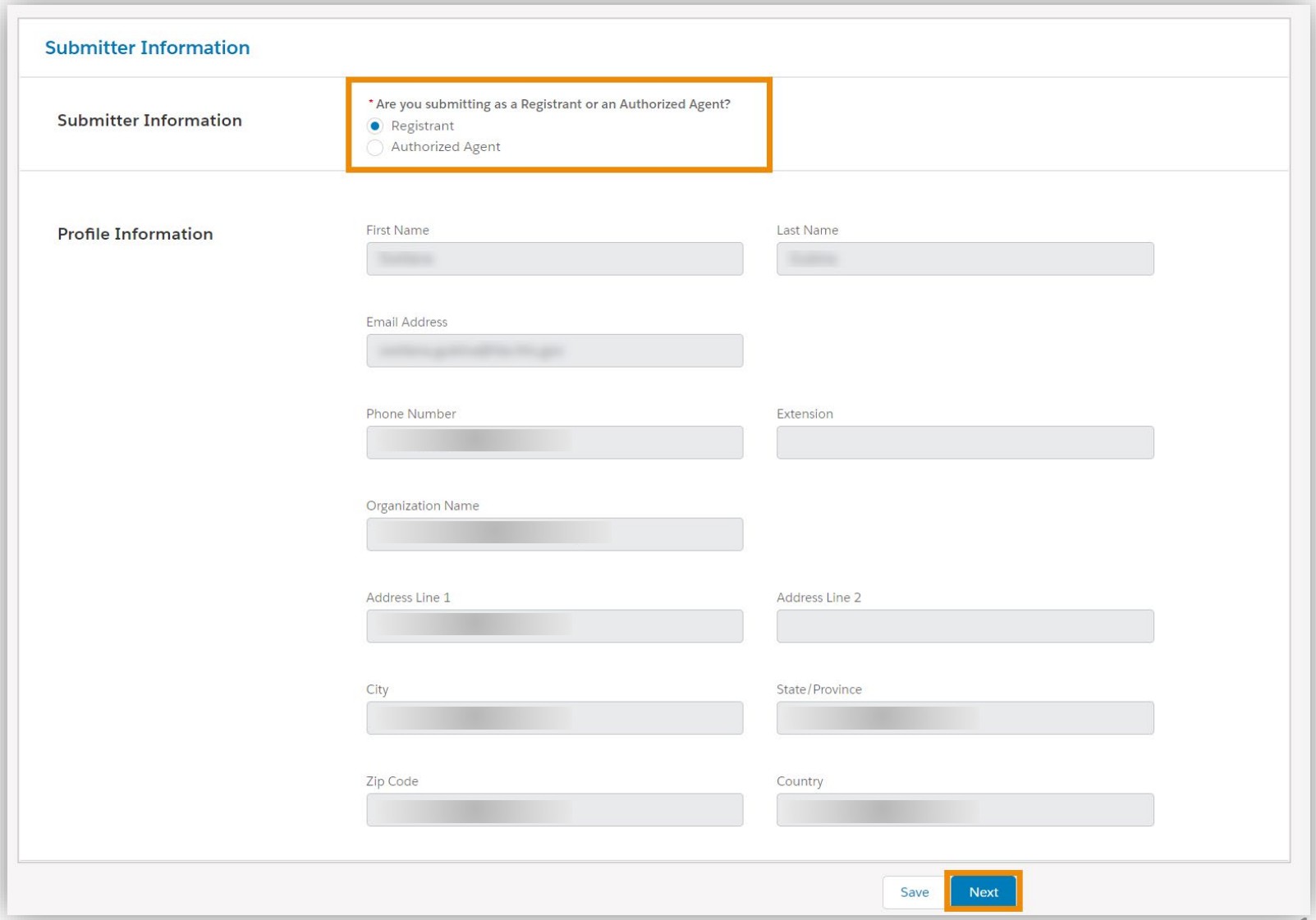


CARES Act Amount Information Reporting

Submitter Information

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

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



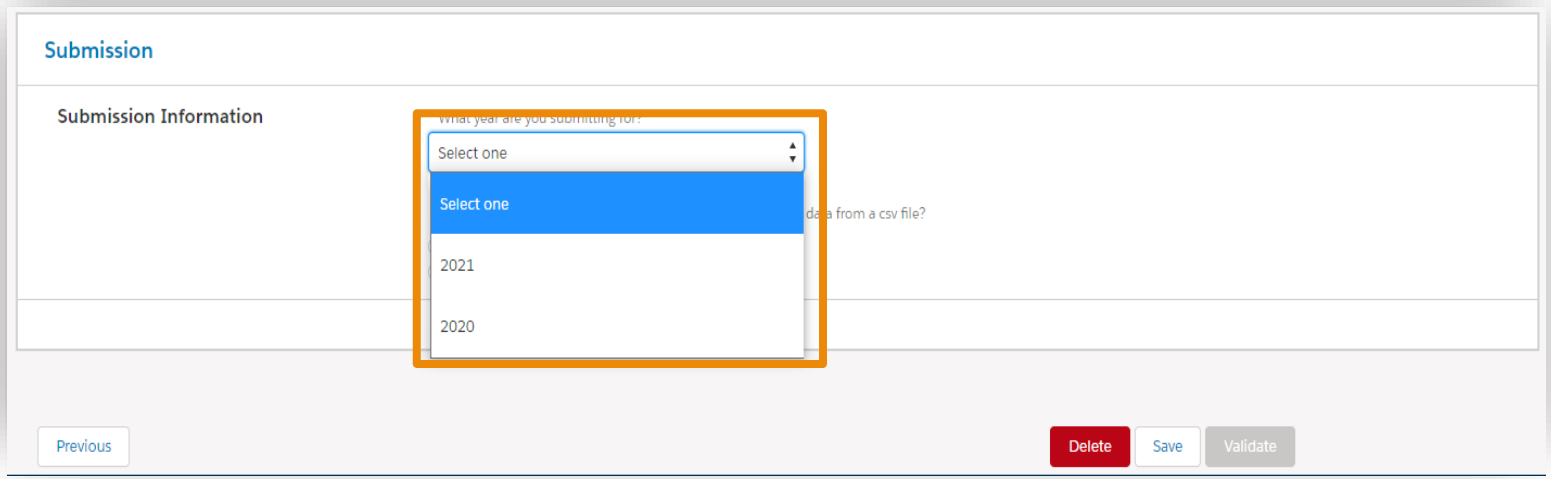
CSVFileUploadSubmission - Finished Package Form

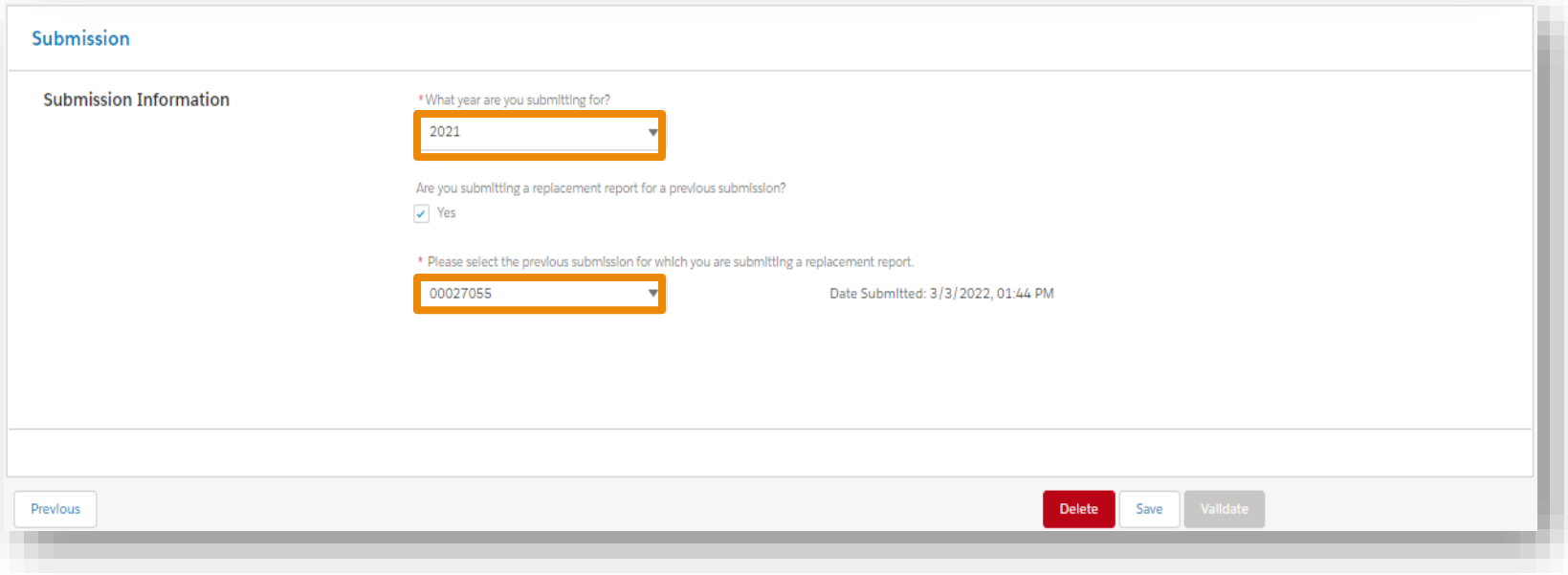
CSV Submission – Finished Package Form

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.





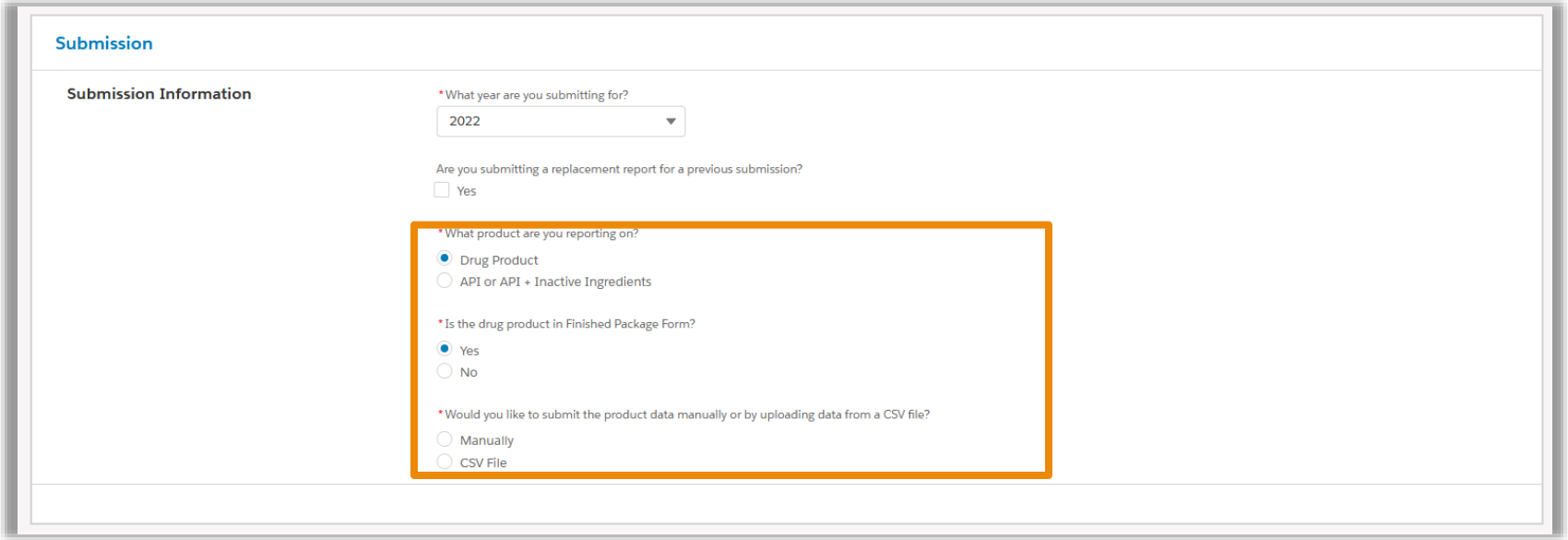
CSV Submission – Finished Package Form

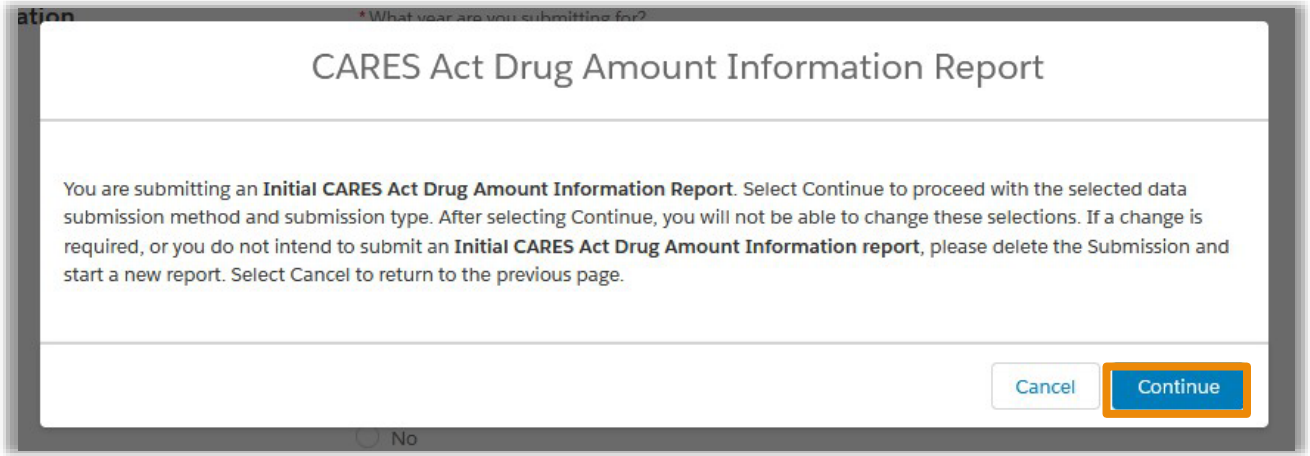
Step 10. Select that you are reporting on a Drug Product.

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.**





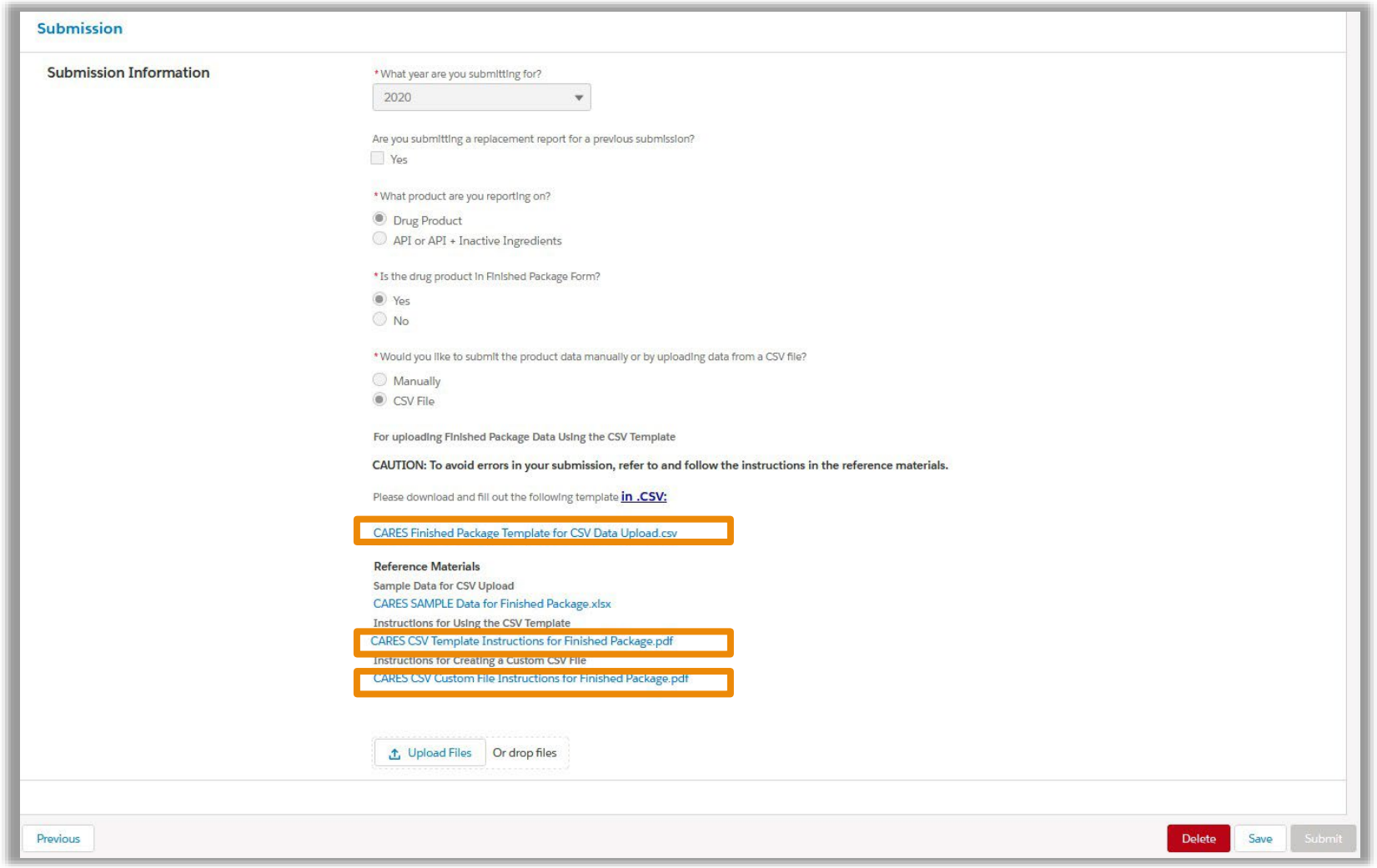
CSV Submission – Finished Package Form

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.



CSV Submission – Finished Package Form

Step 15. Enter the requested information in the CSV template or construct your own CSV file to match this template. Then, save the document to your computer as a CSV file.

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

	A	B	C	D	E	F	G	H	I	J	K	L
1	Establishment DUNS	Business Operation	NDC	Source NDC	Amount Per	Outermost Quantity Manufactured	Outermost Quantity Distributed (Non-US)	Outermost Package Type	Innermost Quantity Manufactured	Innermost Quantity [	Innermost Package Type	Intended to Fulfill 21 CFR 314.81
2	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”

CARES Act Amount Information Reporting

CSV Submission – Finished Package Form

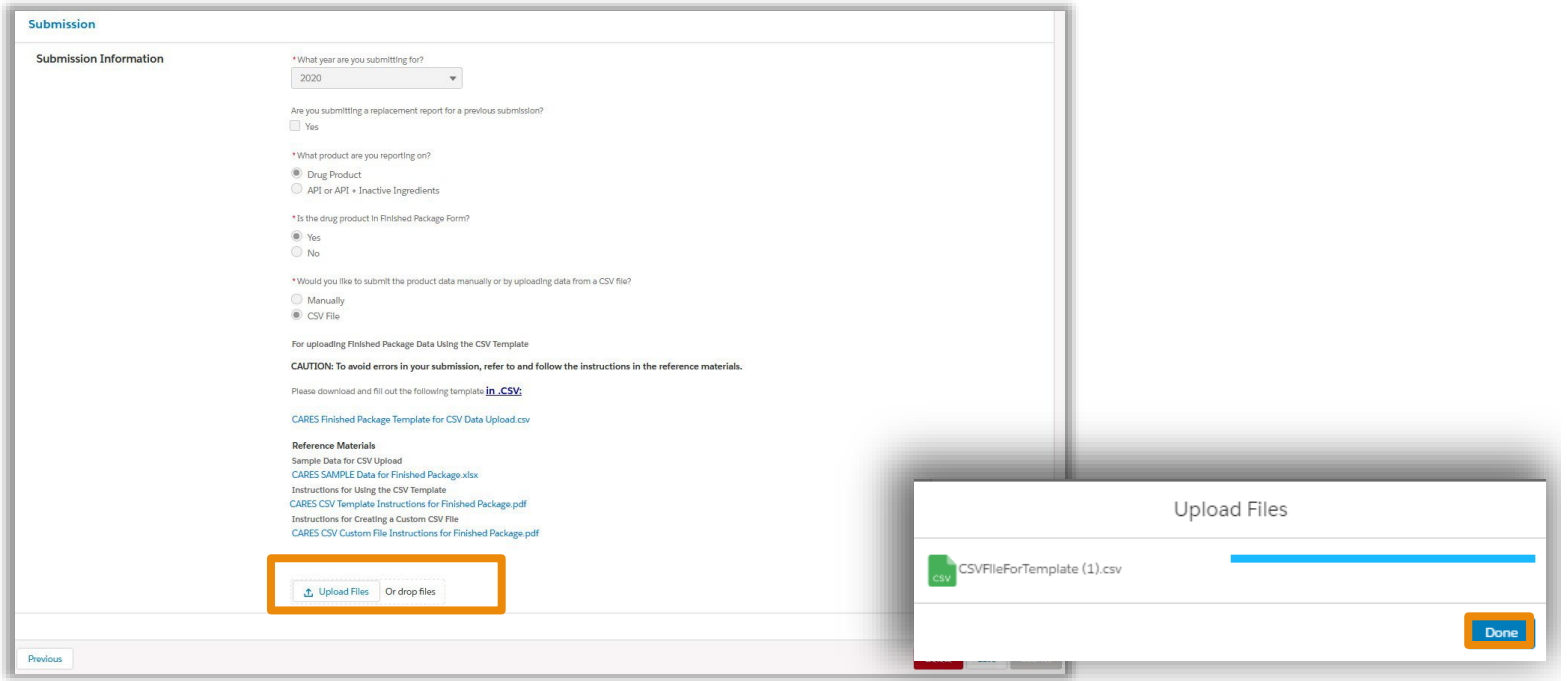
Step 16. Once all data has been entered into the CSV file, upload the data from the document into the portal by

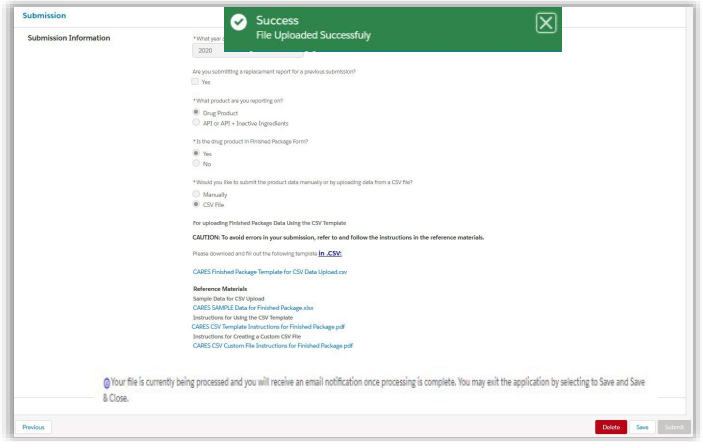
(1) clicking **Upload Files** and selecting the CSV file, or

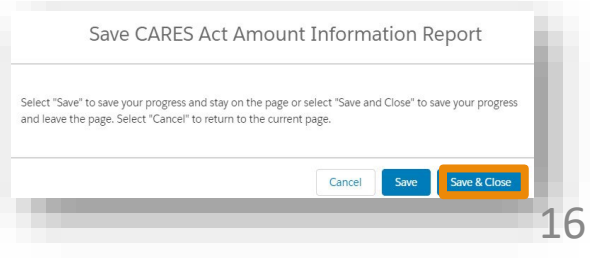
(2) dragging and dropping the CSV file onto **Or drop files**.

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.**



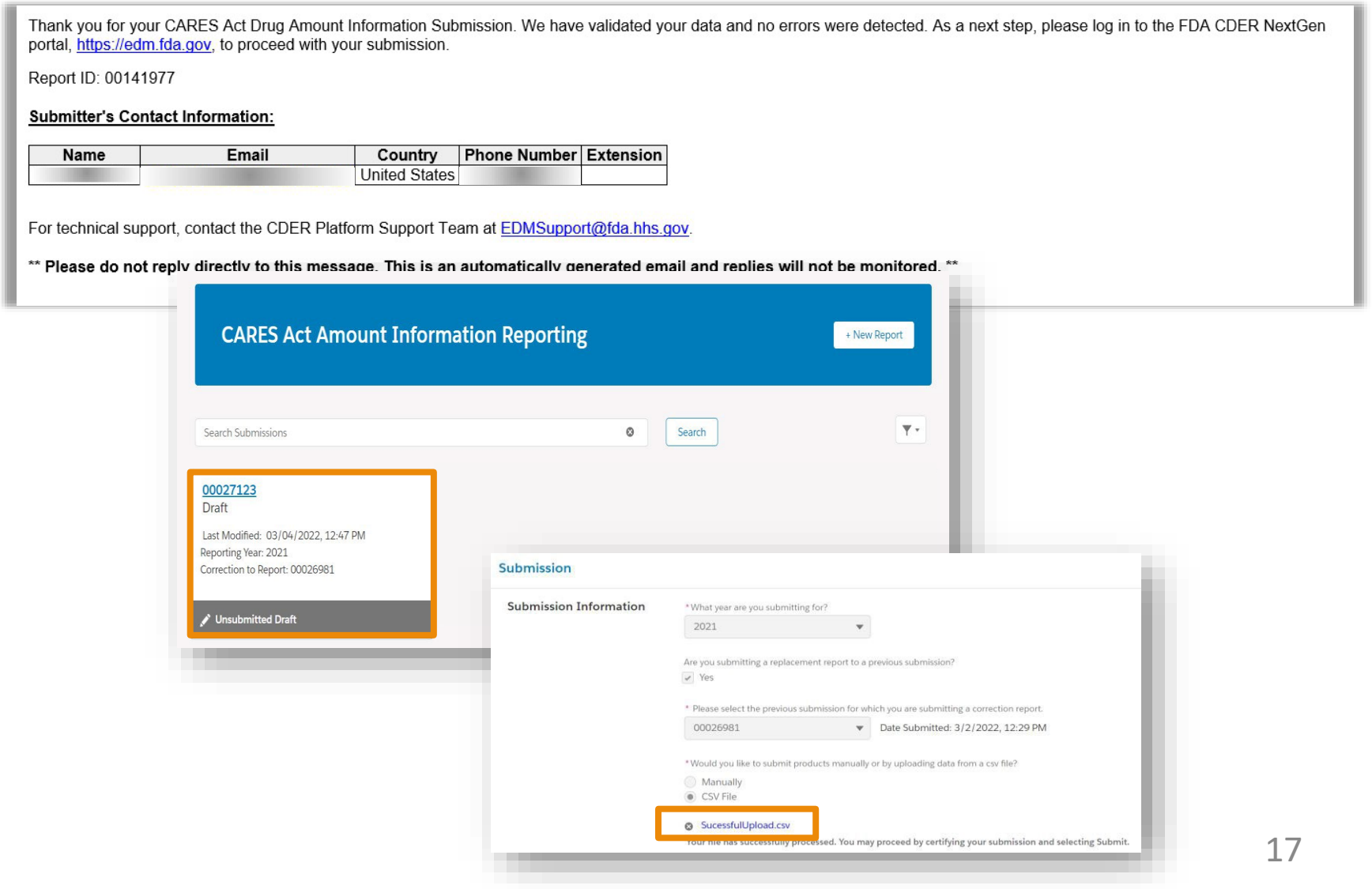




CSV Submission – Finished Package Form

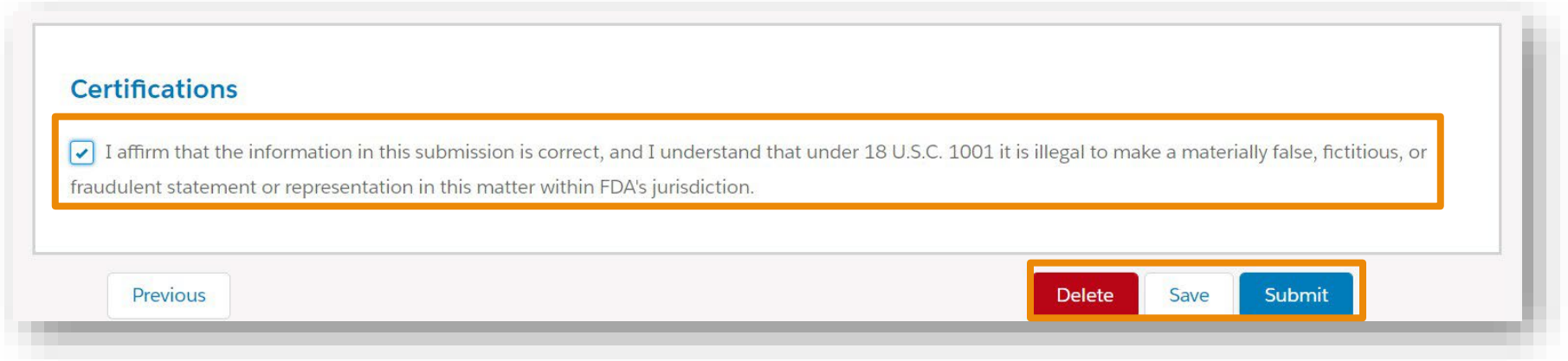
Step 19. Once you receive an email confirming the processing of your CSV file, return to the landing page and click on the report ID.

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.



CARES Act Amount Information Reporting

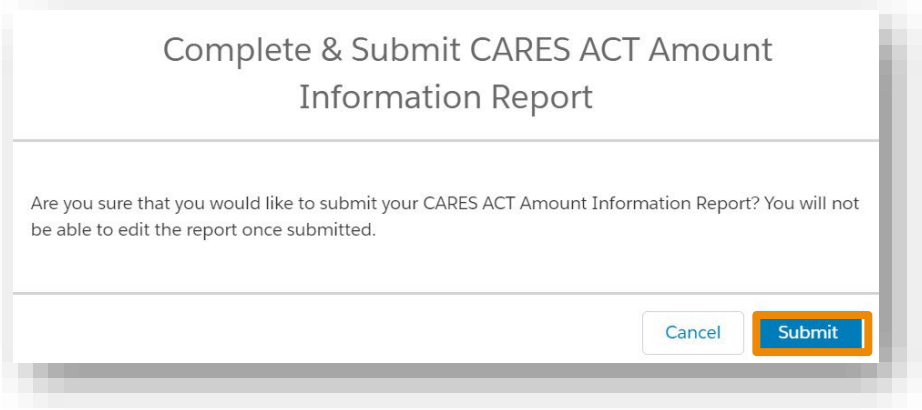
CSV Submission – Finished Package Form



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.

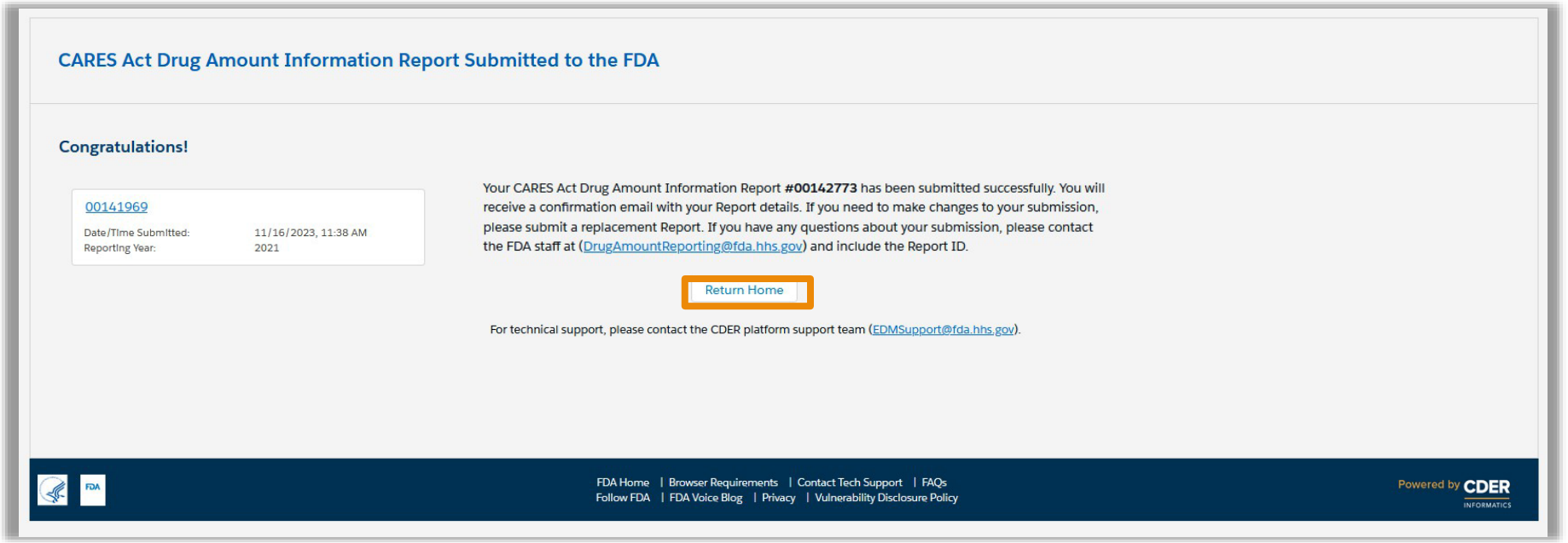


CARES Act Amount Information Reporting

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.



CSVFileUploadSubmission - NotinFinished Package Form

CARES Act Amount Information Reporting

CSV Submission – Not in Finished Package Form

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

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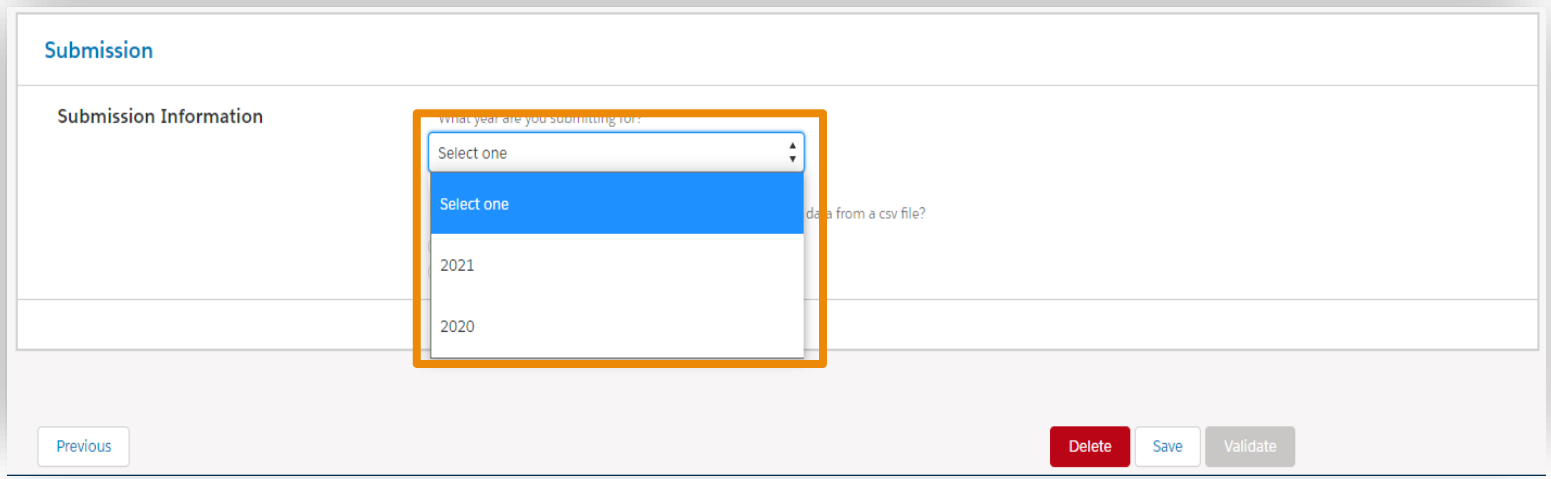
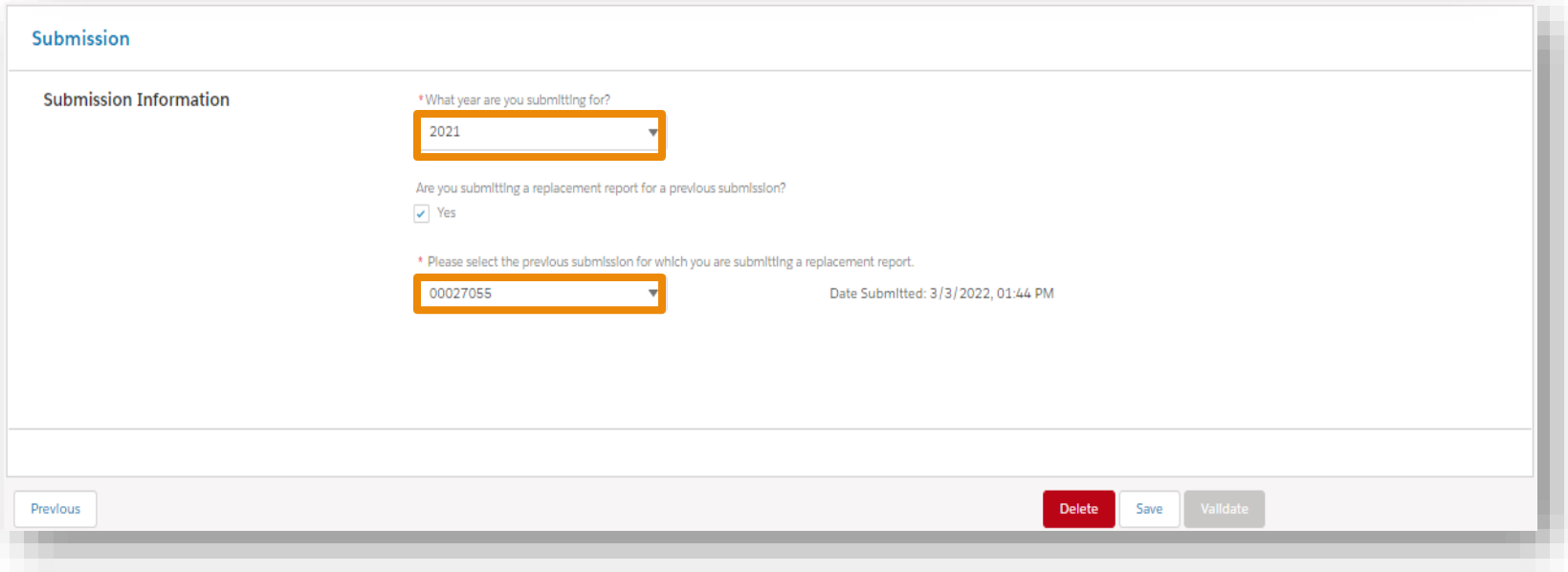




CARES Act Amount Information Reporting

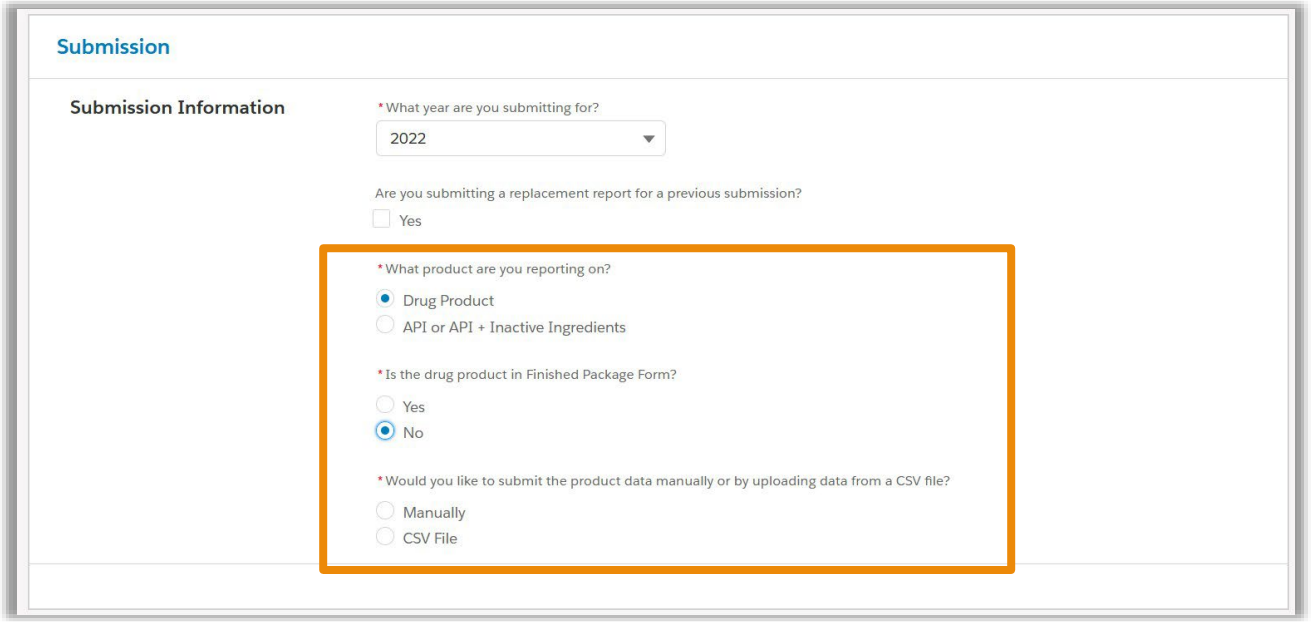
CSV Submission – Not in Finished Package Form

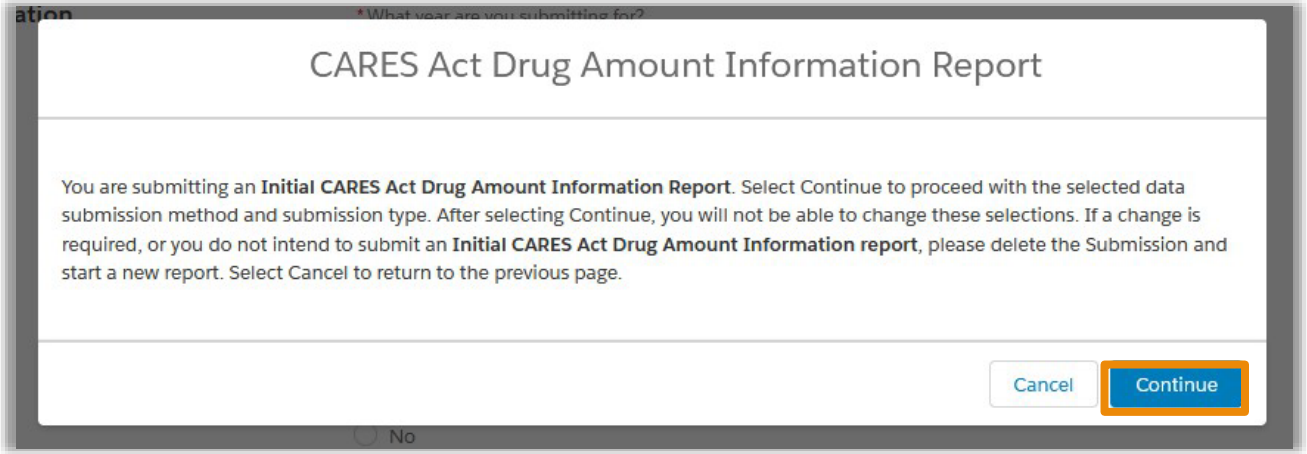
Step 10. Select that you are reporting on a Drug Product.

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

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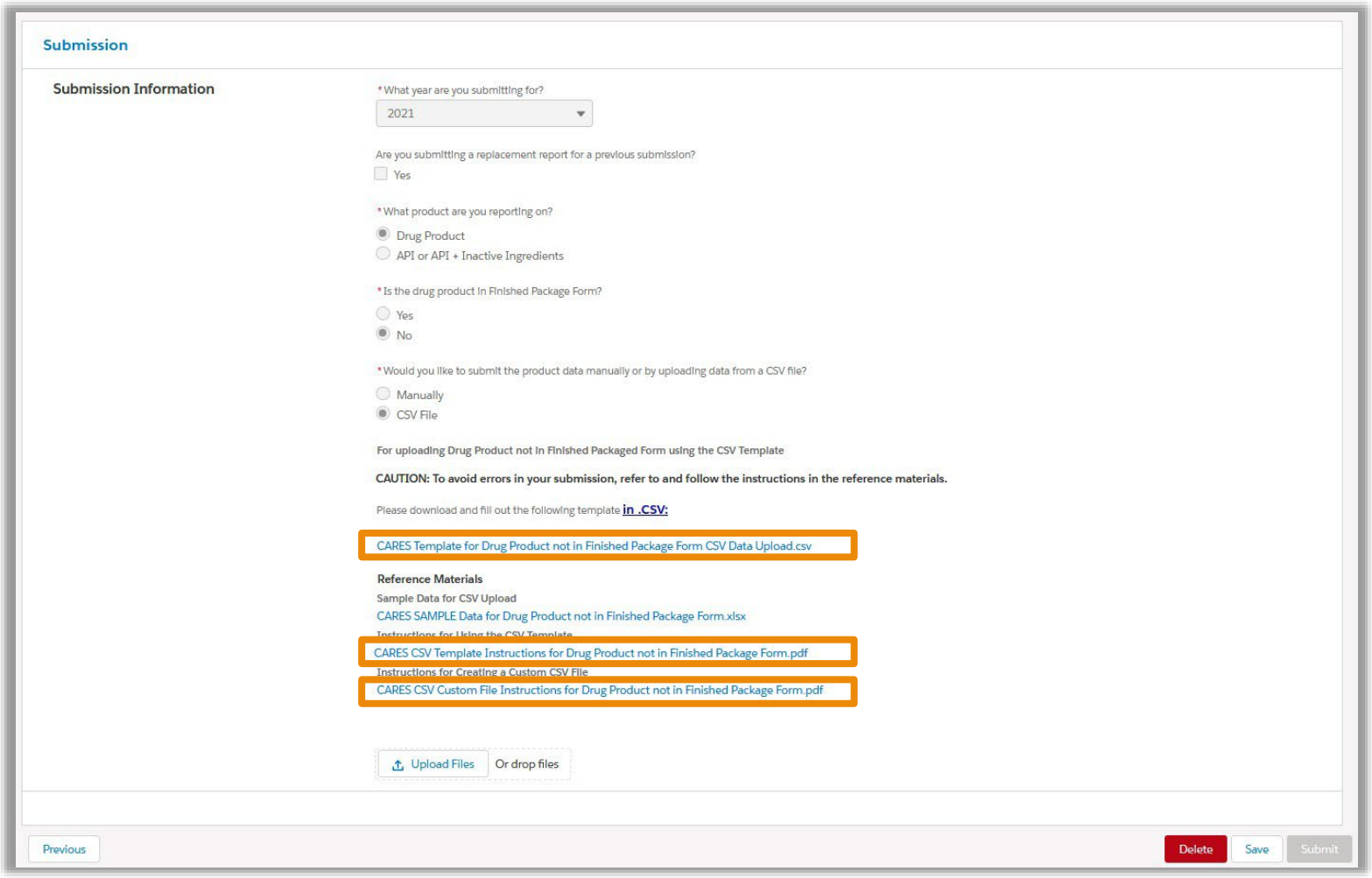

CARES Act Amount Information Reporting

CSV Submission – Not in Finished Package Form

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	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

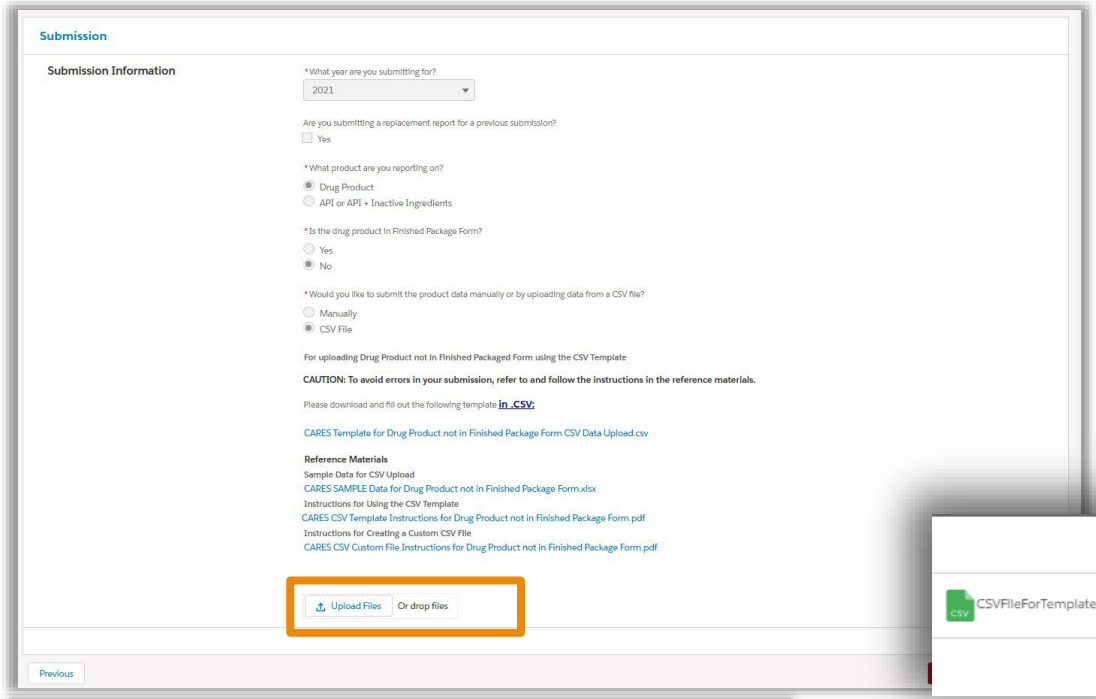
Step 16. Once all data has been entered into the CSV file, upload the data from the document into the portal by

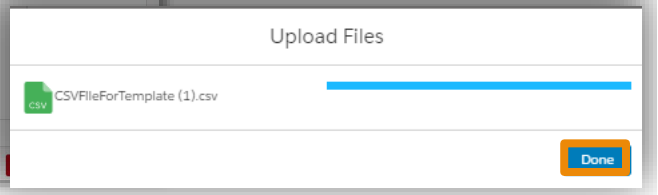
(1) clicking **Upload Files** and selecting the CSV file, or

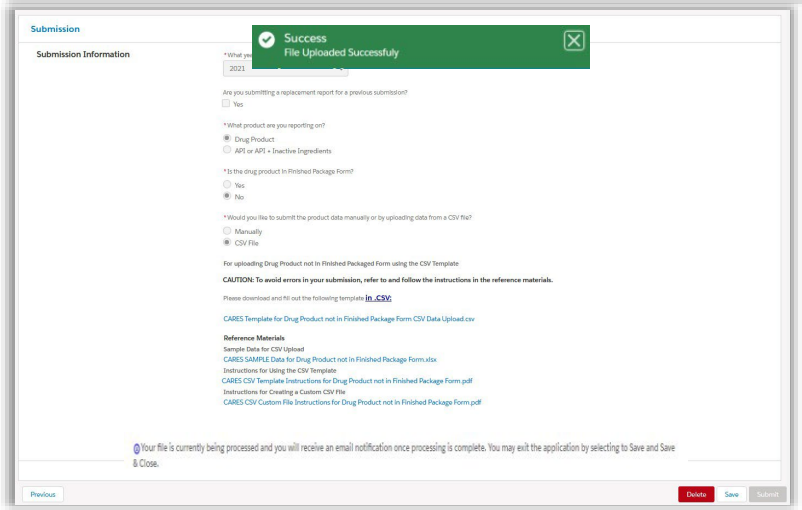
(2) dragging and dropping the CSV file onto **Or drop files**.

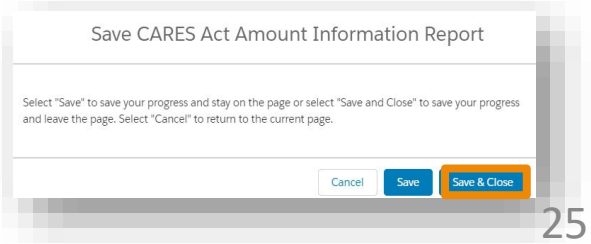
Step 17. When the status bar indicates that the data has finished uploading, click **Done**.

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.**







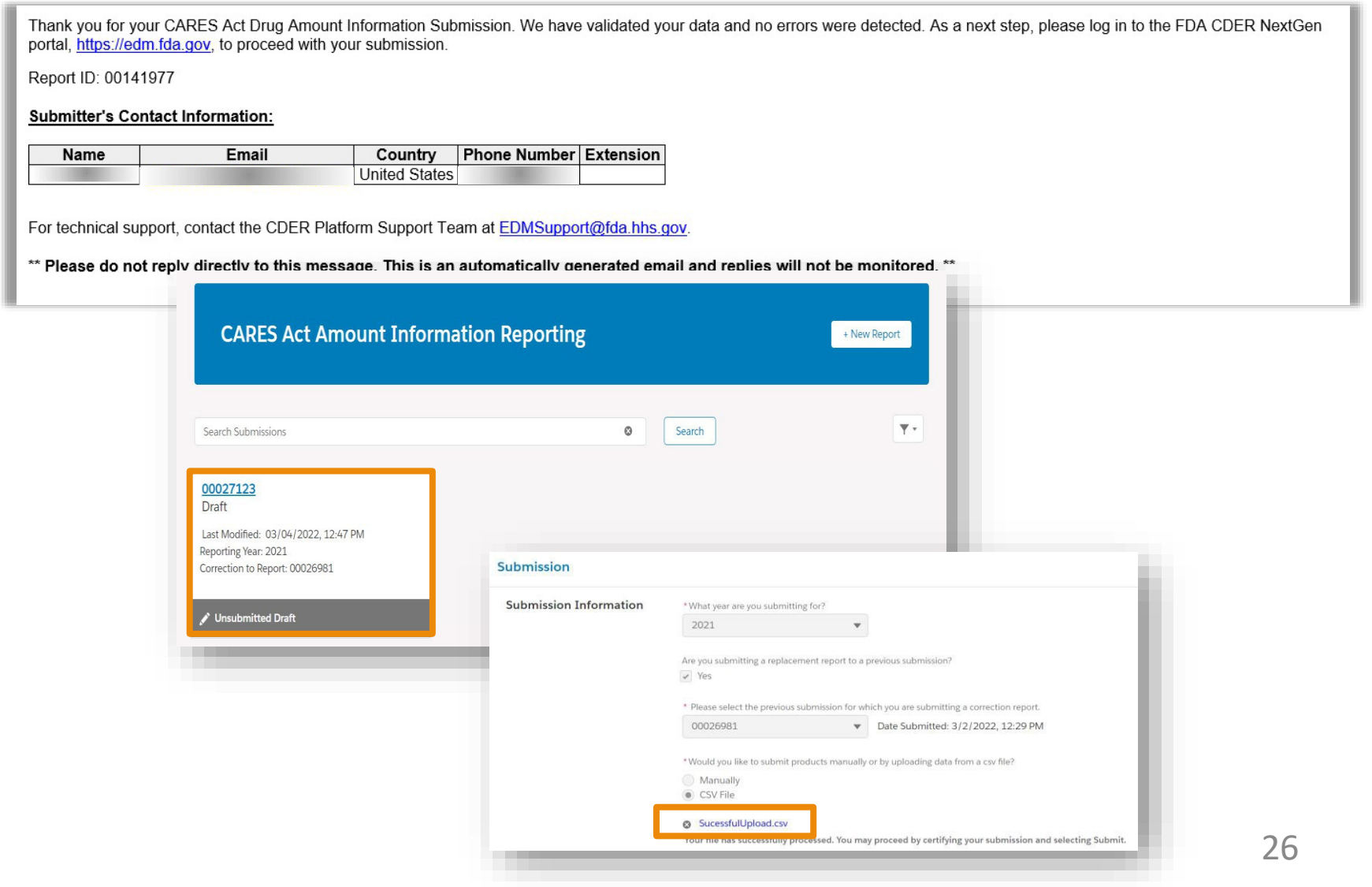


CARES Act Amount Information Reporting

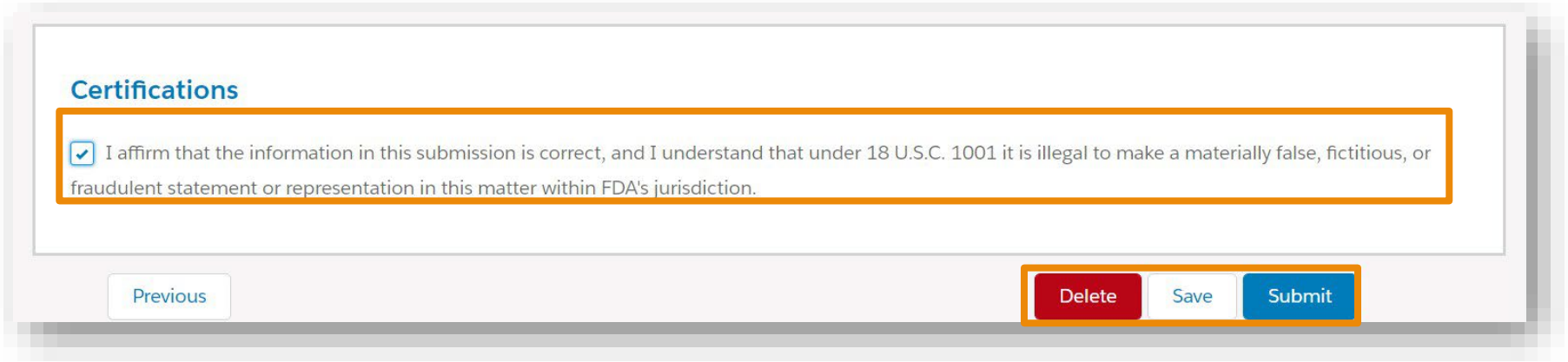
CSV Submission – Not in Finished Package Form

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.



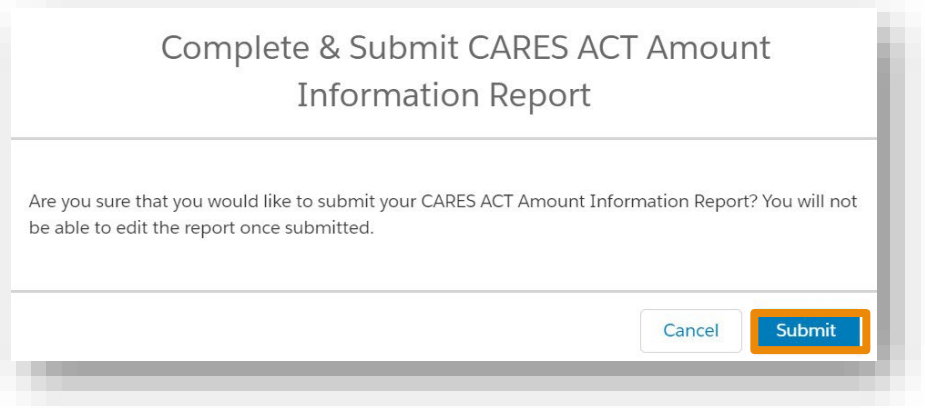
CSV Submission – Not In Finished Package Form



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.

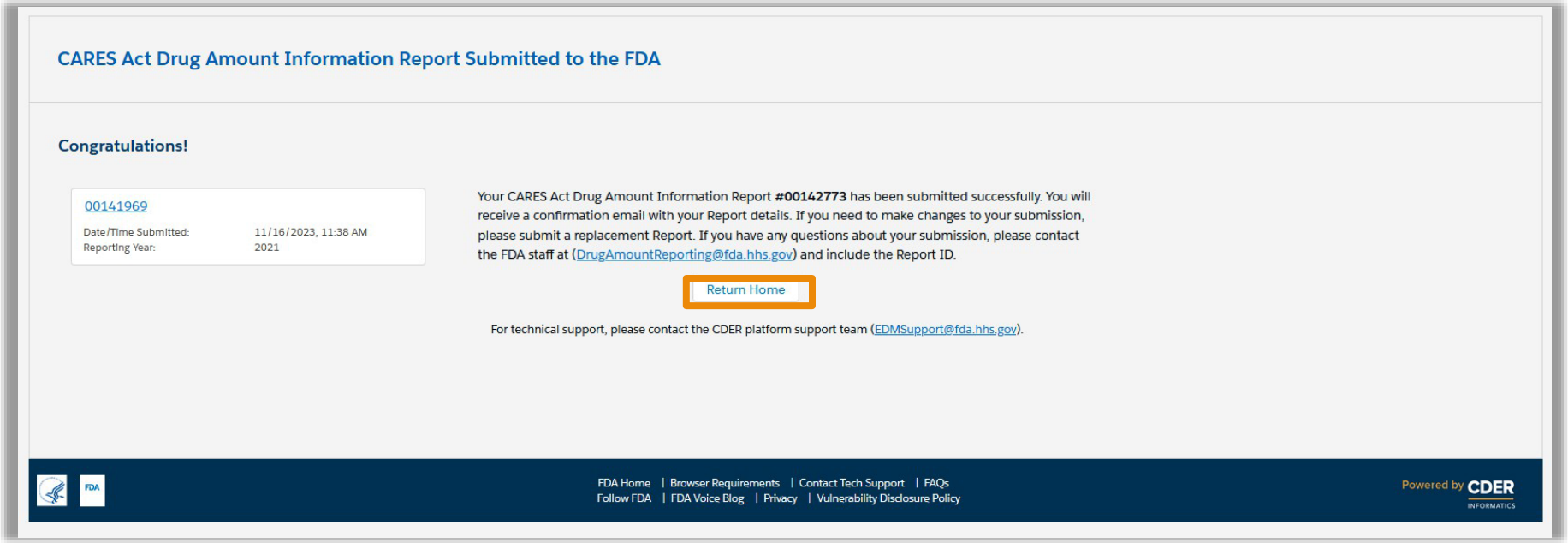


CARES Act Amount Information Reporting

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.

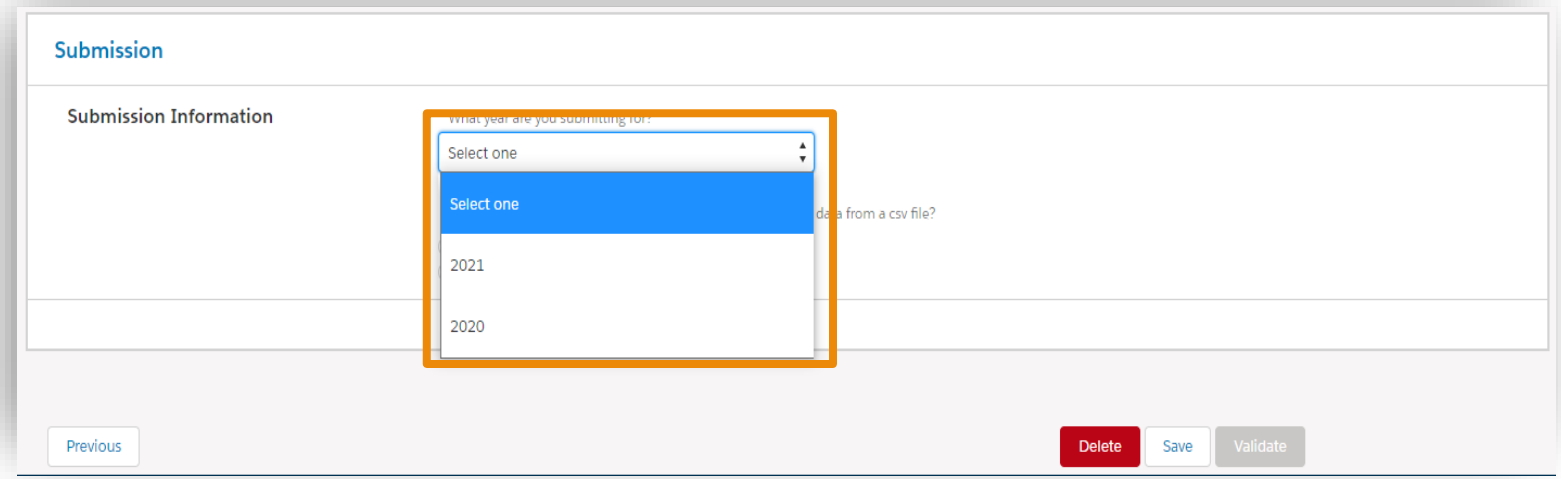


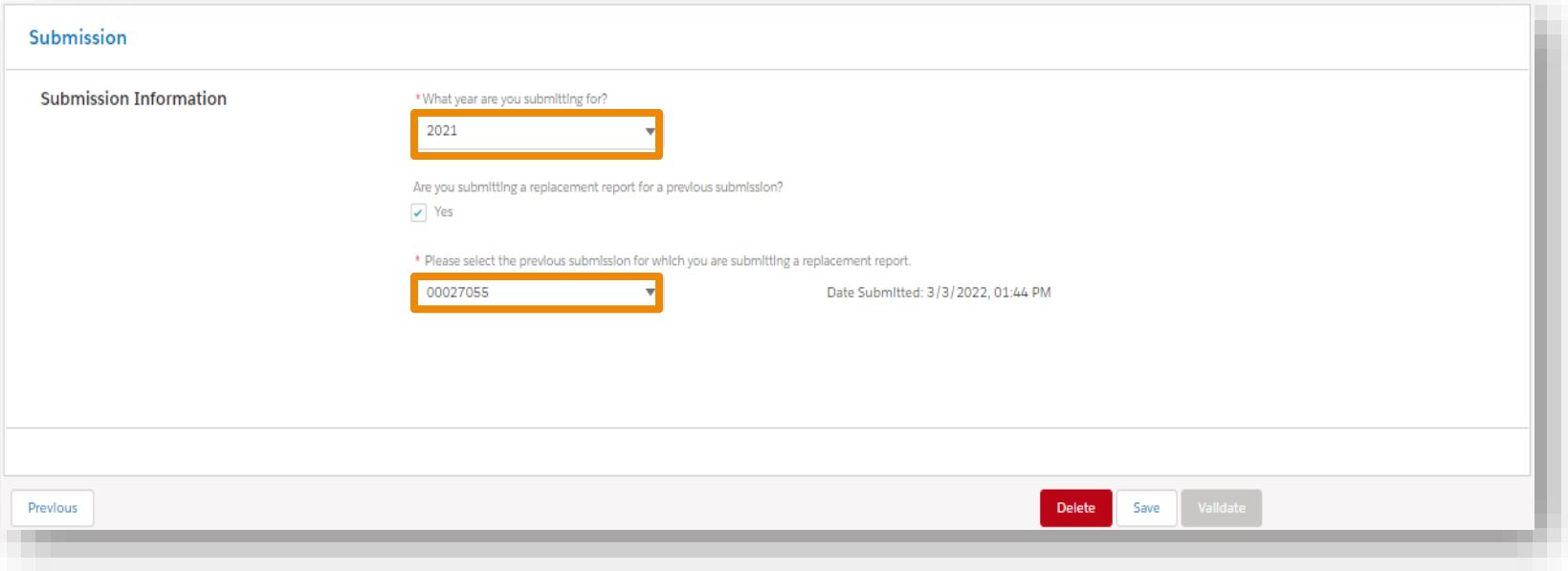
CSVFileUploadSubmission - APIorAPI+InactiveIngredients

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.





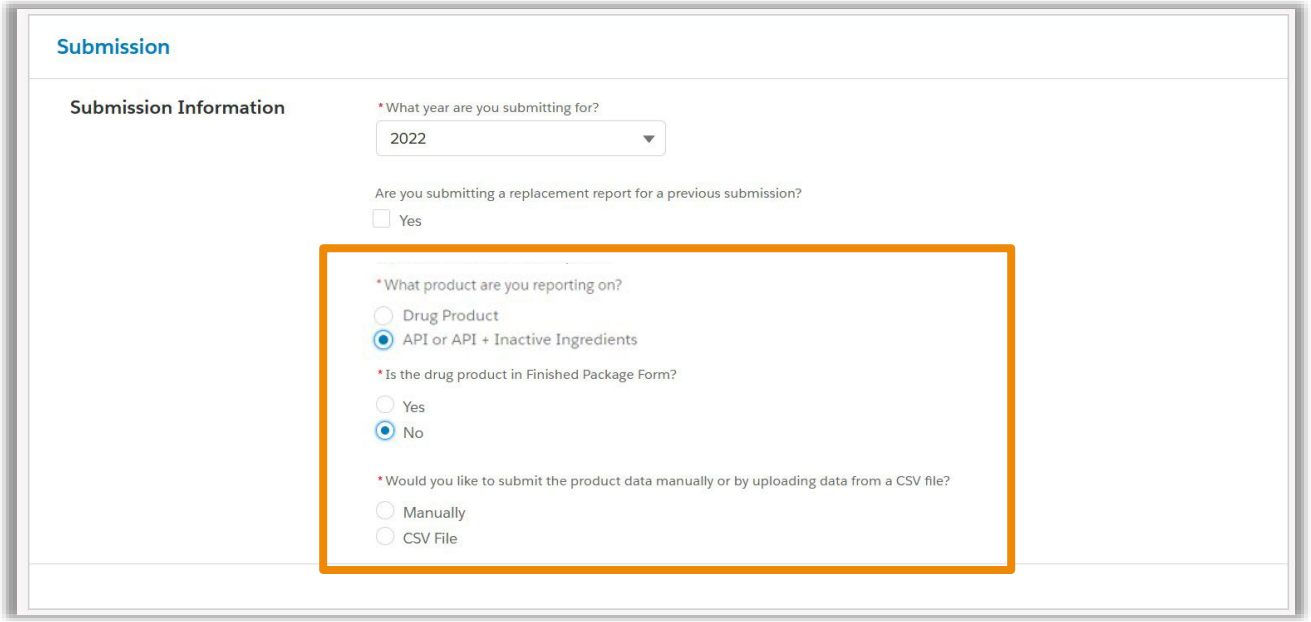
CARES Act Amount Information Reporting

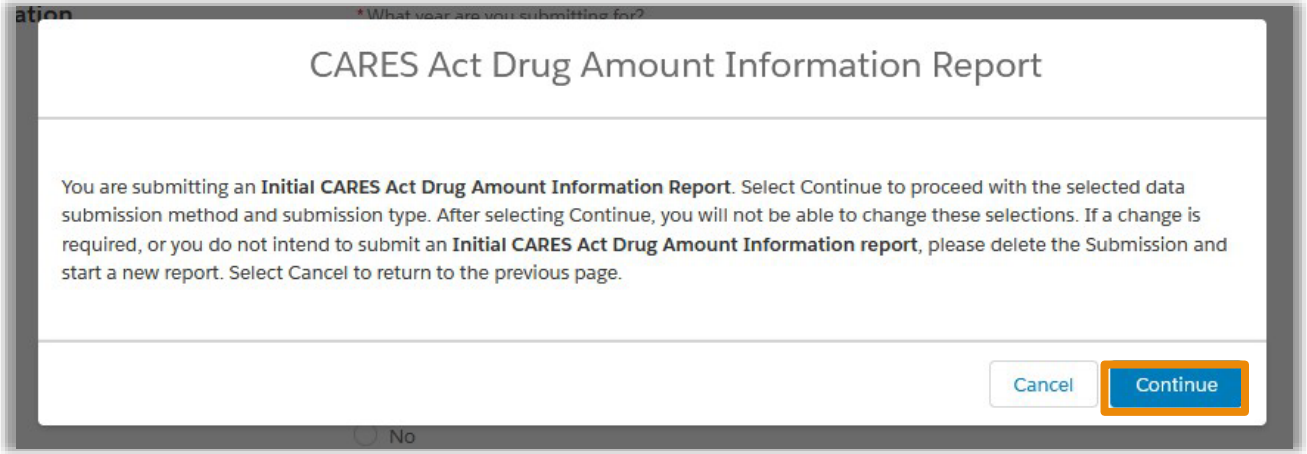
CSV Submission – API or API + Inactive Ingredients

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.**





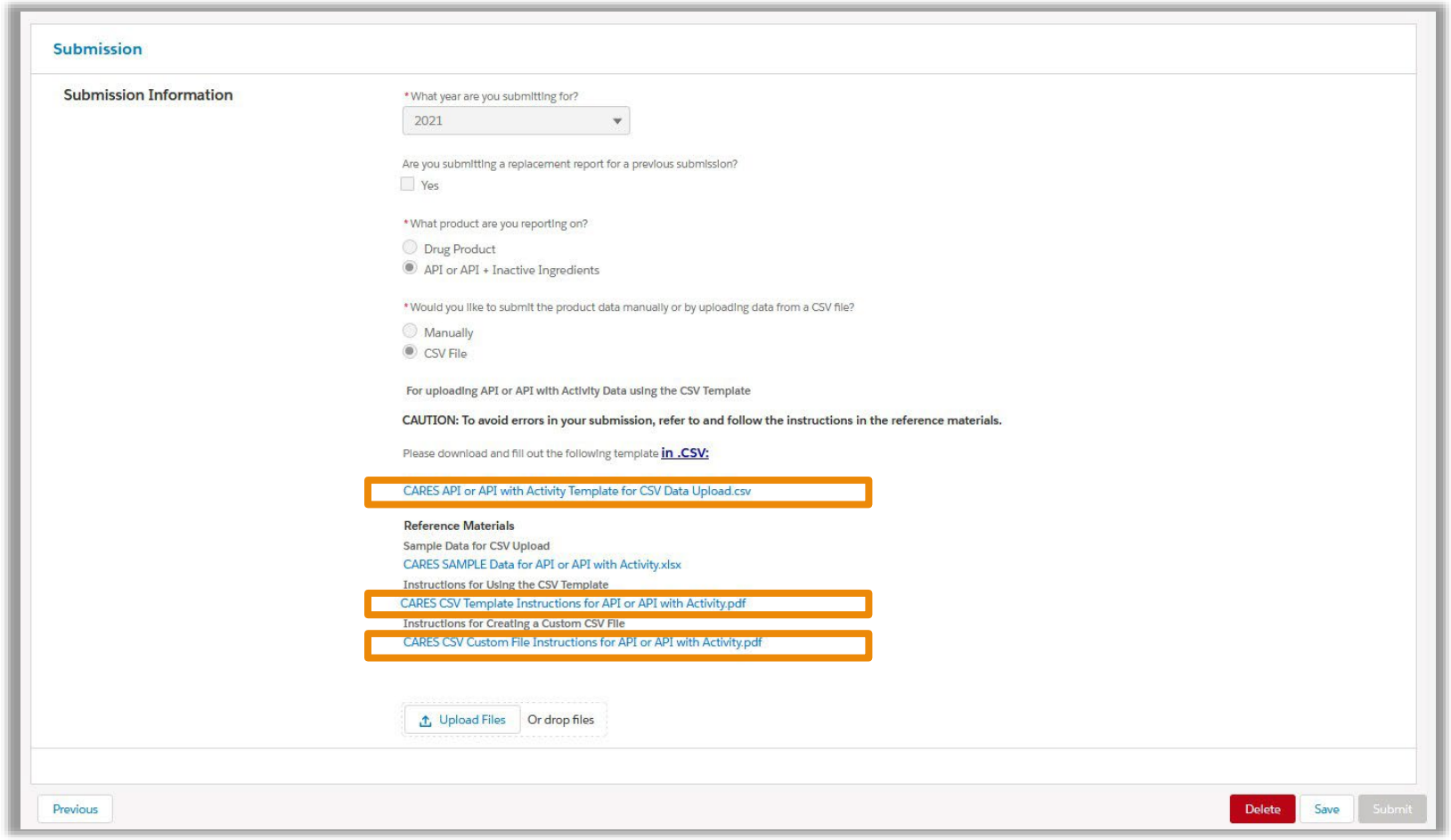
CSV Submission – API or API + Inactive Ingredients

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.



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

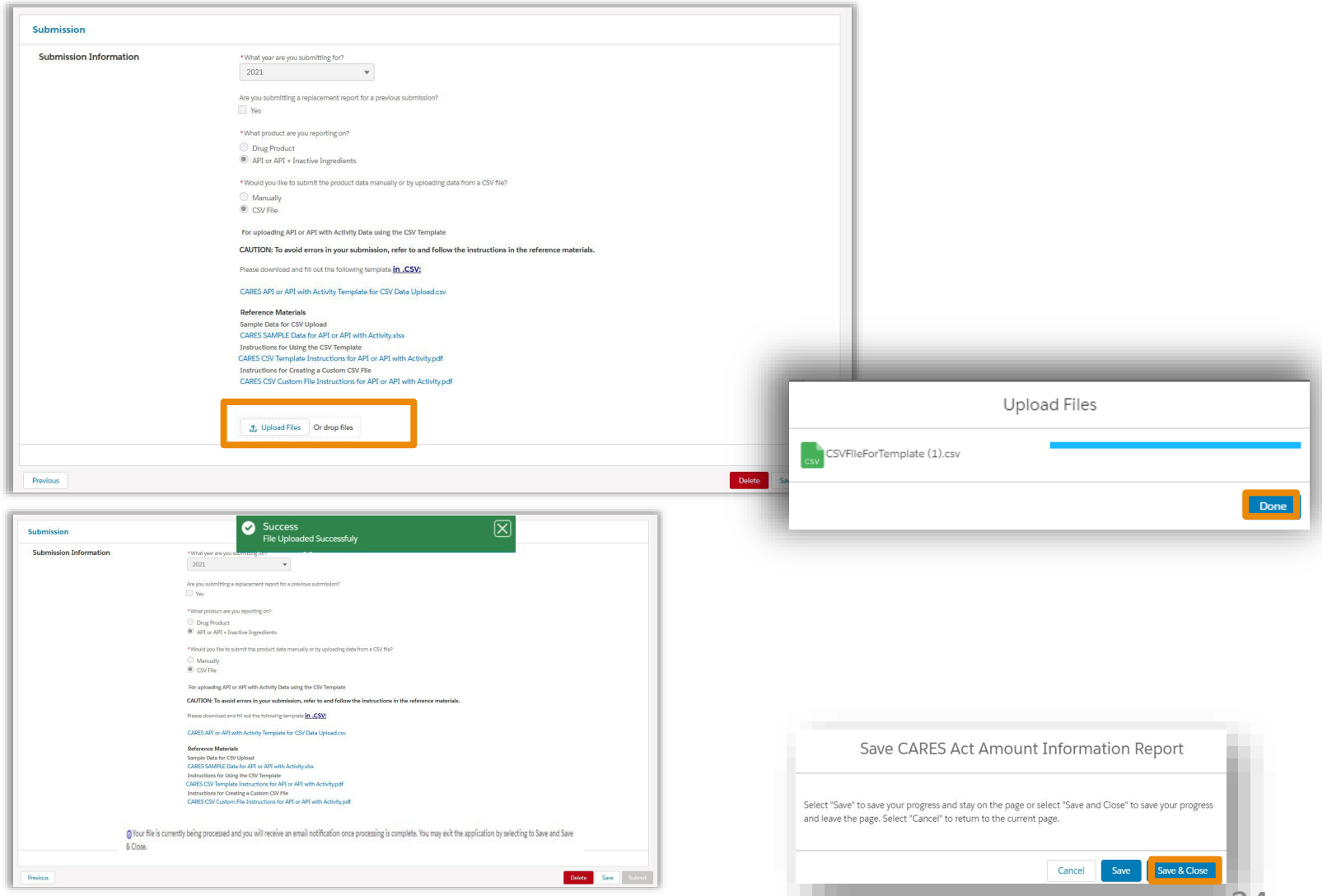
Step 15. Once all data has been entered into the CSV file, upload the data from the document into the portal by

(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**.

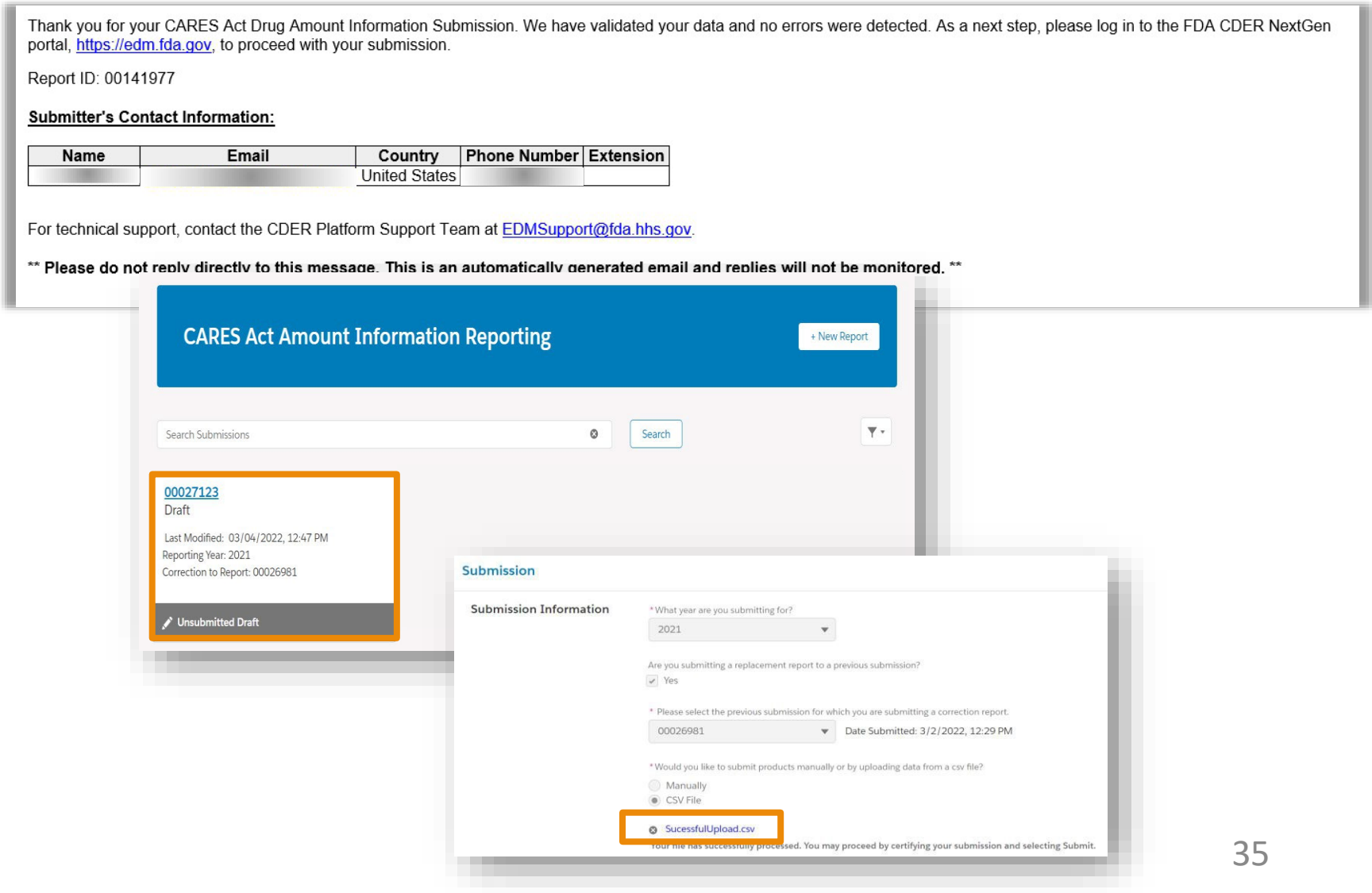
Step 17. Your file is now being processed. You will receive an email once processing is complete. Exit the Submission page by clicking **Save** and **Save & Close.**



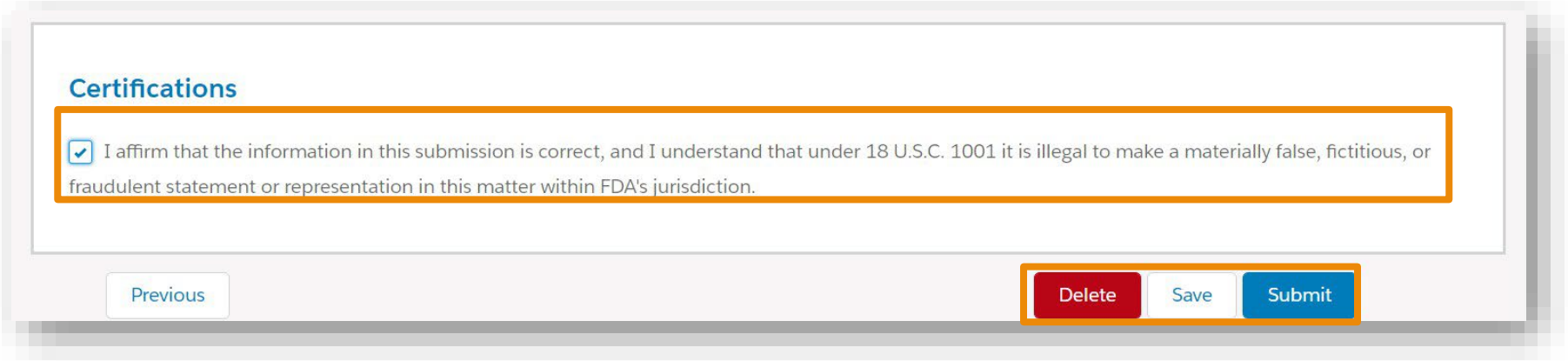
CSV Submission – API or API + Inactive Ingredients

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.



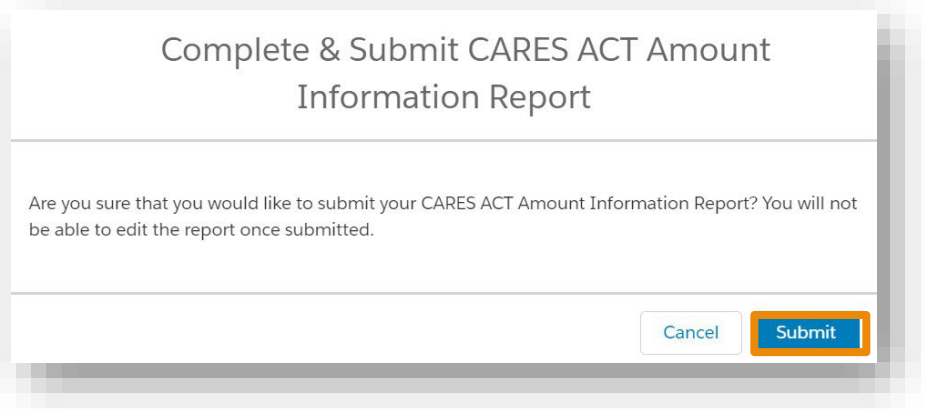
CSV Submission – API or API + Inactive Ingredients



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.

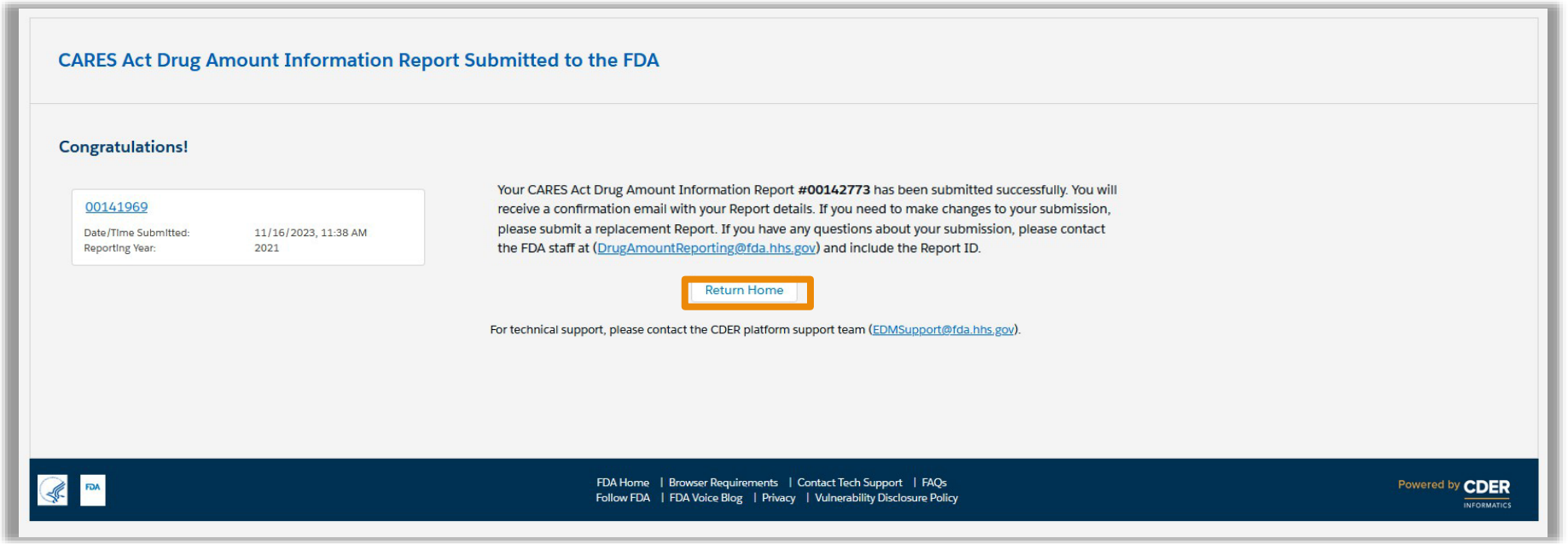
Step 20. In the confirmation screen, click **Submit** to send the report. Click **Cancel** to return to the Submission section.



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.



CSVFileSubmissionErrors

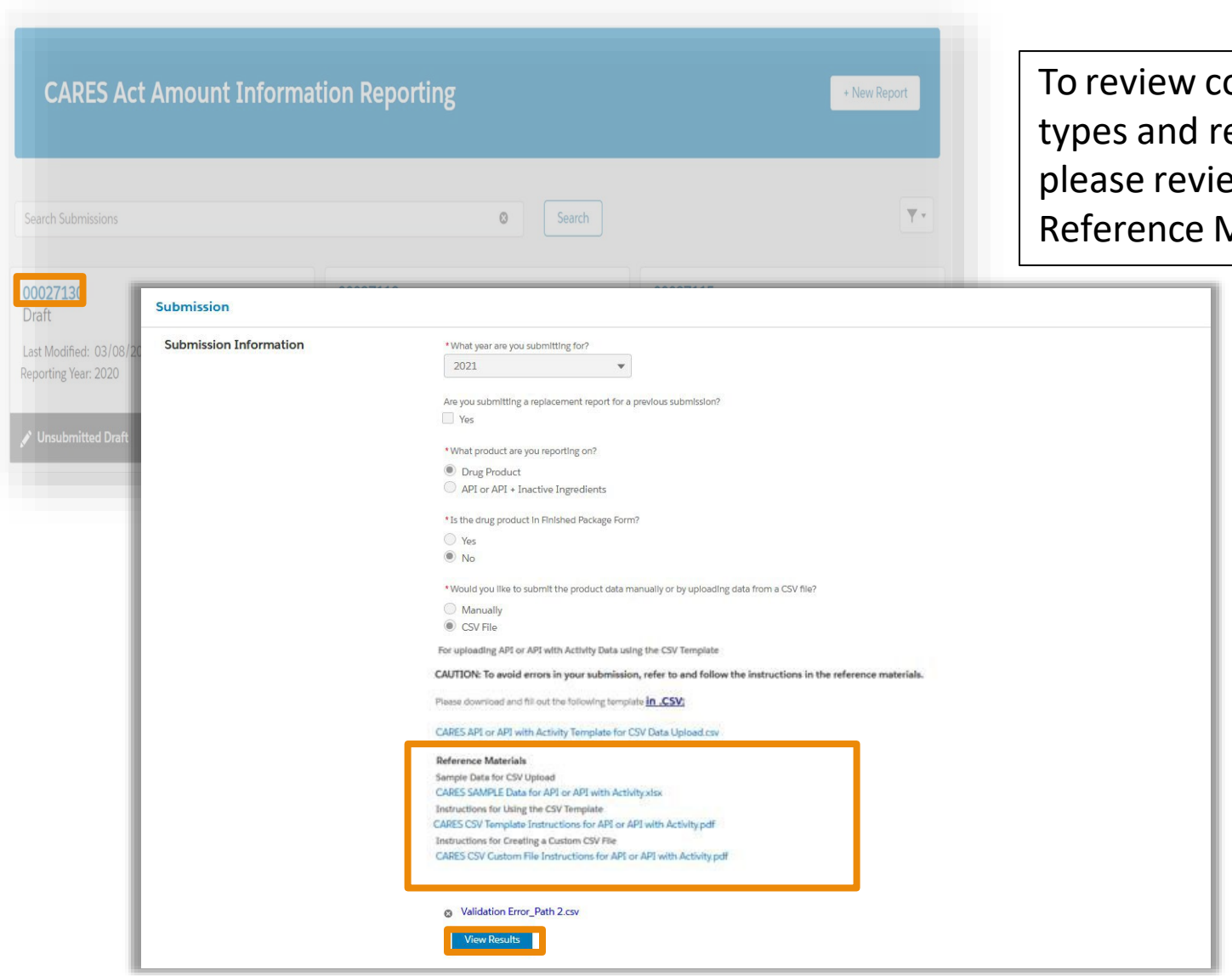
Submission Errors

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

CARES Act Amount Information Reporting

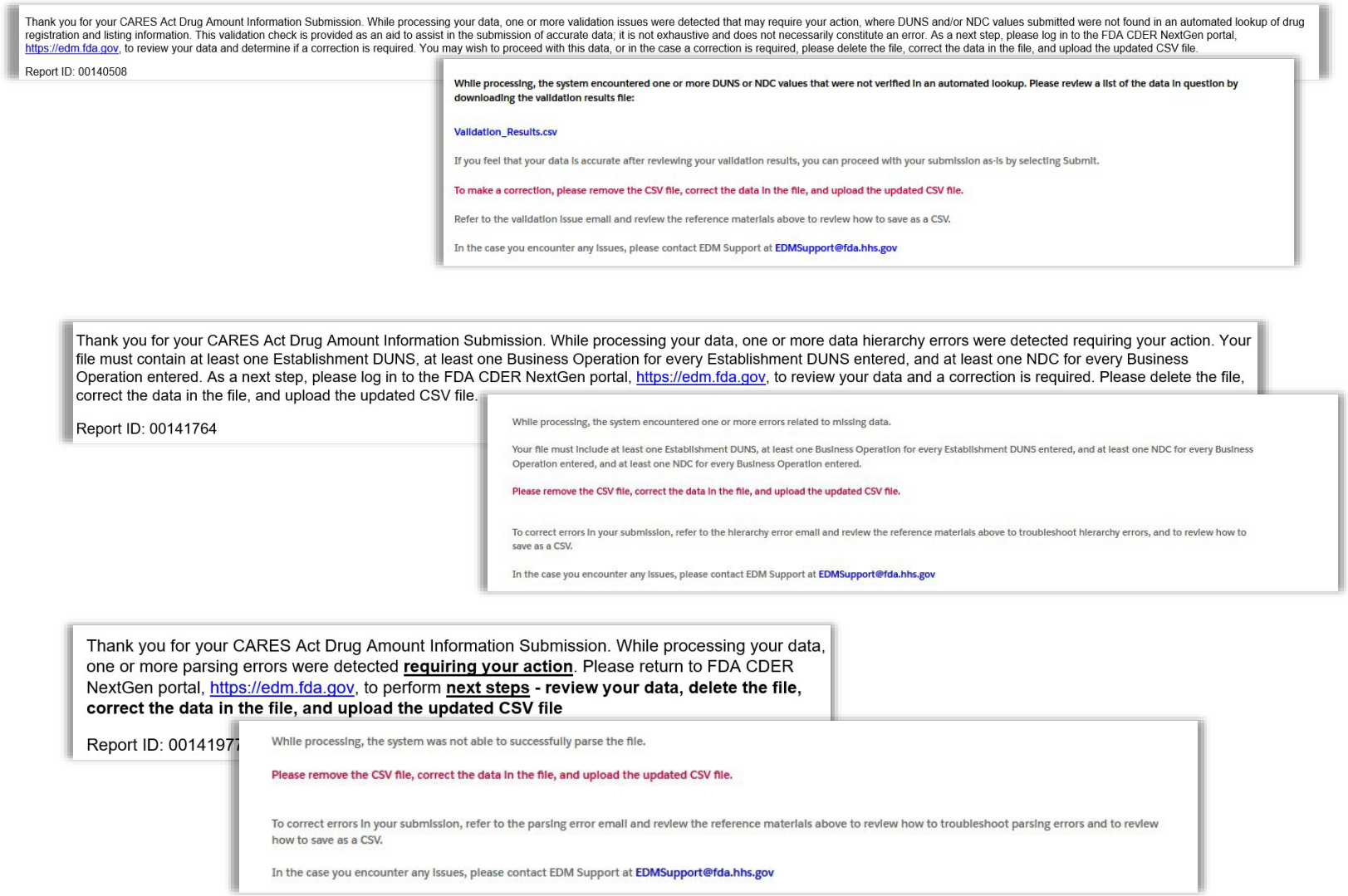
Submission Errors

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

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

Hierarchy error: One or more required values are missing.

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

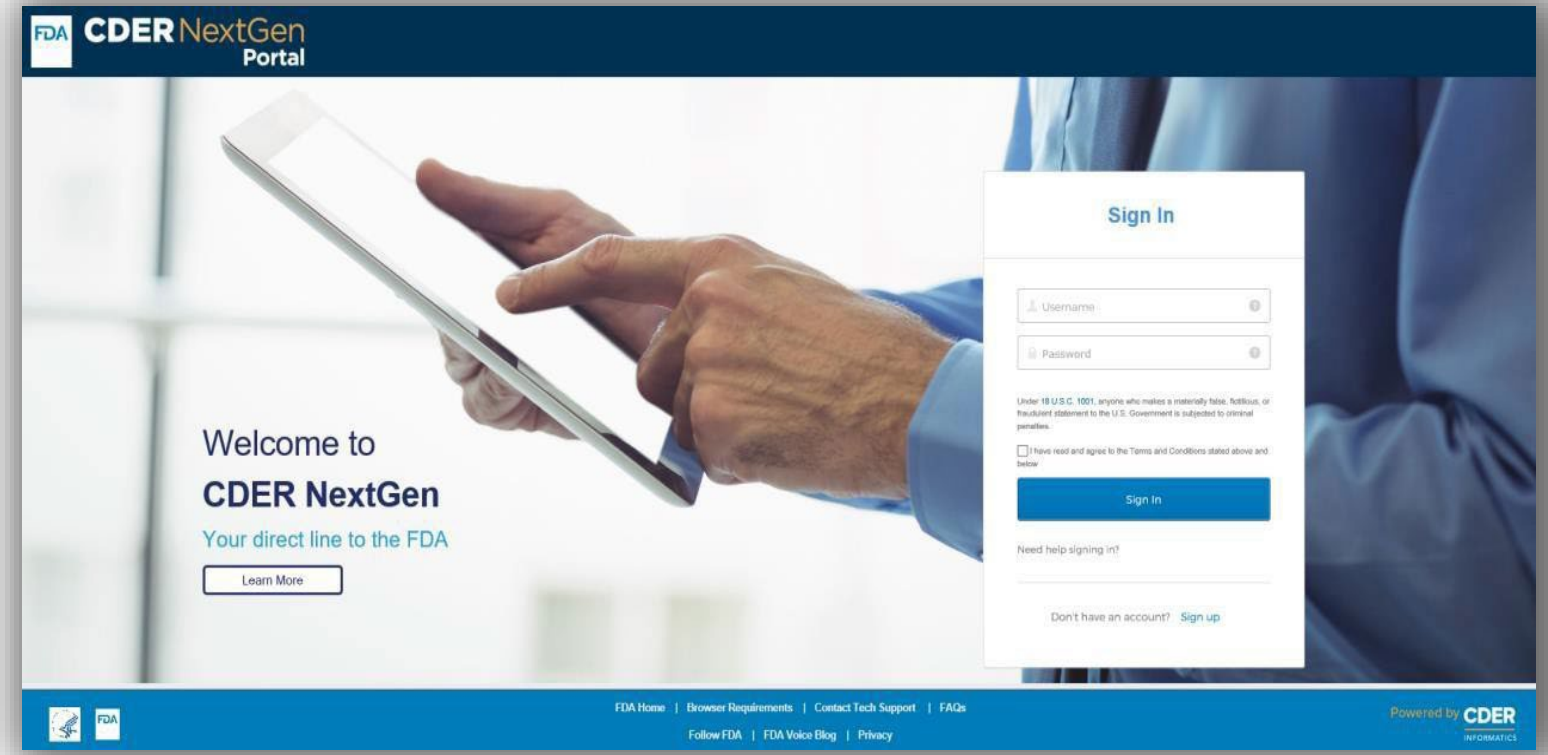


Manual Submission

Manual Submission – Creating a New Report and Entering Submitter Details

CDER NextGen Portal Homepage

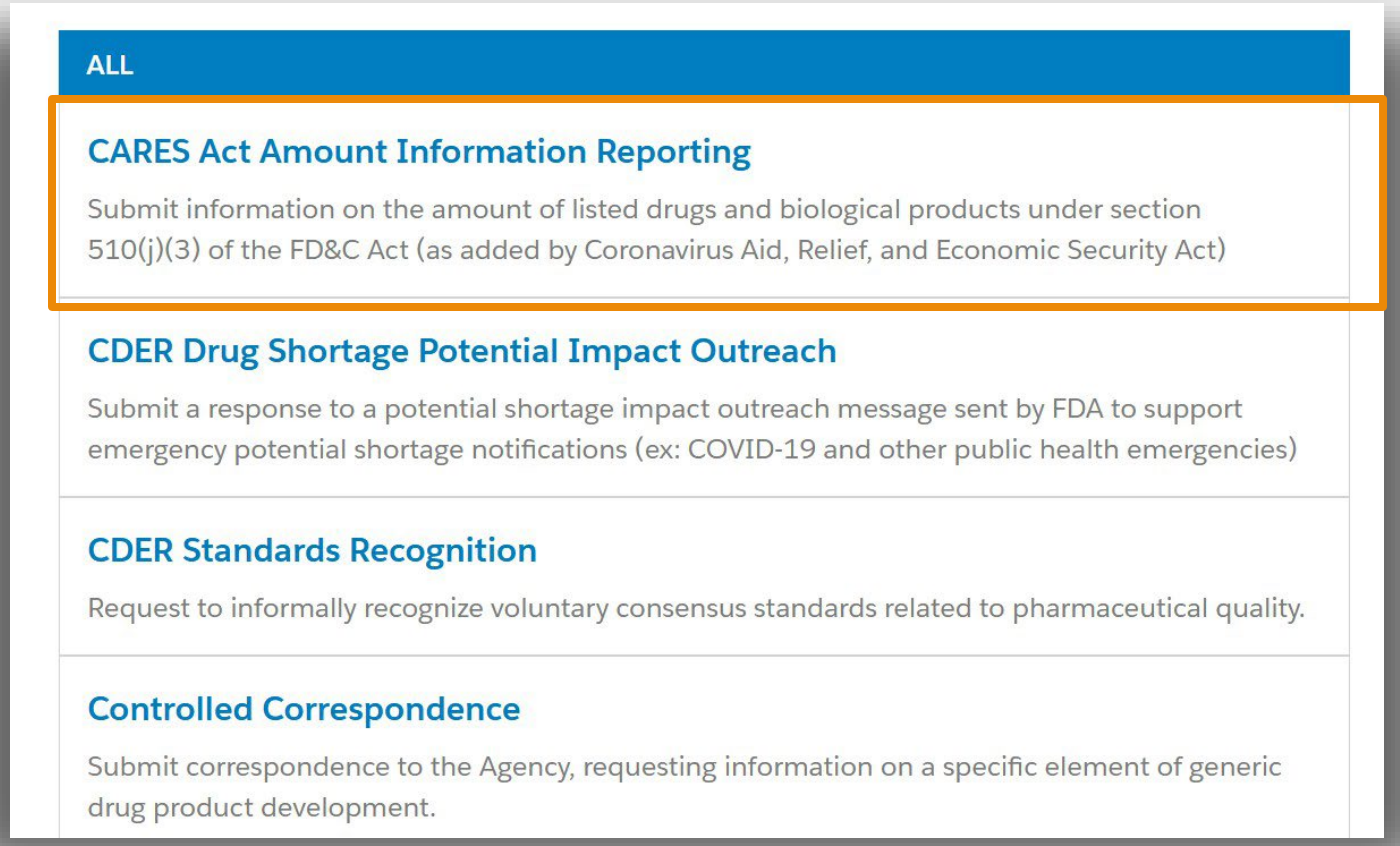
Step 1. First, sign in on the CDER NextGen Portal homepage.



CARES Act Amount Information Reporting

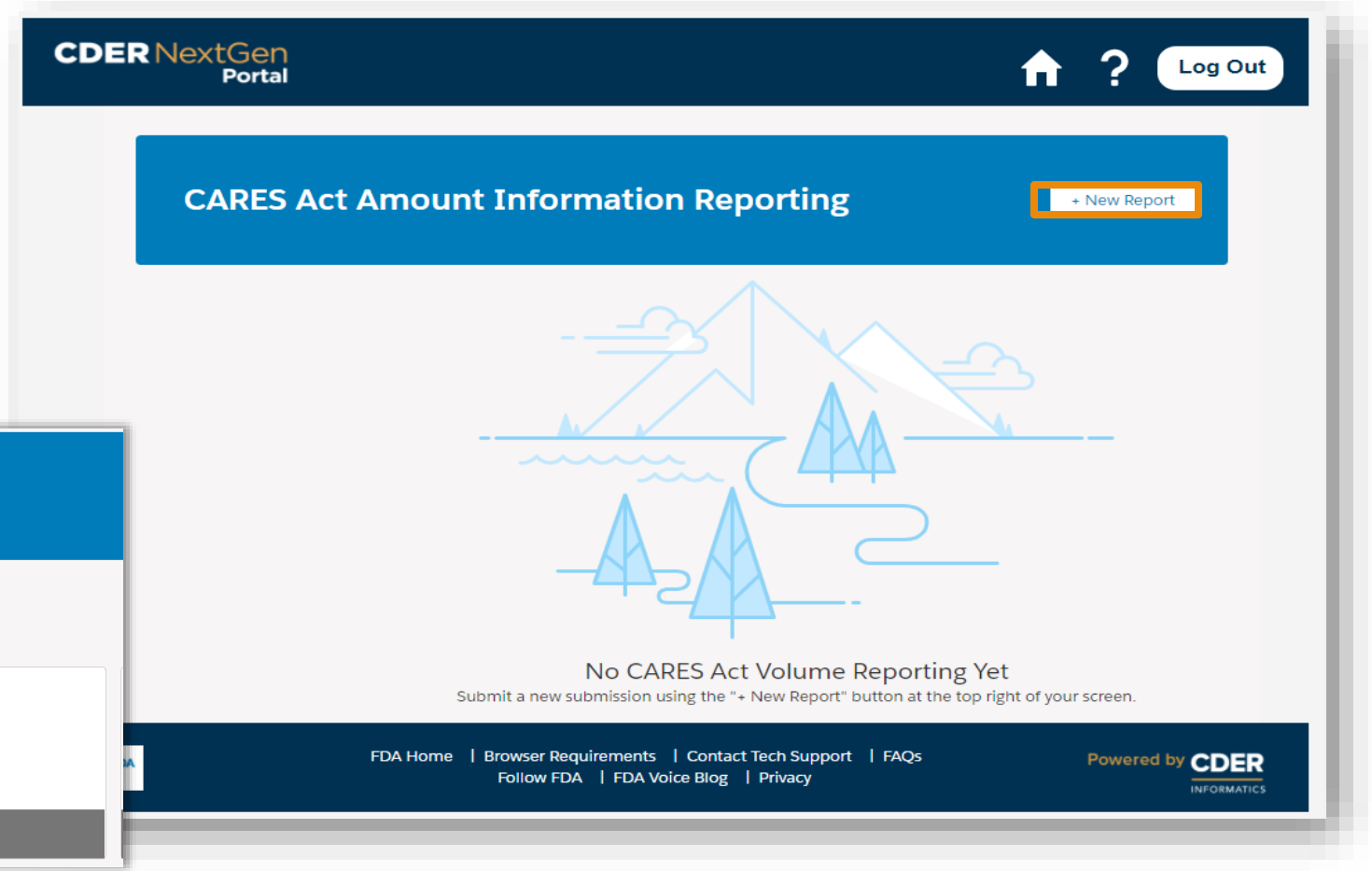
CDER NextGen Portal Homepage

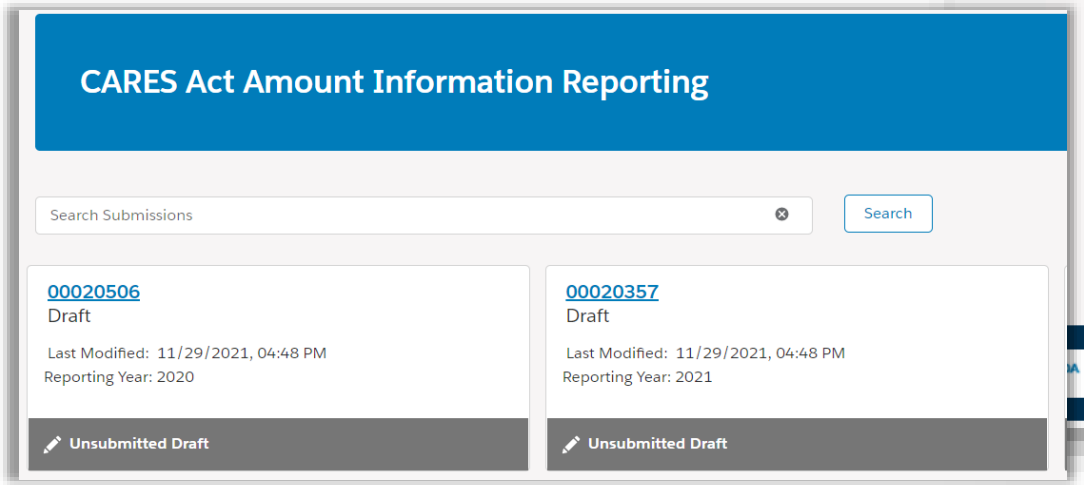
Step 2. From the main menu, click **CARES Act Amount Information Reporting**.



CARES Act Amount Information Report

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

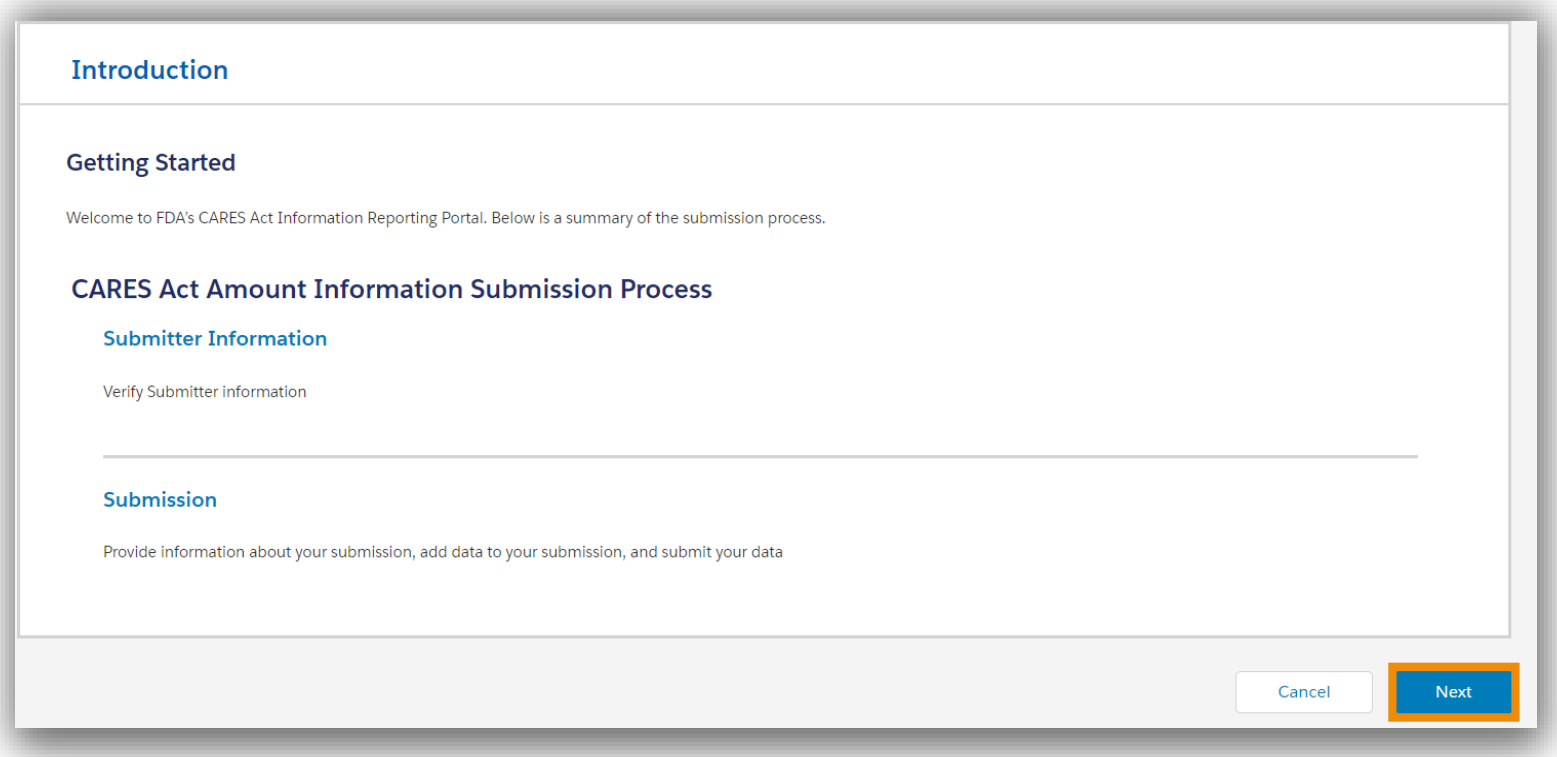




CARES Act Amount Information Report

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.

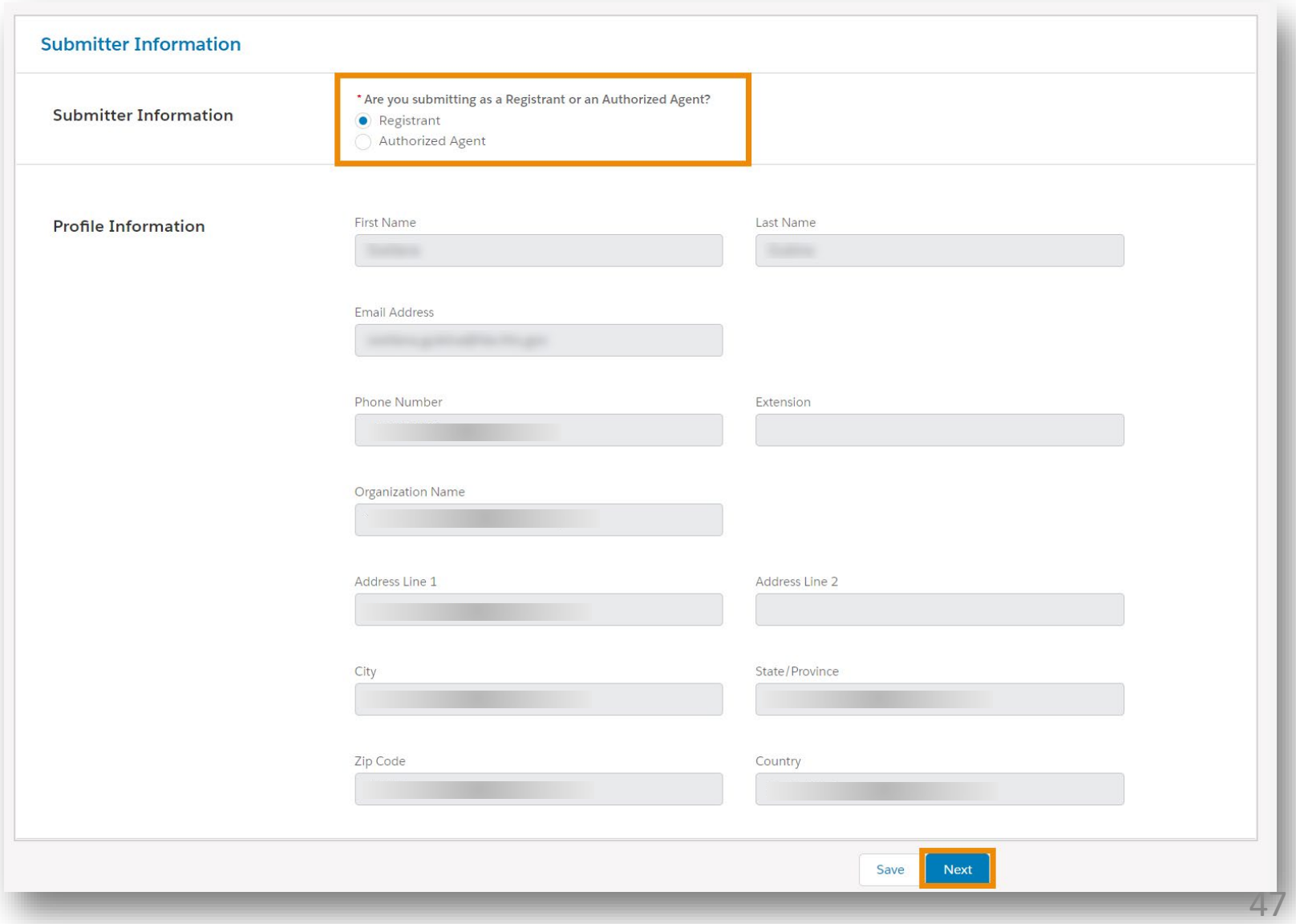
Step 5. Click **Next.**



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.



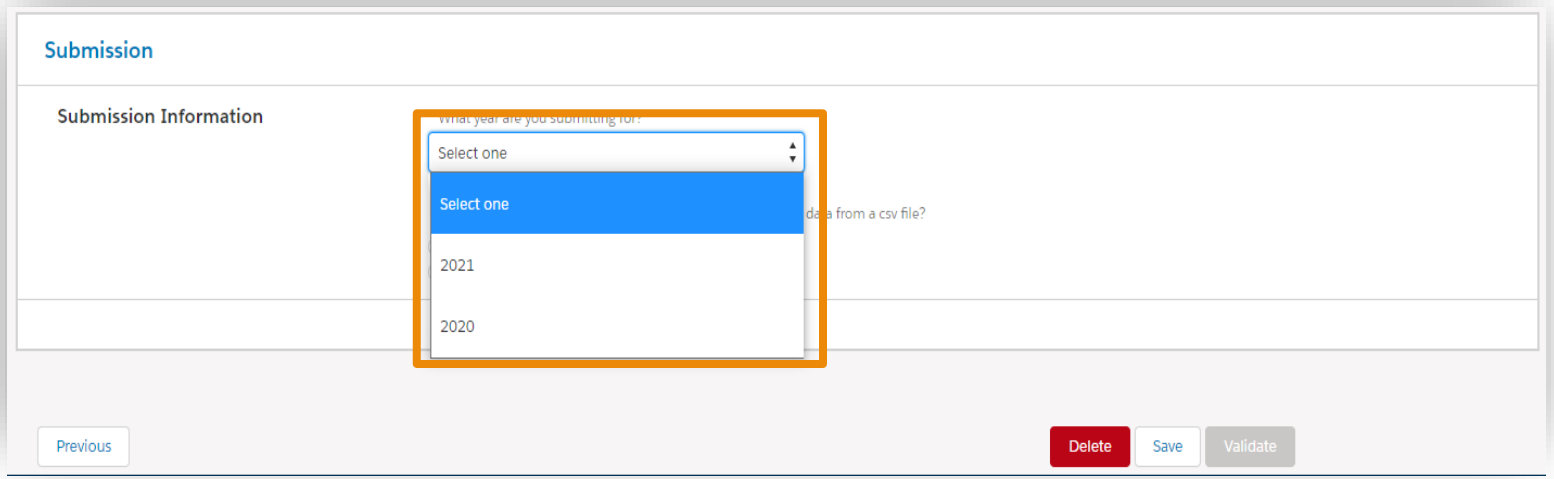
Manual Submission - Finished Package Form

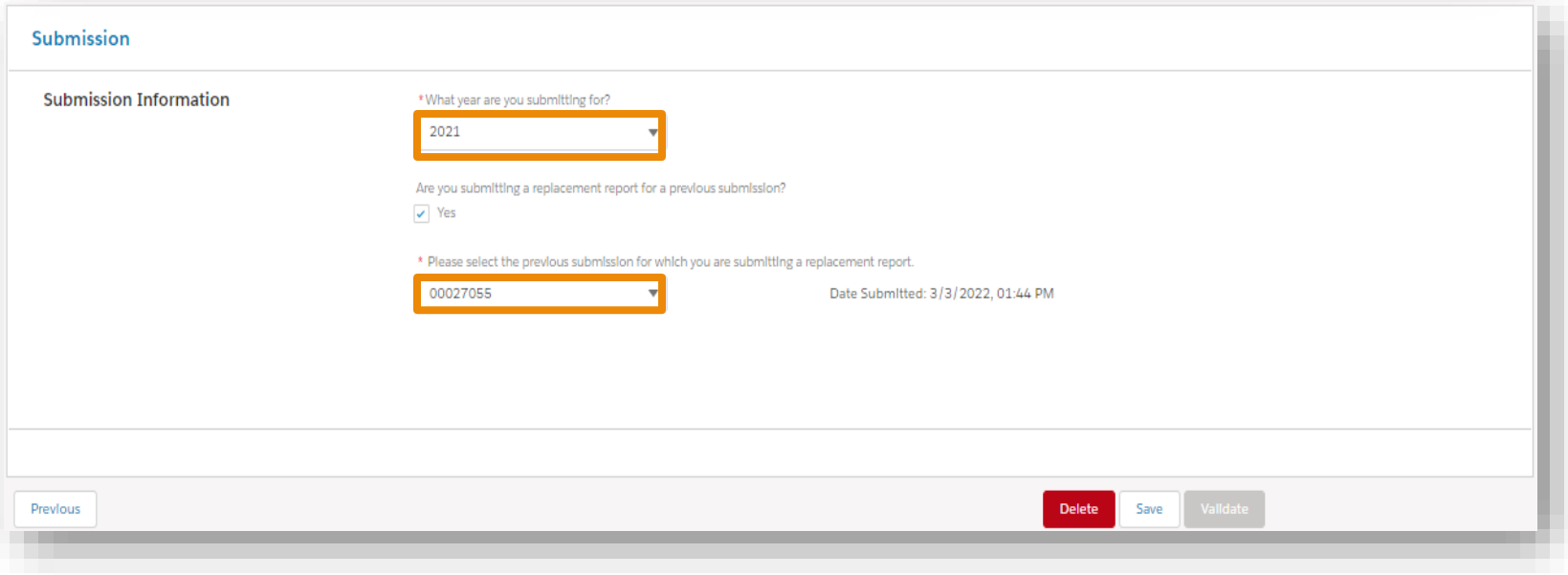
Manual Submission – Finished Package Form

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.





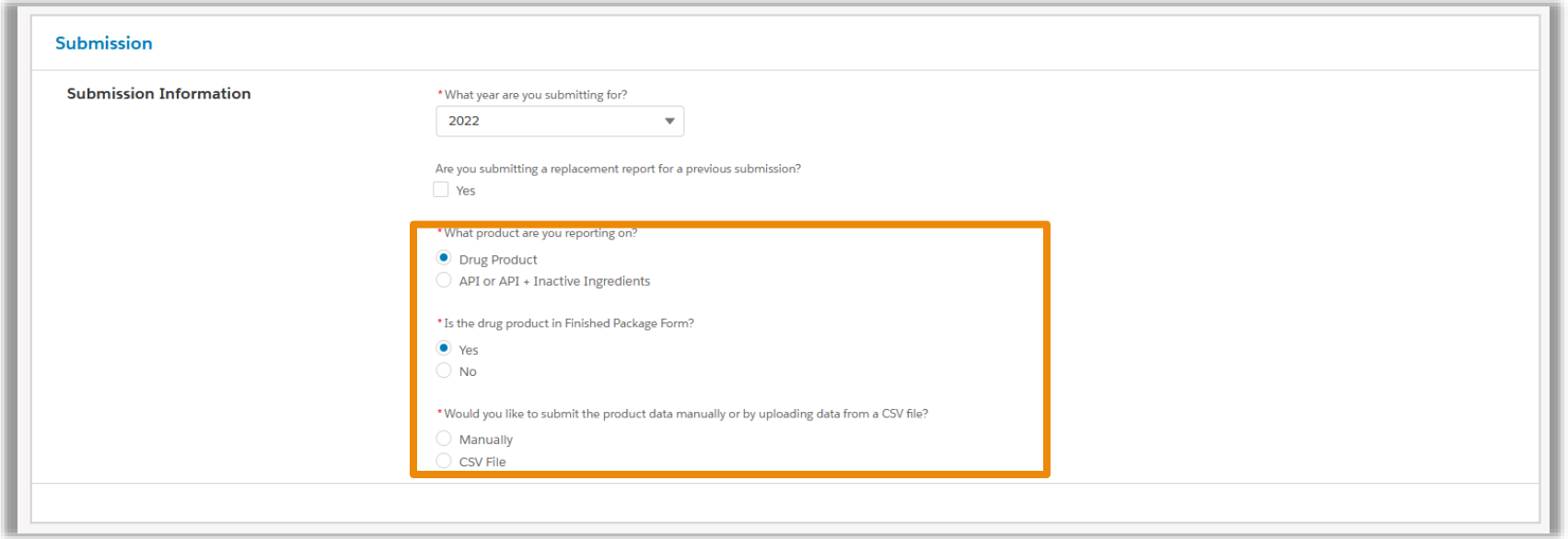
Manual Submission – Finished Package Form

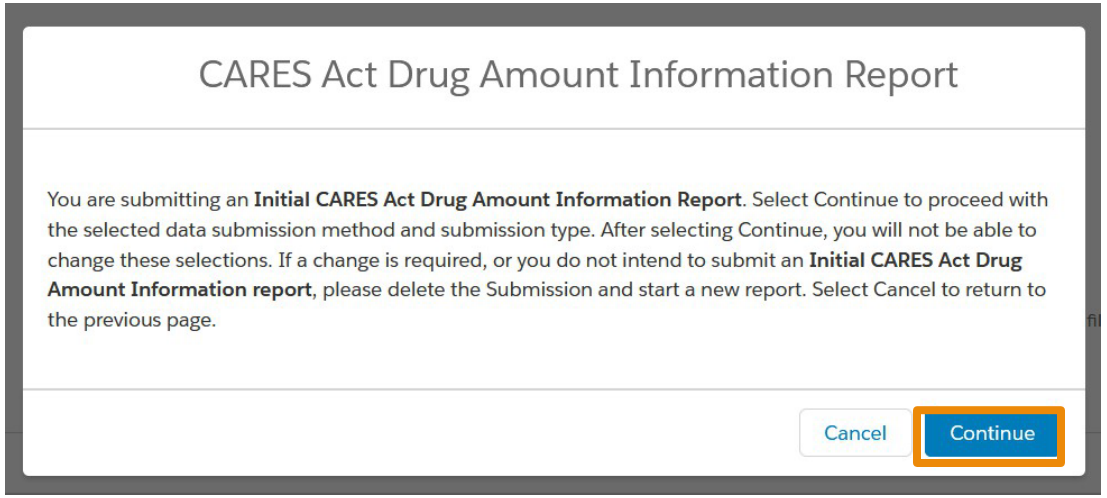
Step 10. Select that you are reporting on a Drug Product.

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

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

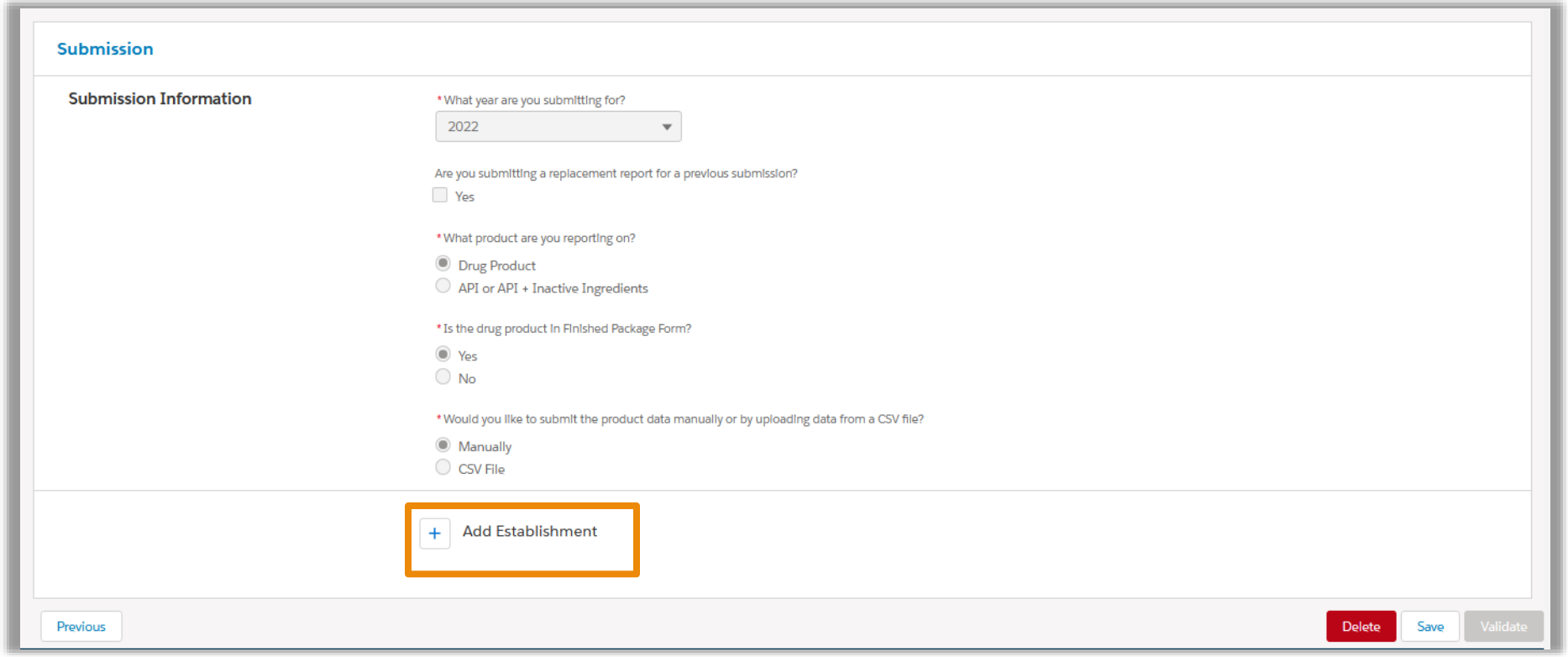
Step 13. In the confirmation screen, click **Continue.**





Manual Submission – Finished Package Form

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



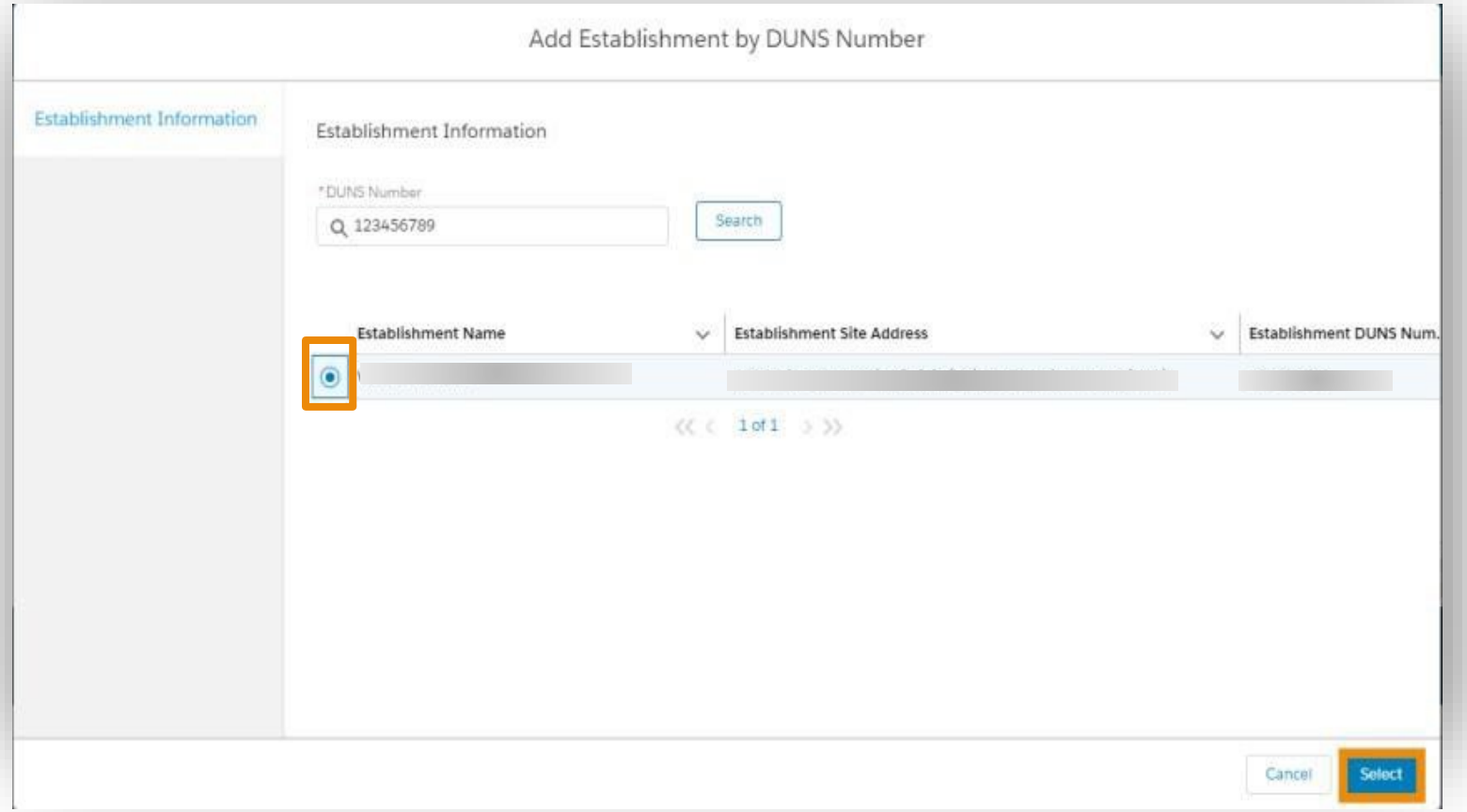
Manual Submission – Finished Package Form

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.

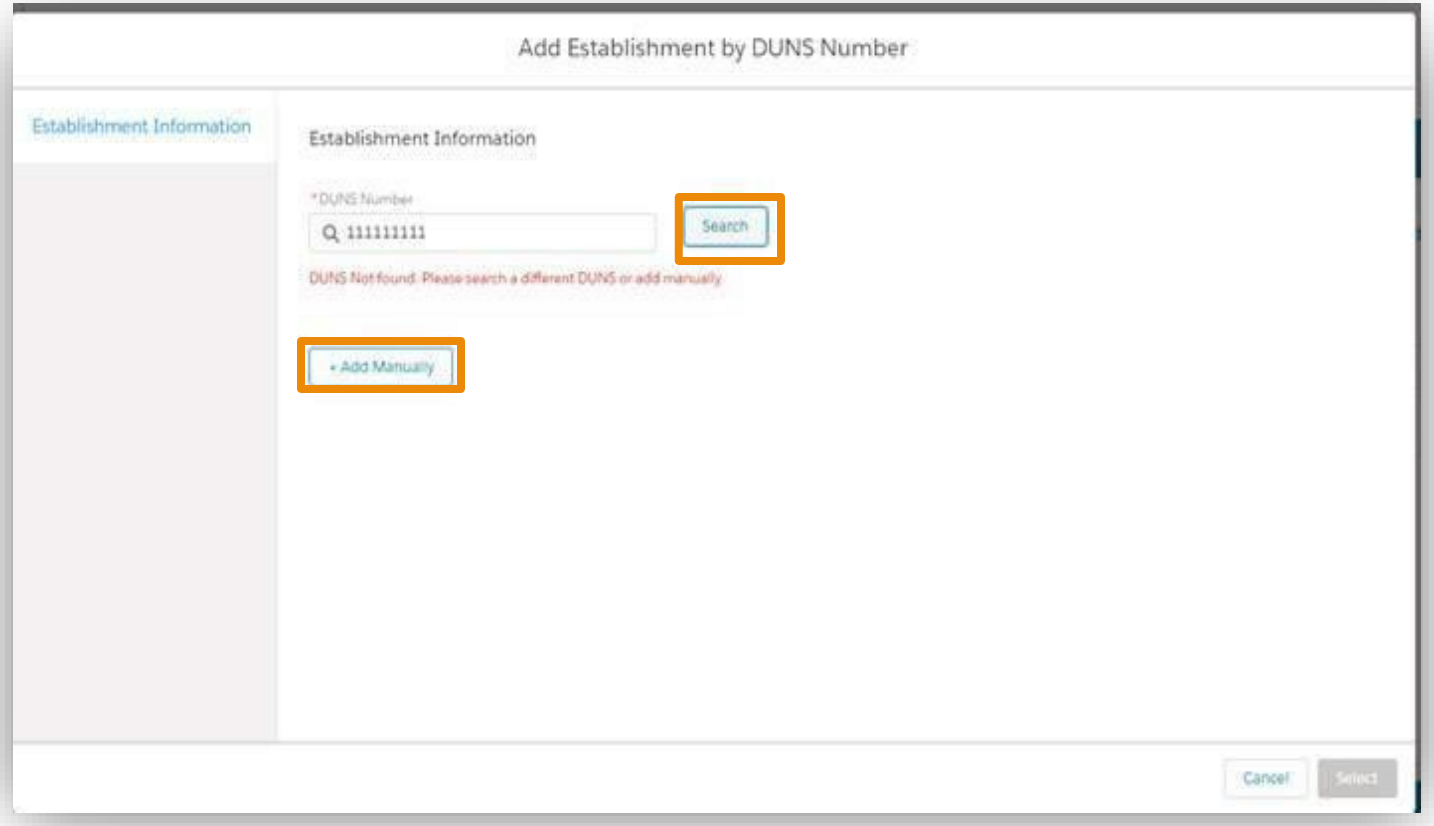
If this is the correct establishment, click in the radio button on the left and then click **Select**.

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



Manual Submission – Finished Package Form

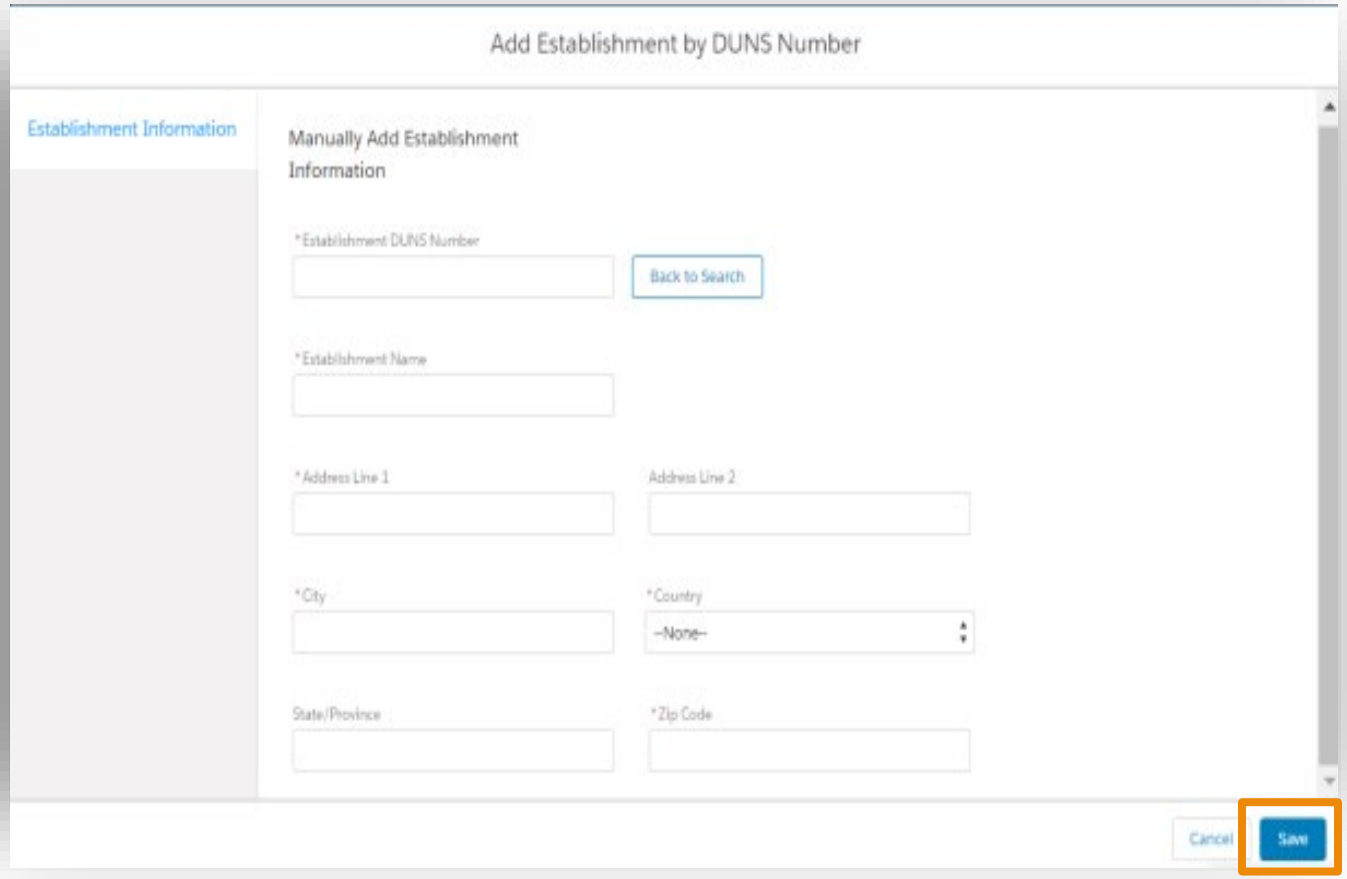
Step 16. If the search for a DUNS number fails, an error message and an +**Add Manually** button will appear. Click the button to enter establishment information.



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.**



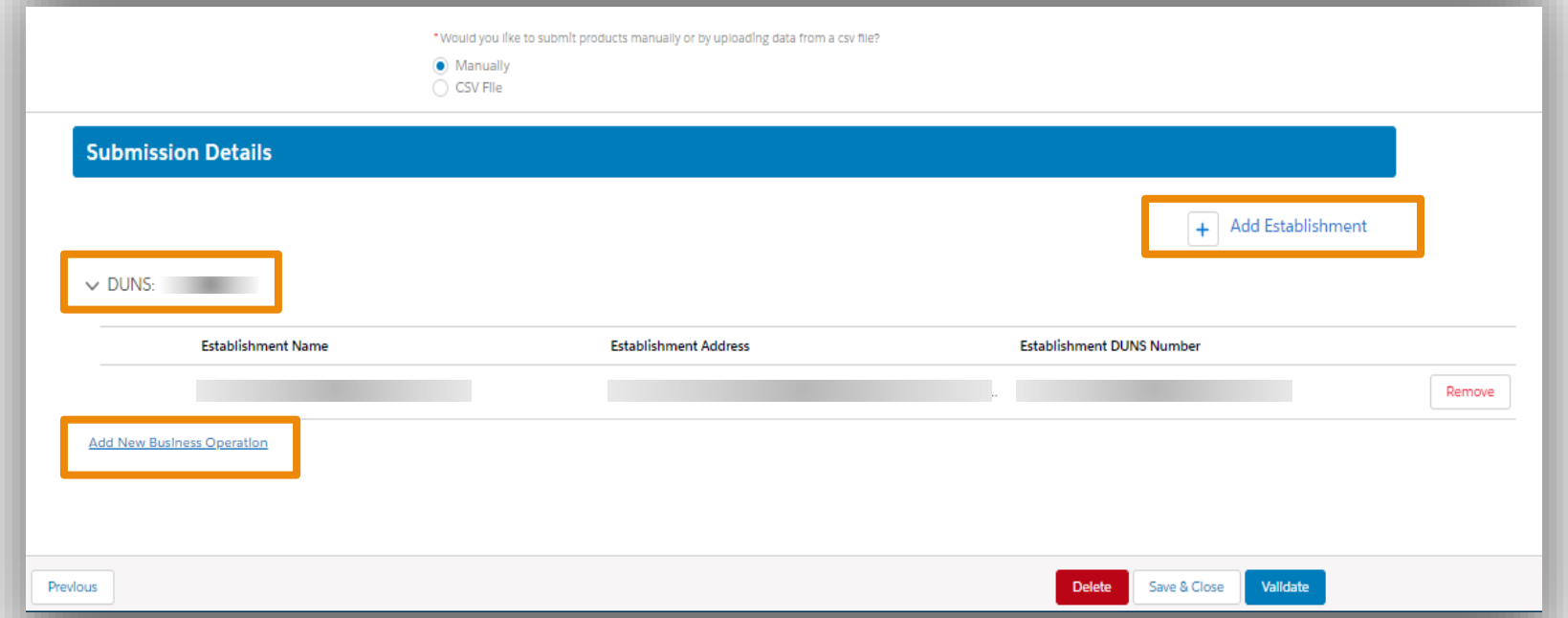
Manual Submission – Finished Package Form

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**.

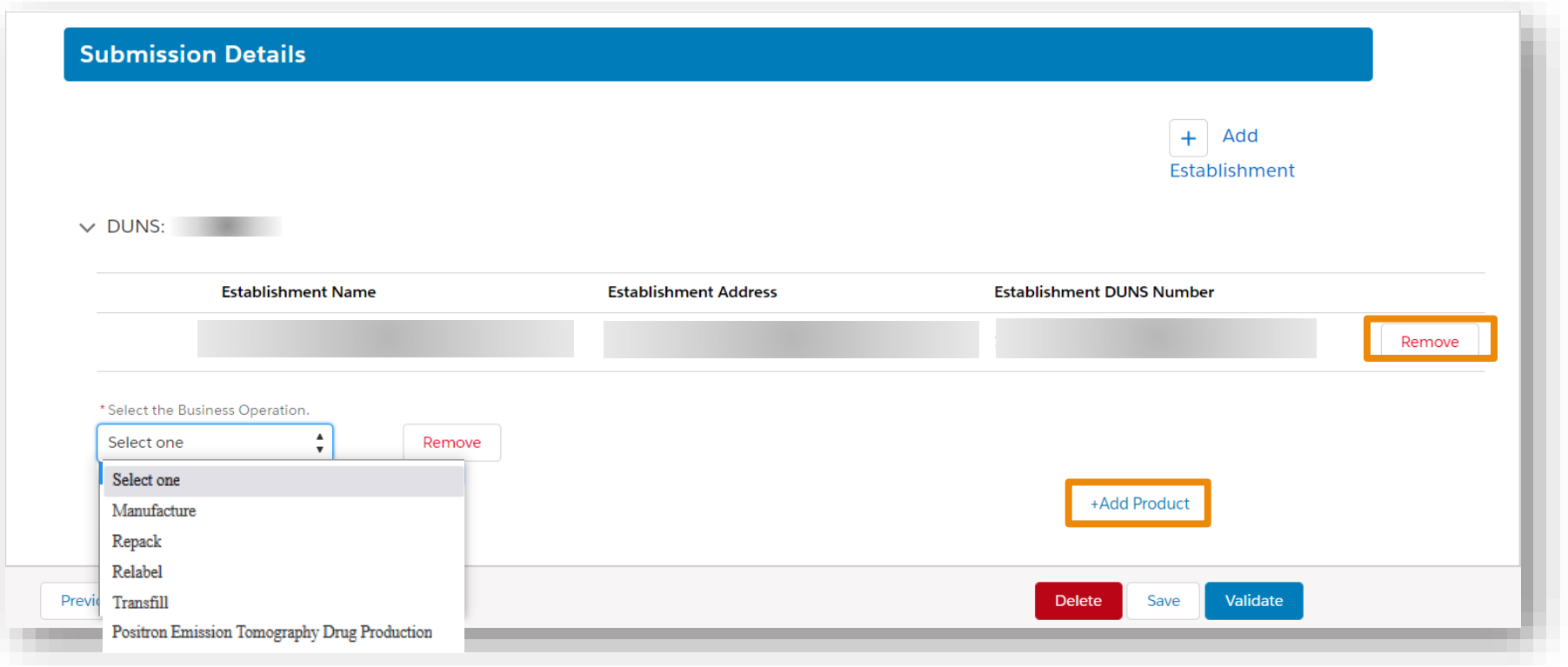
To enter data for another DUNS number, click on **Add Establishment** and repeat the process of adding a DUNS number.



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.

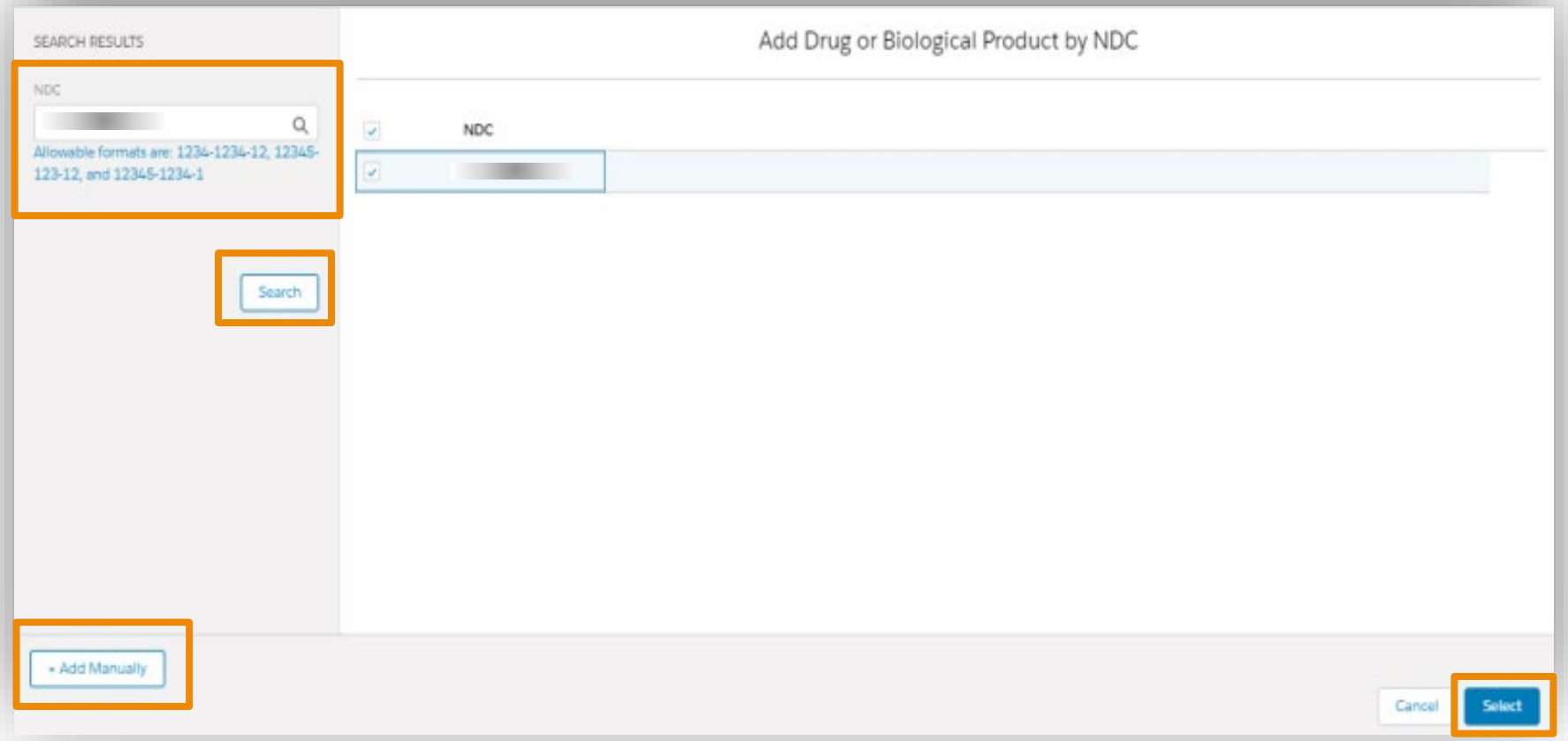


Manual Submission – Finished Package Form

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

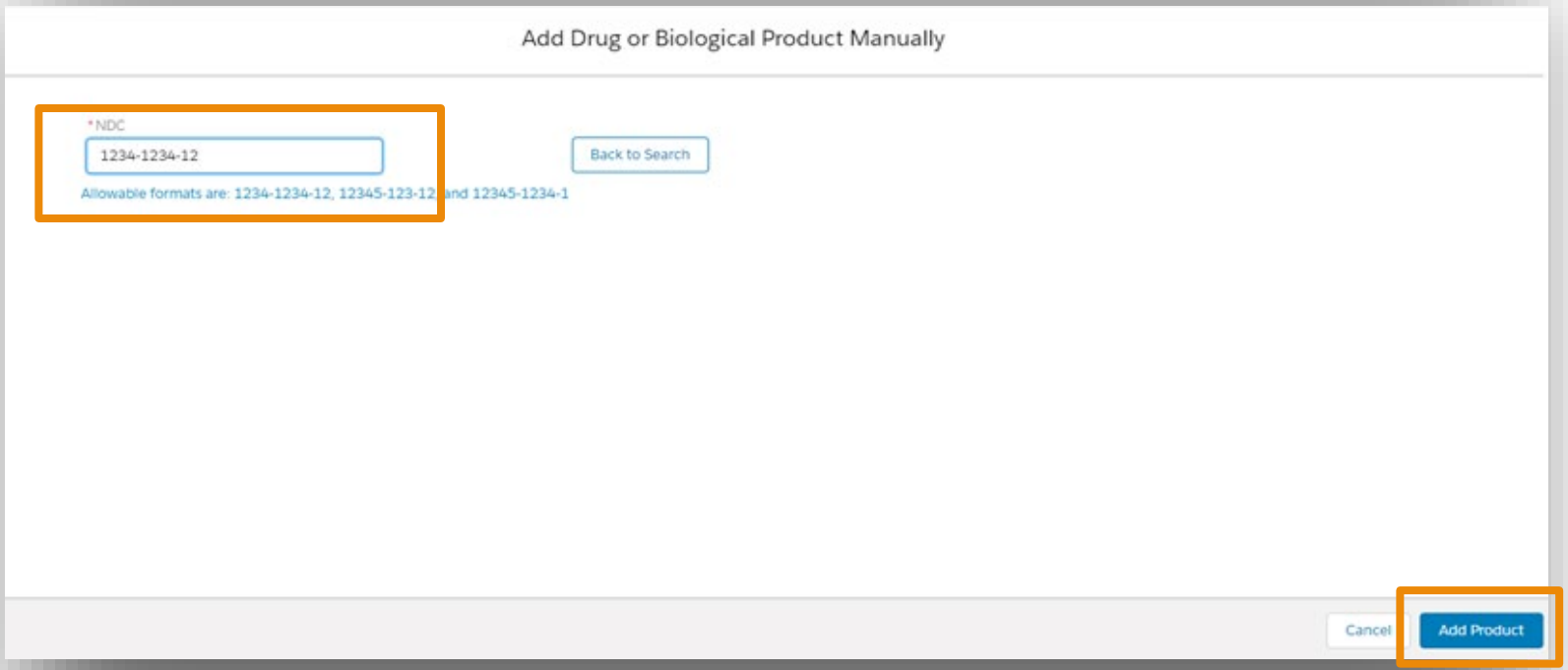
If the NDC appears on the right, check the box next to it and then click **Select**, which will return you to the **Submission** screen.

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

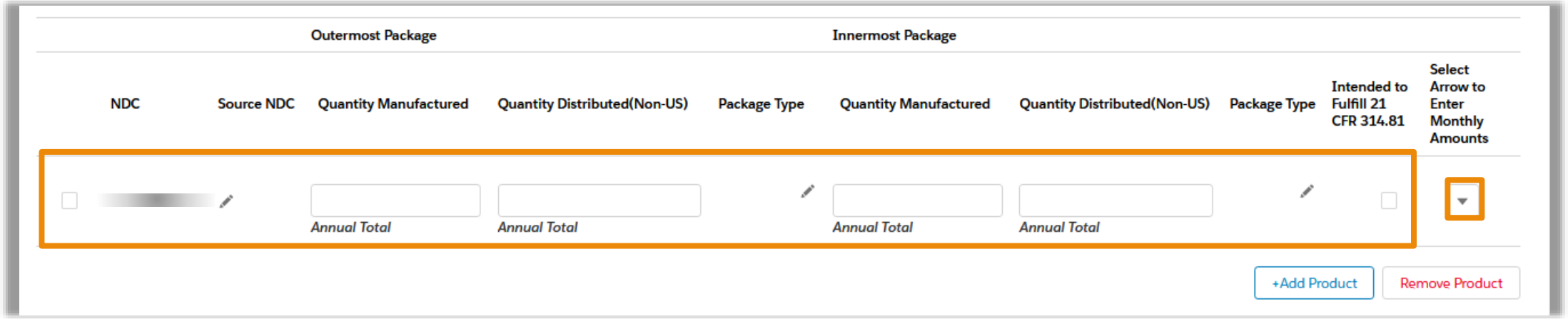


Manual Submission – Finished Package Form

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



Manual Submission – Finished Package Form



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

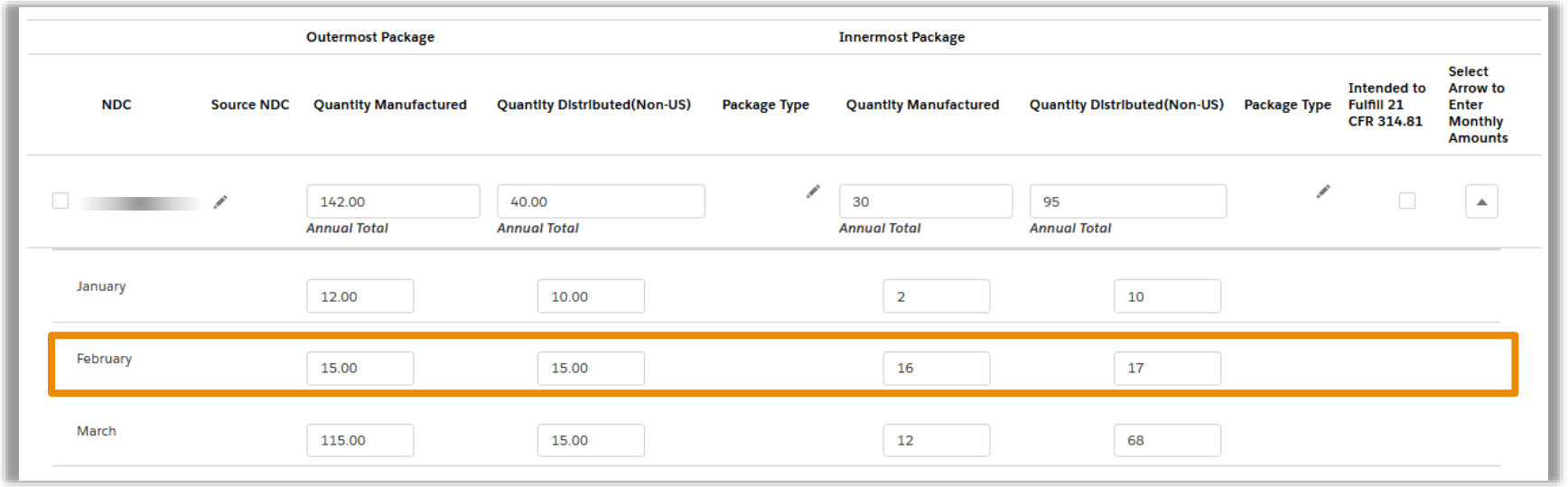
Click **+Add Product and/or Remove Product** as needed.

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				
NDC	Source NDC	Quantity Manufactured	Quantity Distributed(Non-US)	Package Type	Quantity Manufactured	Quantity Distributed(Non-US)	Package Type	Intended to Fulfill 21 CFR 314.81	Select Arrow to Enter Monthly Amounts
[redacted]		142.00 *Annual Total*	40.00 *Annual Total*		30 *Annual Total*	95 *Annual Total*			
January		12.00	10.00		2	10			
February		15.00	15.00		16	17			
March		115.00	15.00		12	68			

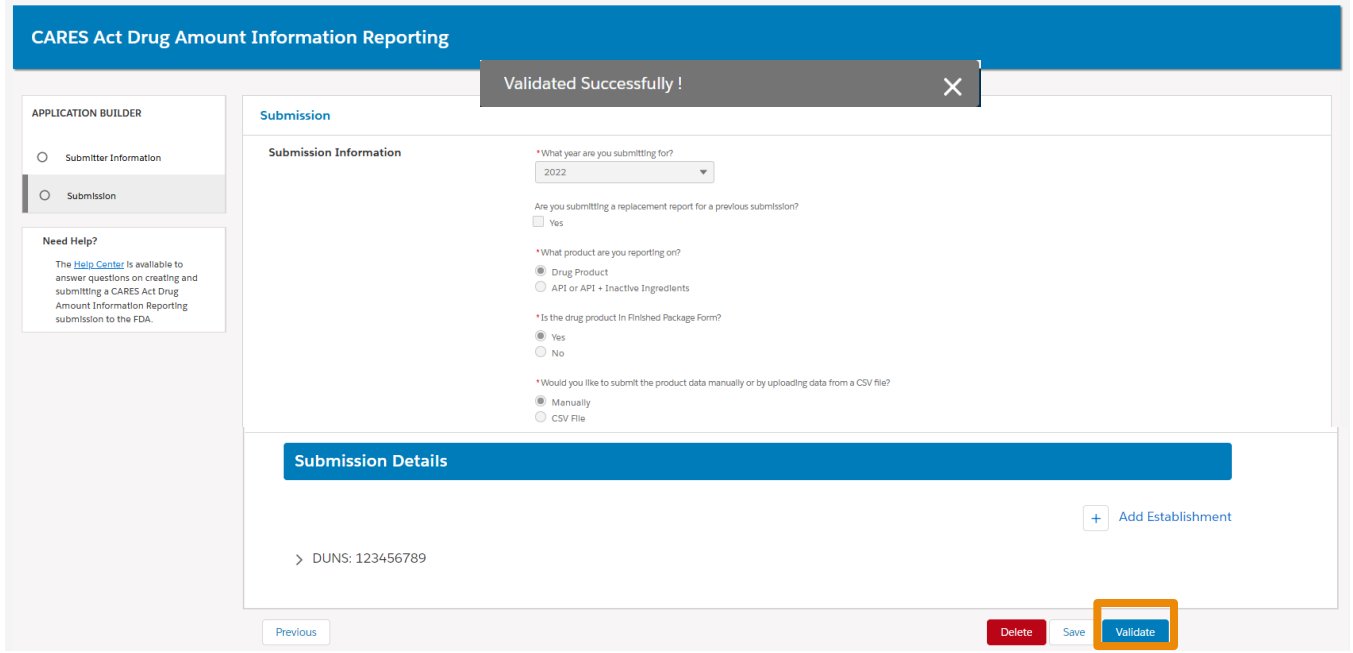
Manual Submission – Finished Package Form

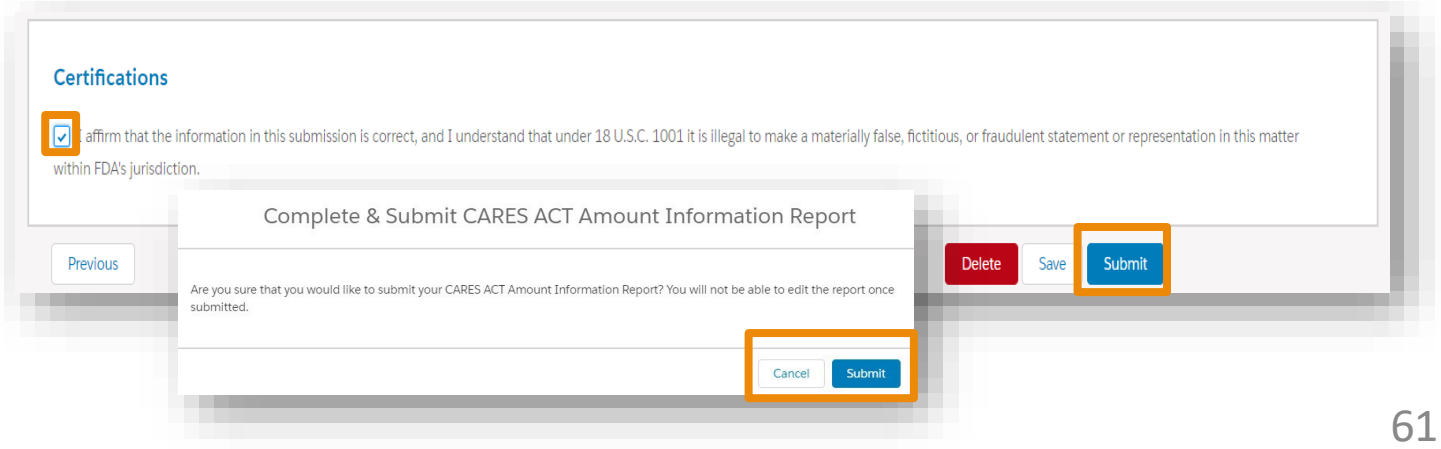
Step 25. Click the **Validate** button at the bottom of the page.

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.

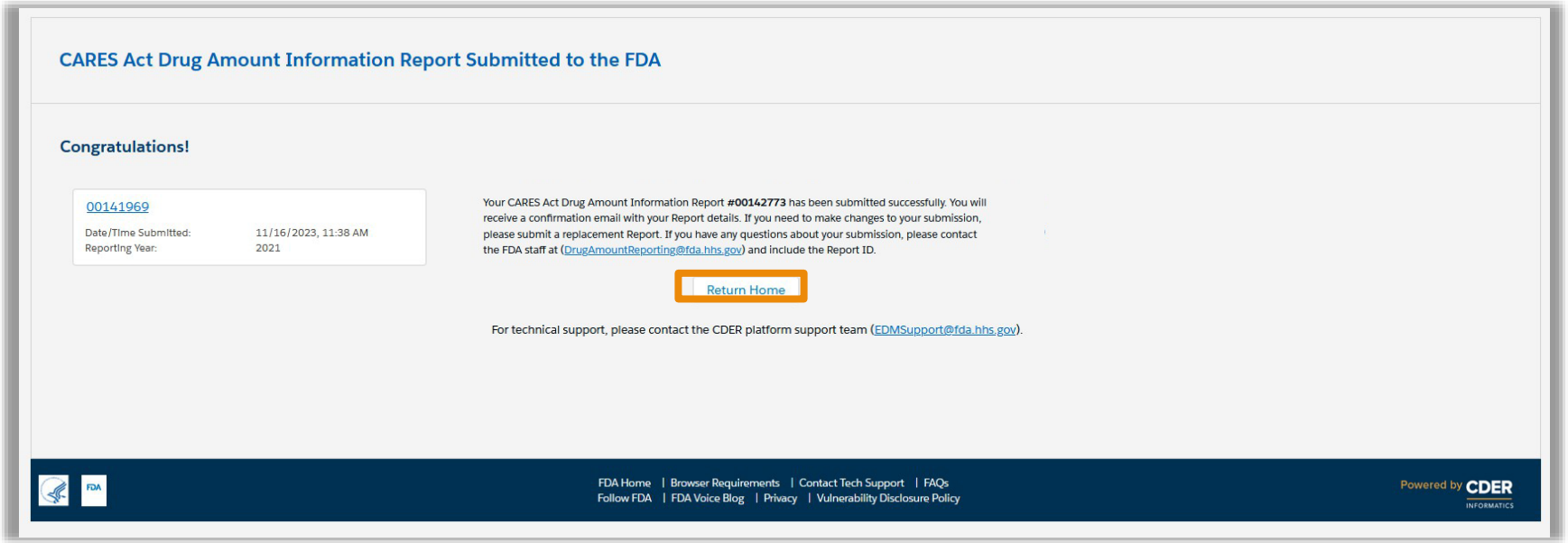




Manual Submission – Finished Package Form

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.



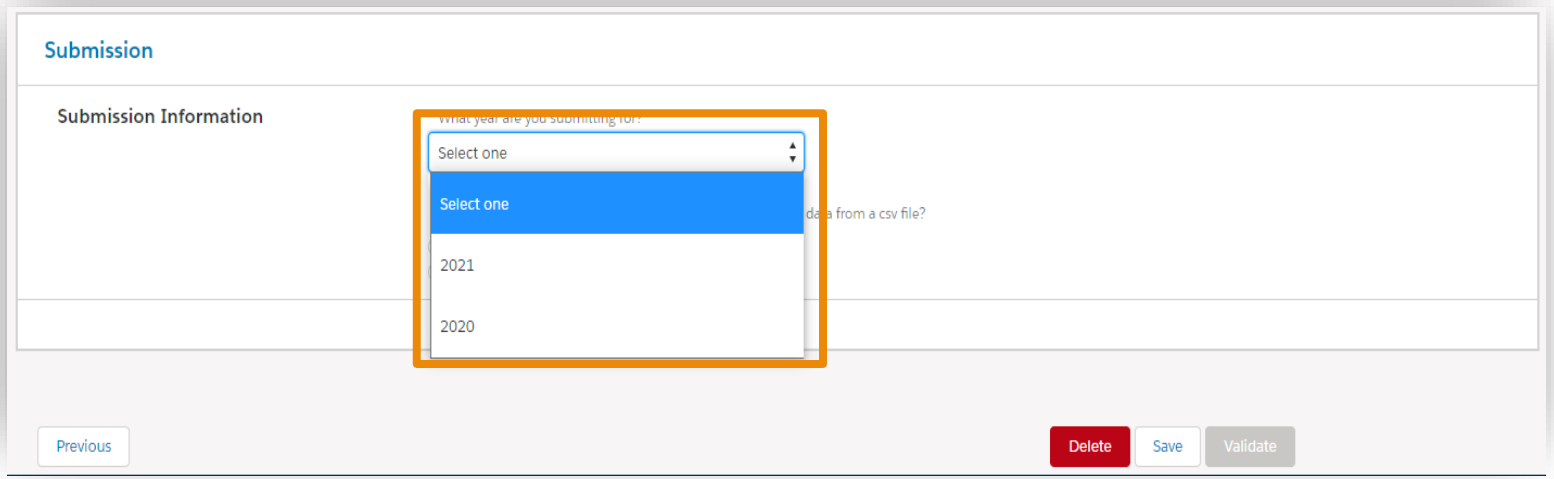
Manual Submission - Not in Finished Package Form

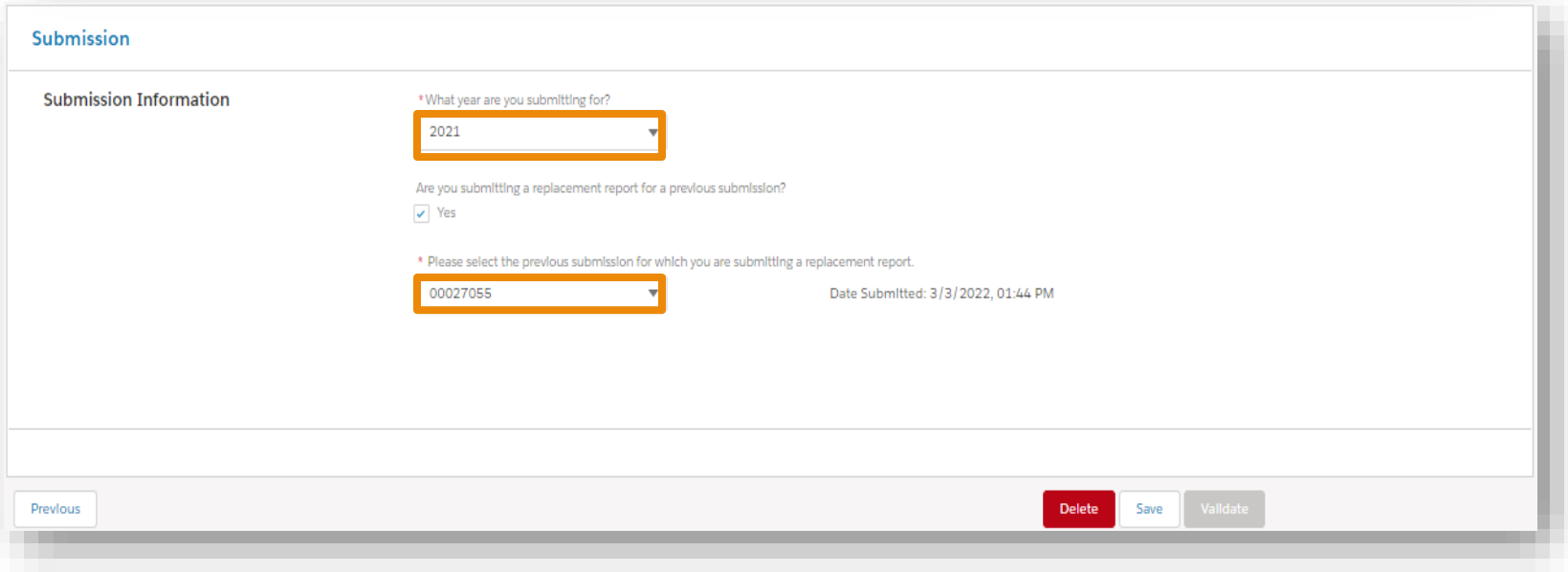
Manual Submission – Not in Finished Package Form

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

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

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





CARES Act Amount Information Reporting

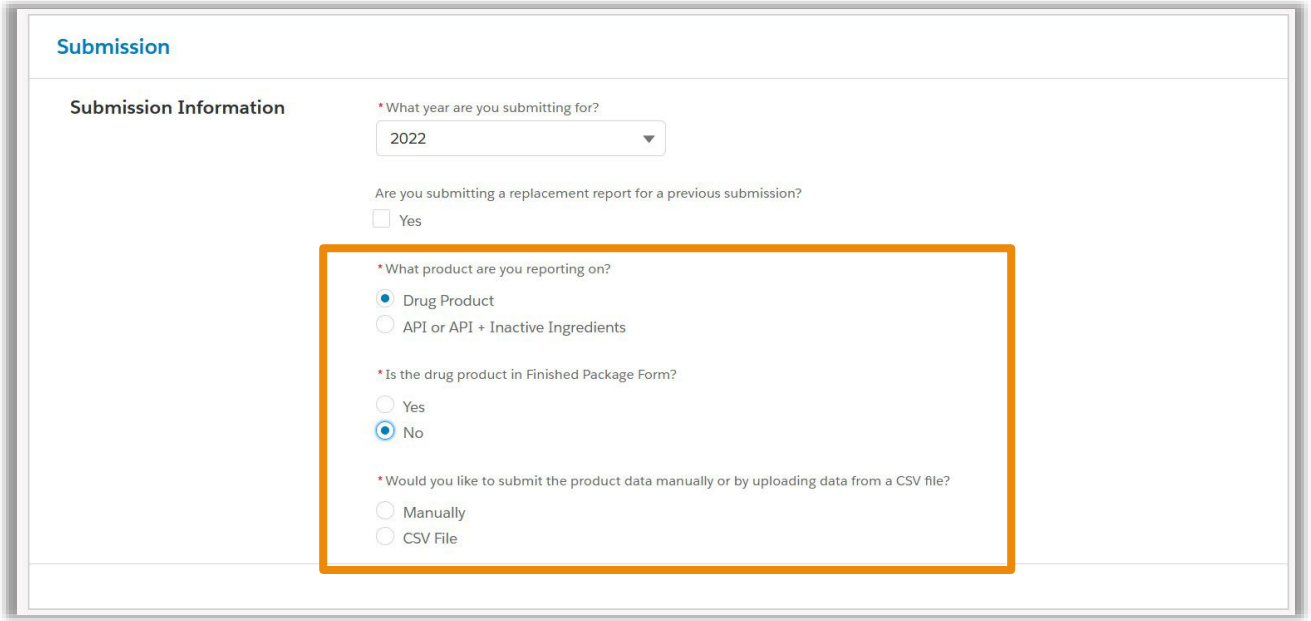
Manual Submission – Not in Finished Package Form

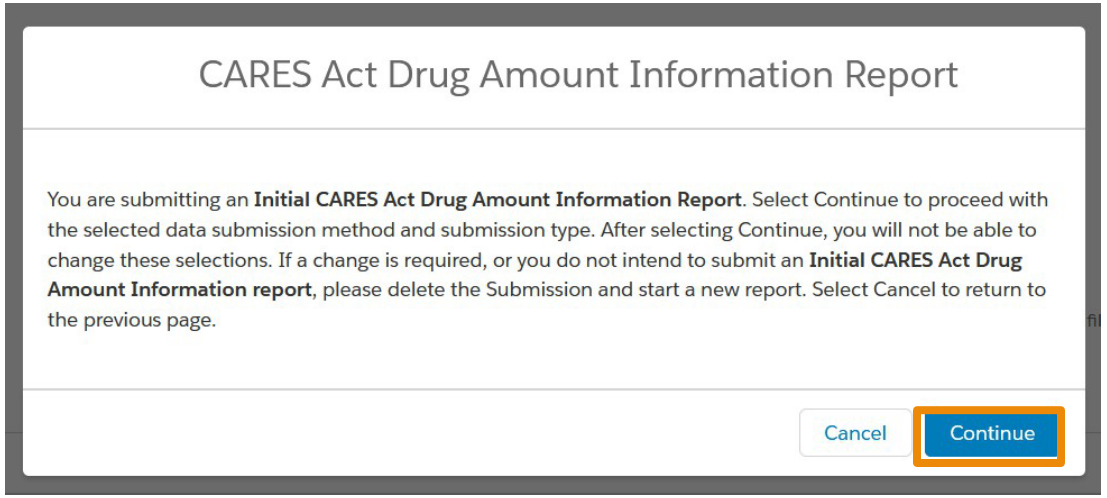
Step 10. Select that you are reporting on a Drug Product.

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

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

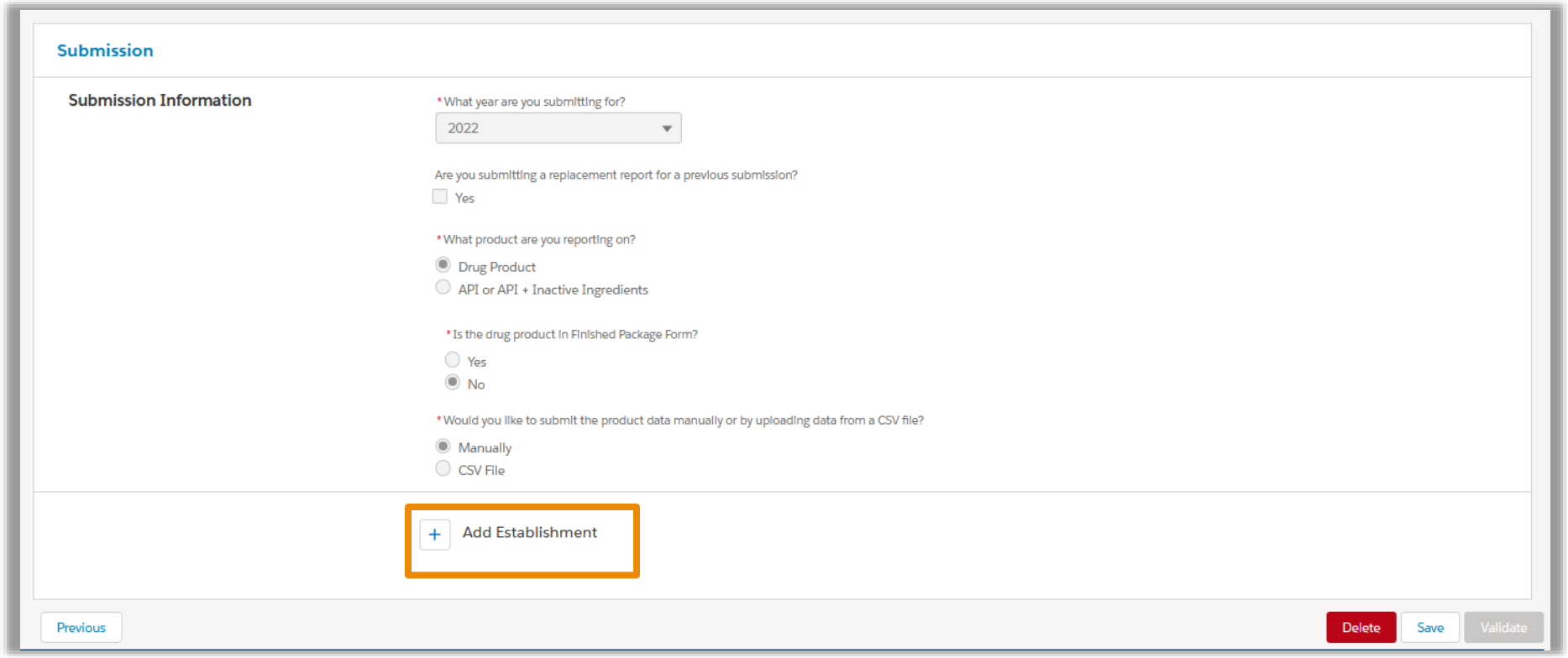
Step 13. In the confirmation screen, click **Continue.**





Manual Submission – Not in Finished Package Form

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



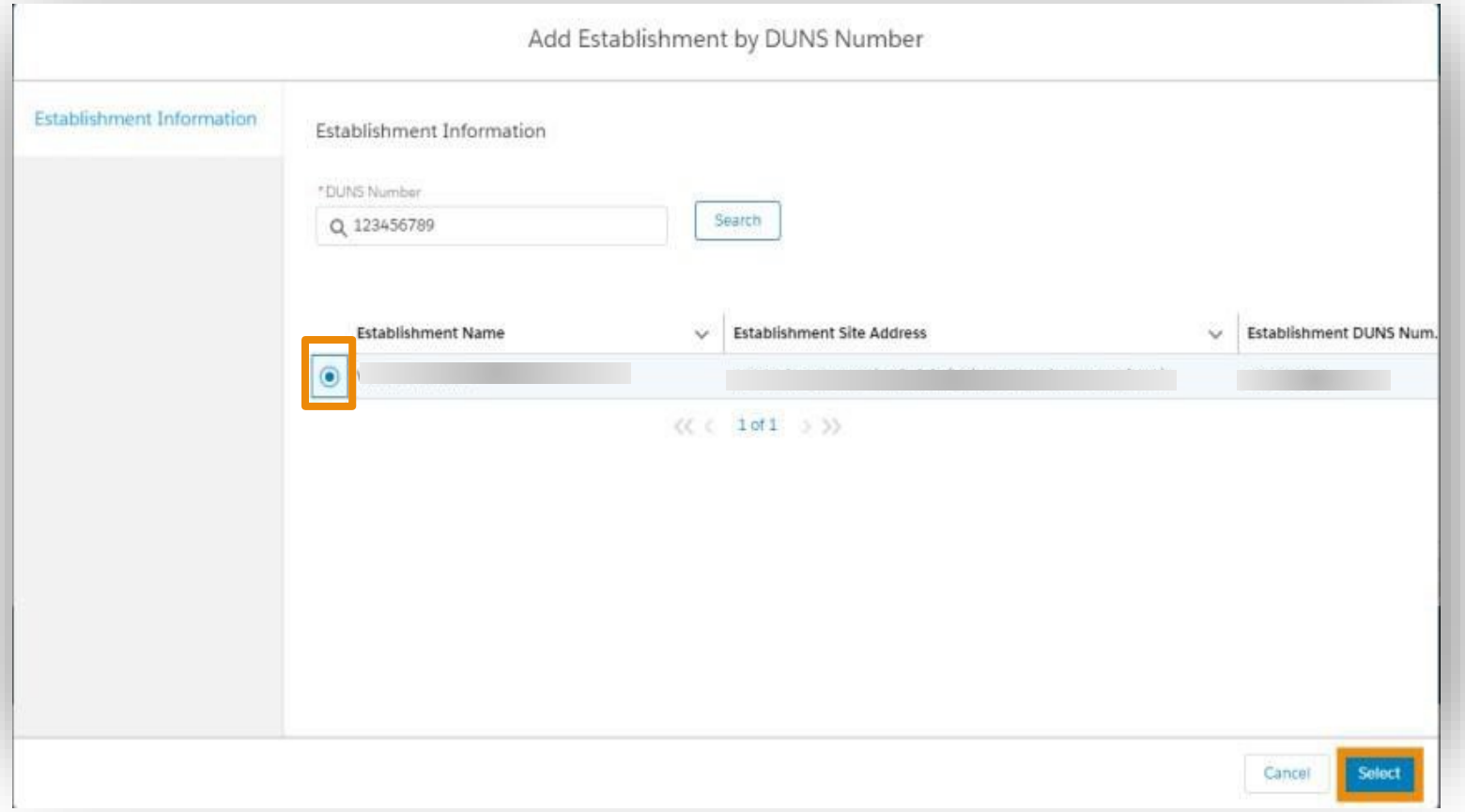
Manual Submission – Not in Finished Package Form

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.

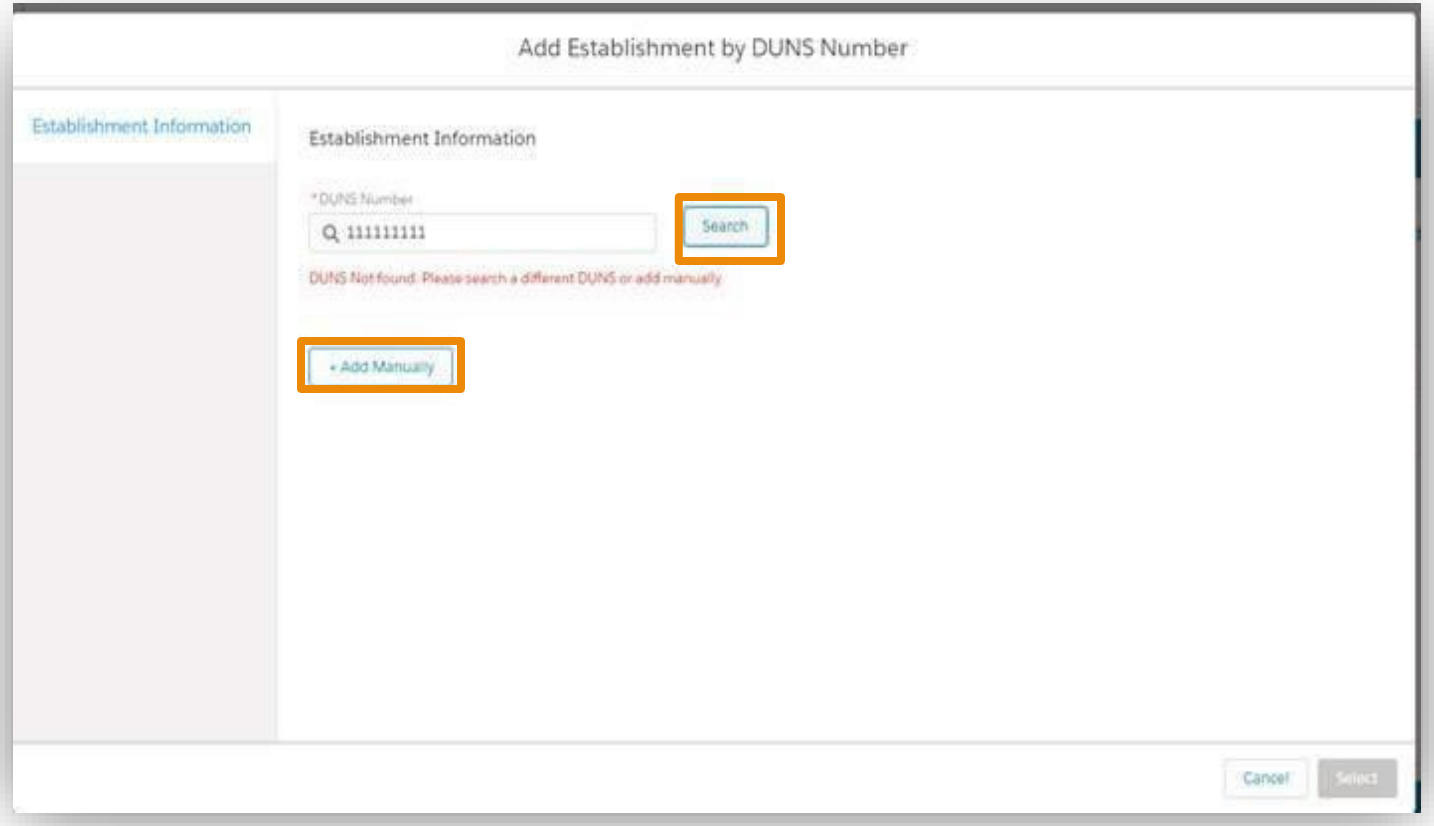
If this is the correct establishment, click in the radio button on the left and then click **Select**.

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



Manual Submission – Not in Finished Package Form

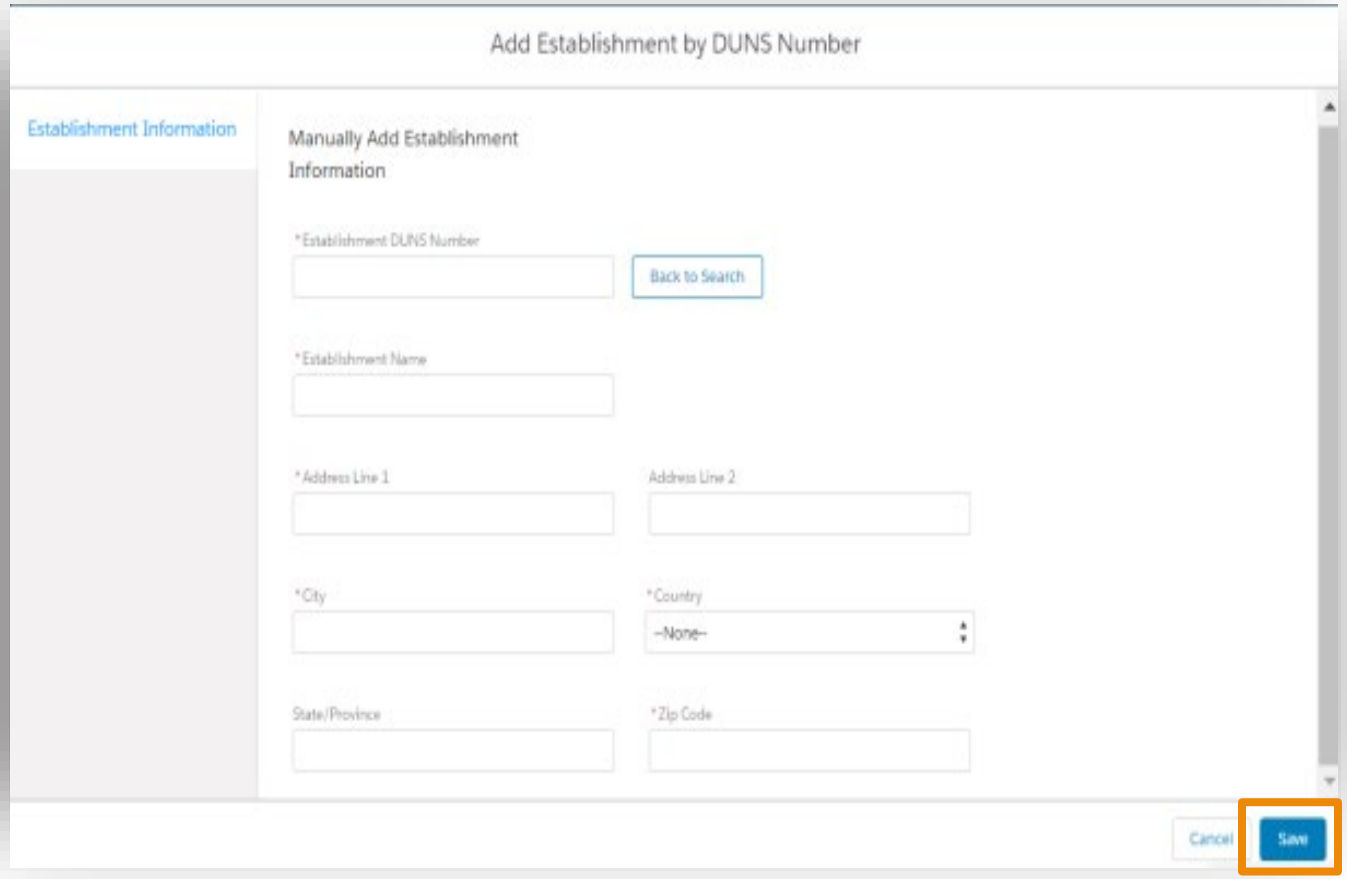
Step 16. If the search for a DUNS number fails, an error message and an +**Add Manually** button will appear. Click the button to enter establishment information.



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.**



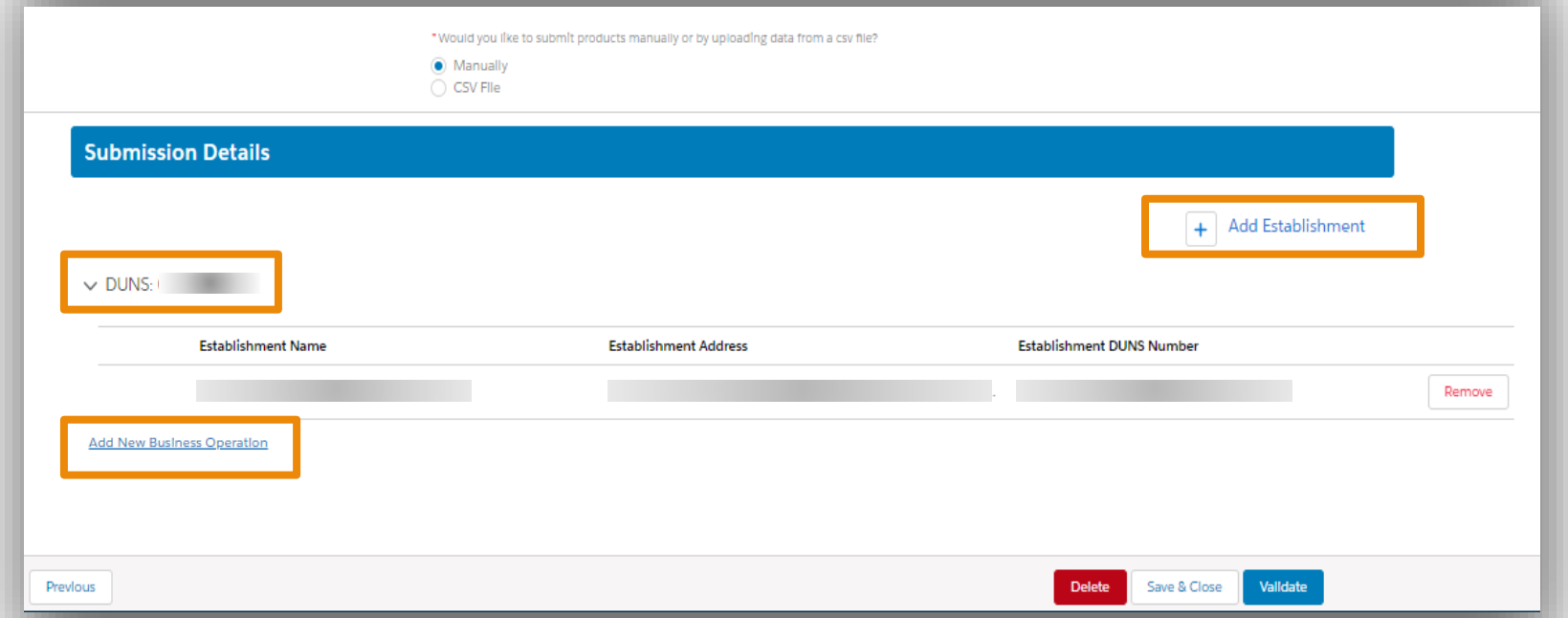
Manual Submission – Not in Finished Package Form

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**.

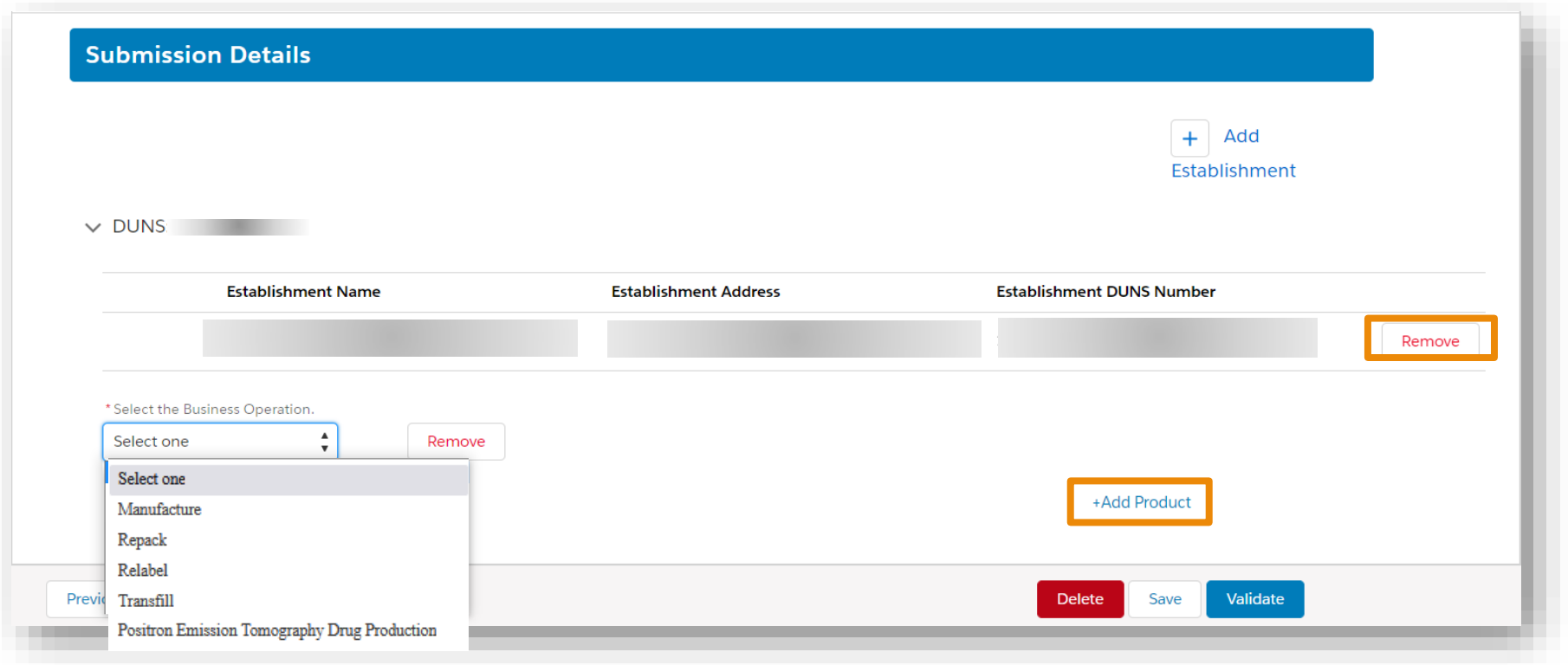
To enter data for another DUNS number, click on **Add Establishment** and repeat the process of adding a DUNS number.



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.

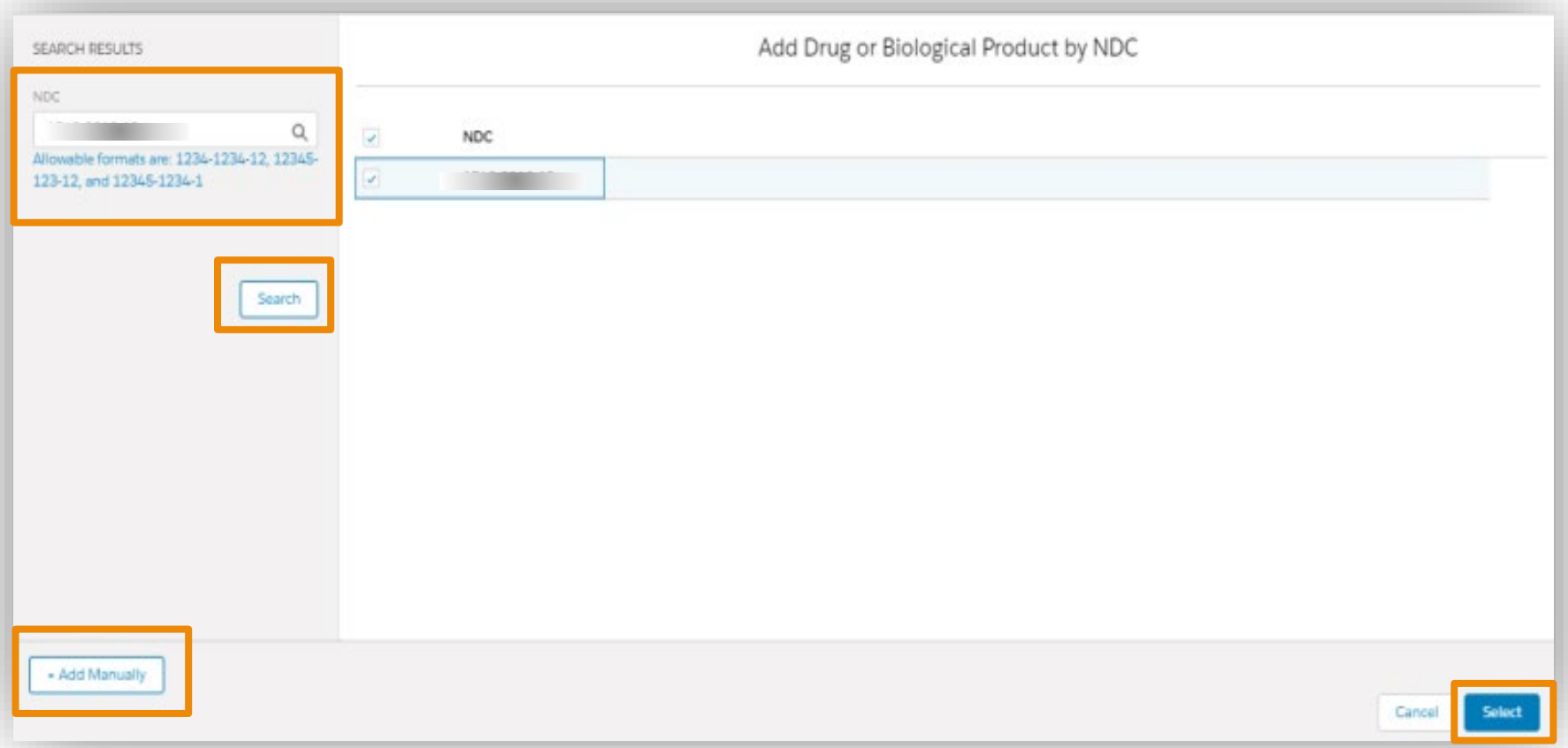


Manual Submission – Not in Finished Package Form

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

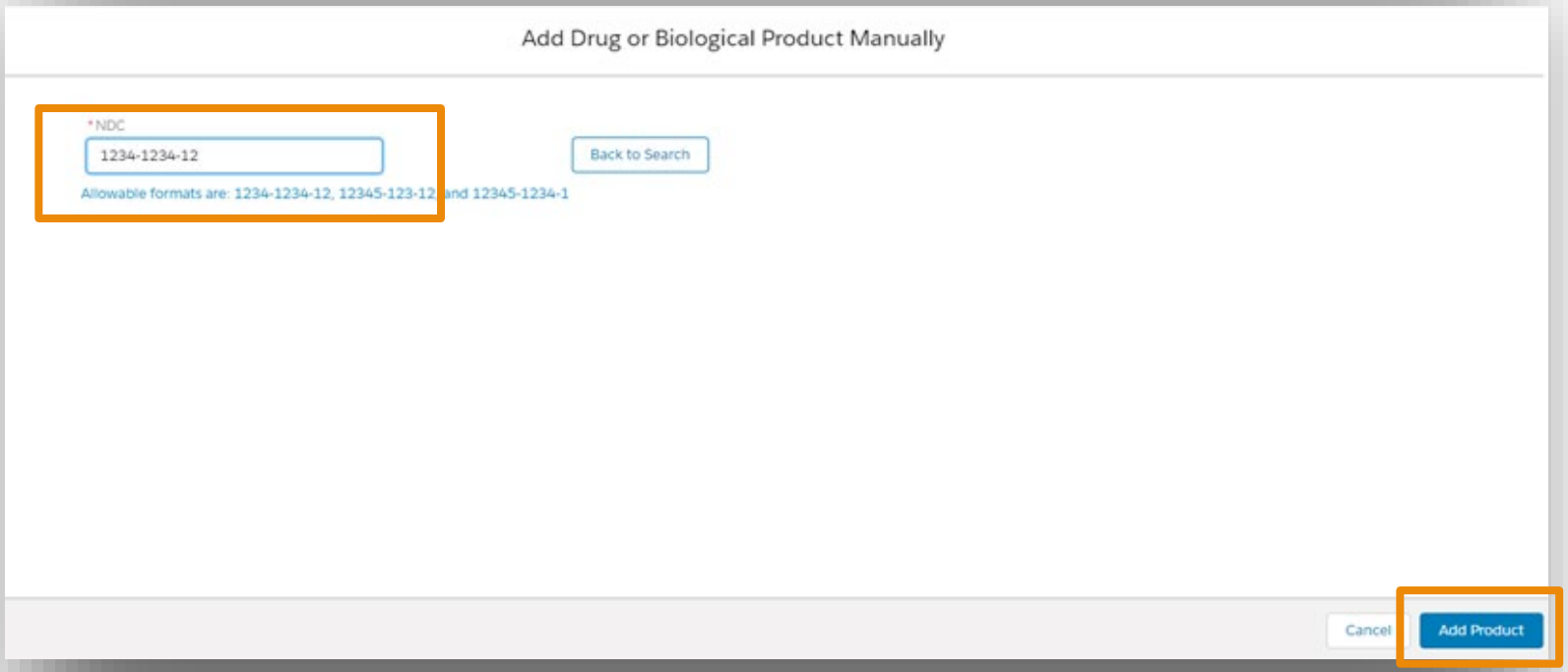
If the NDC appears on the right, check the box next to it and then click **Select**, which will return you to the **Submission** screen.

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

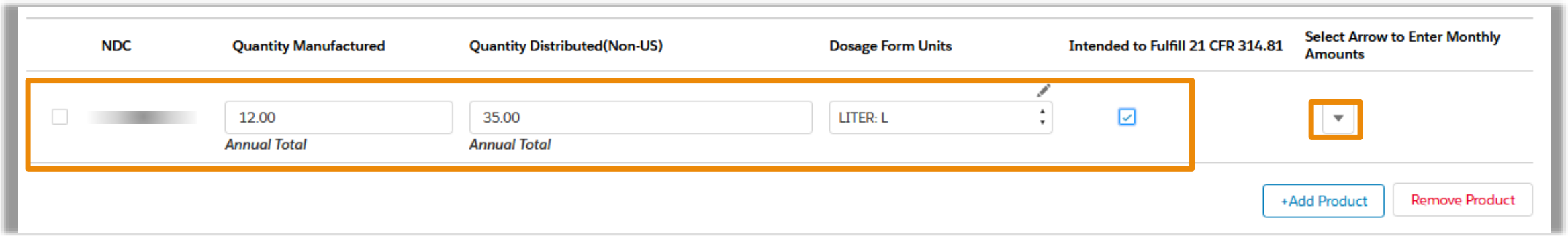


Manual Submission – Not in Finished Package Form

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



Manual Submission – Not in Finished Package Form



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

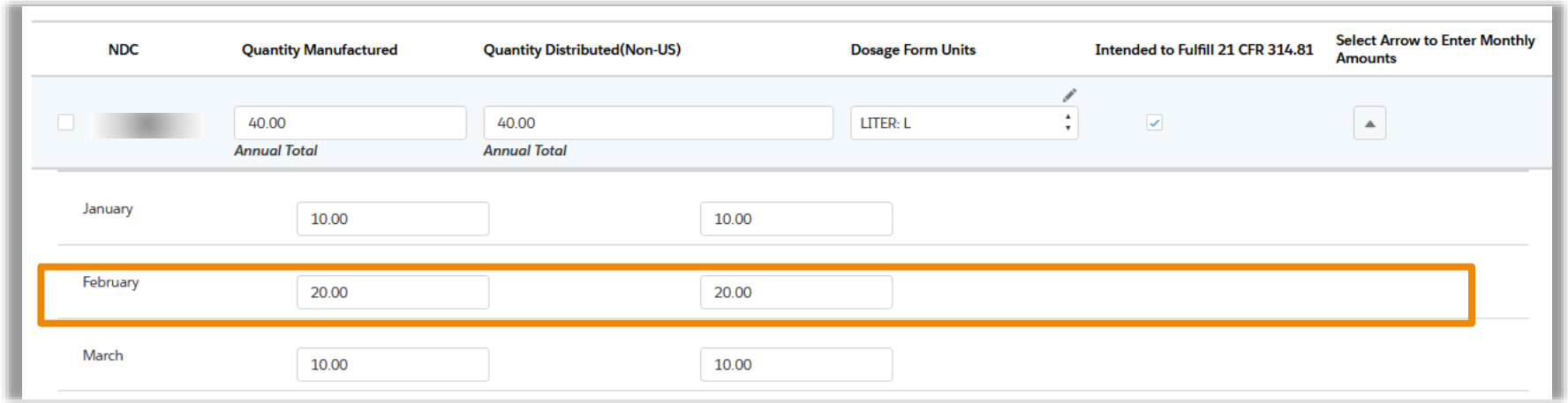
Click **+Add Product and/or Remove Product** as needed.

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.



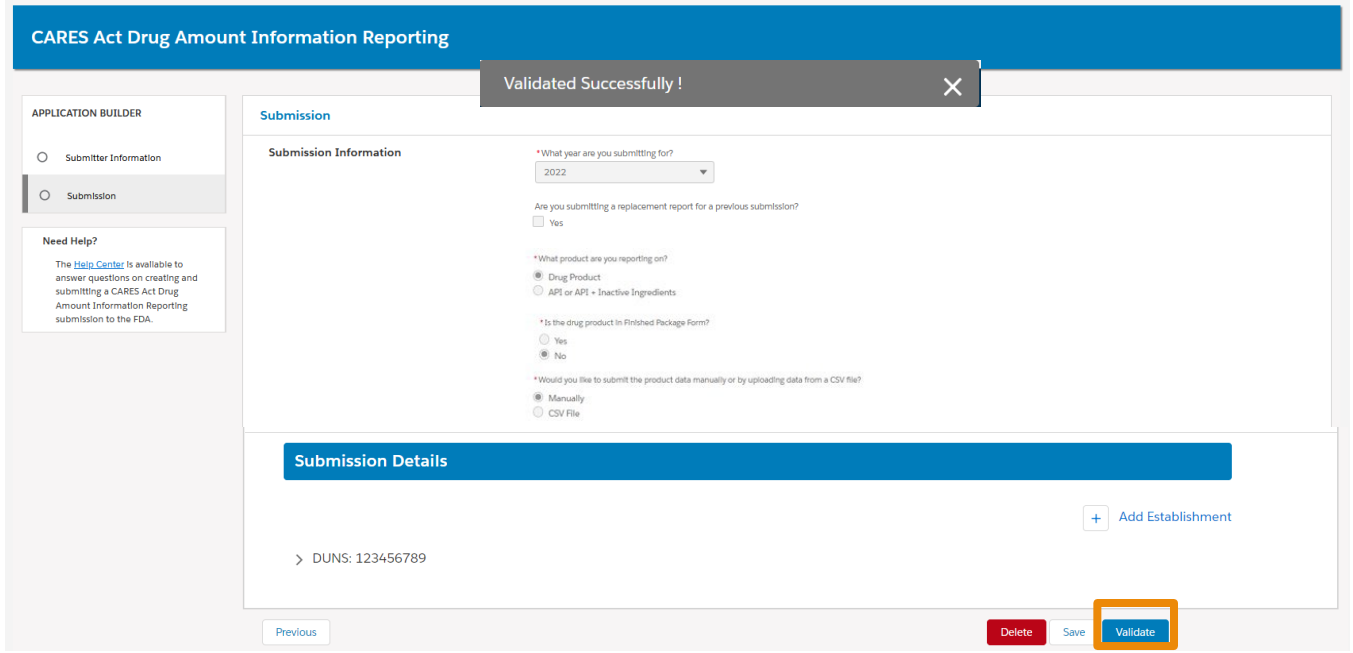
Manual Submission – Not in Finished Package Form

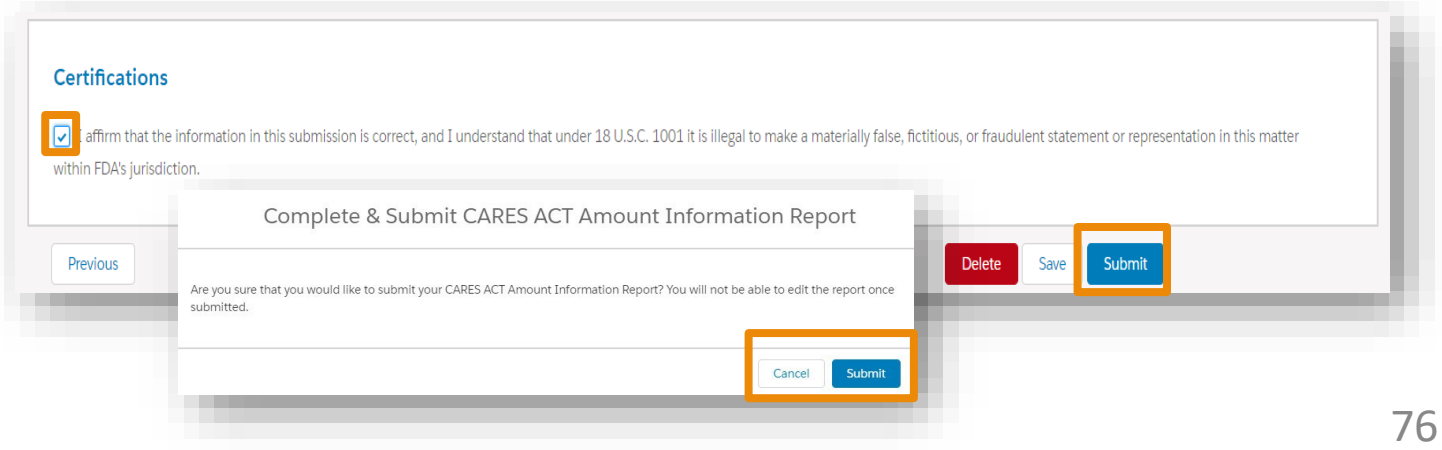
Step 25. Click the **Validate** button at the bottom of the page.

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.

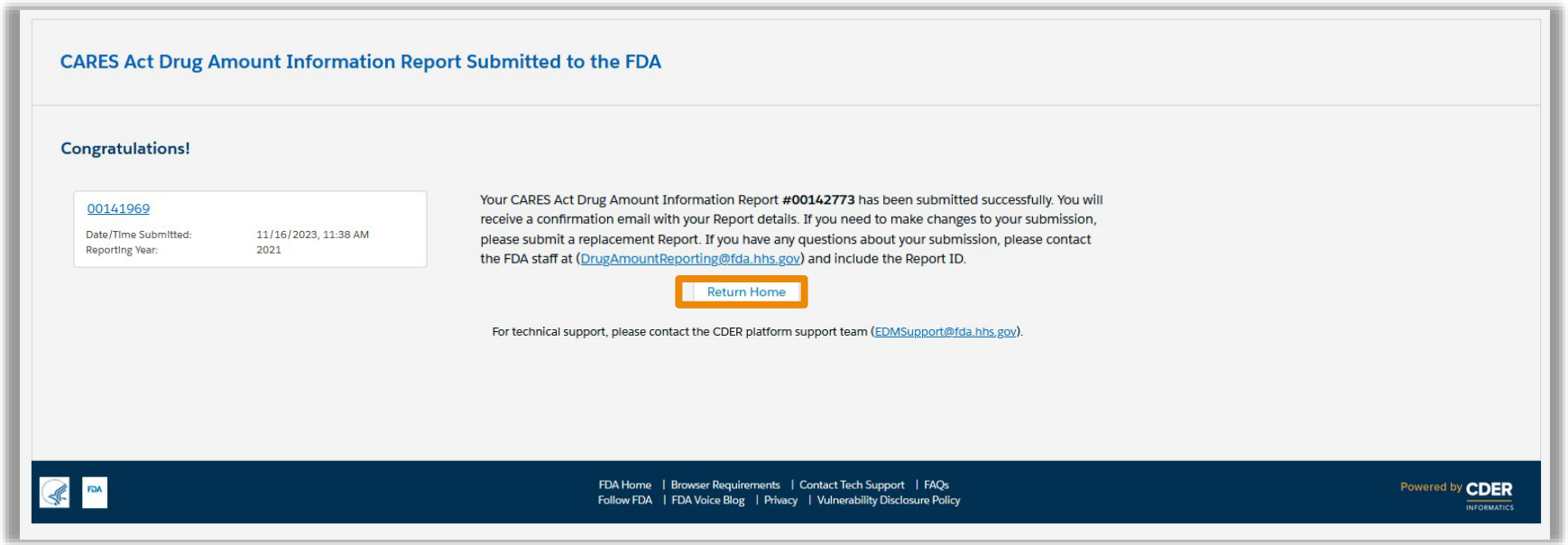




Manual Submission – Not in Finished Package Form

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.



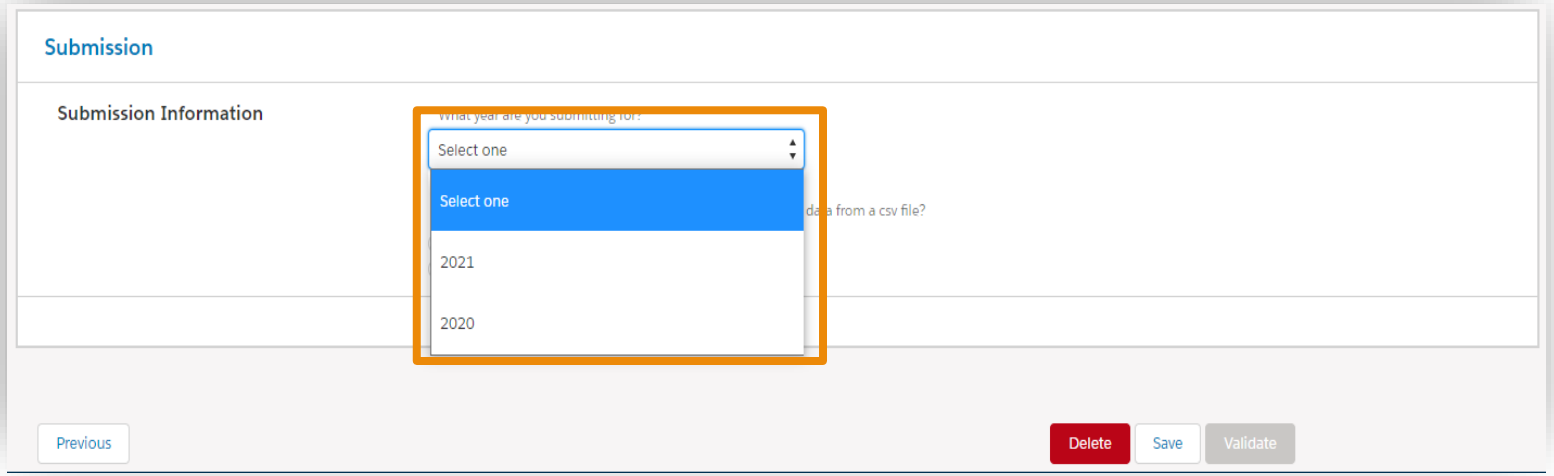
ManualSubmission - APIorAPI+InactiveIngredients

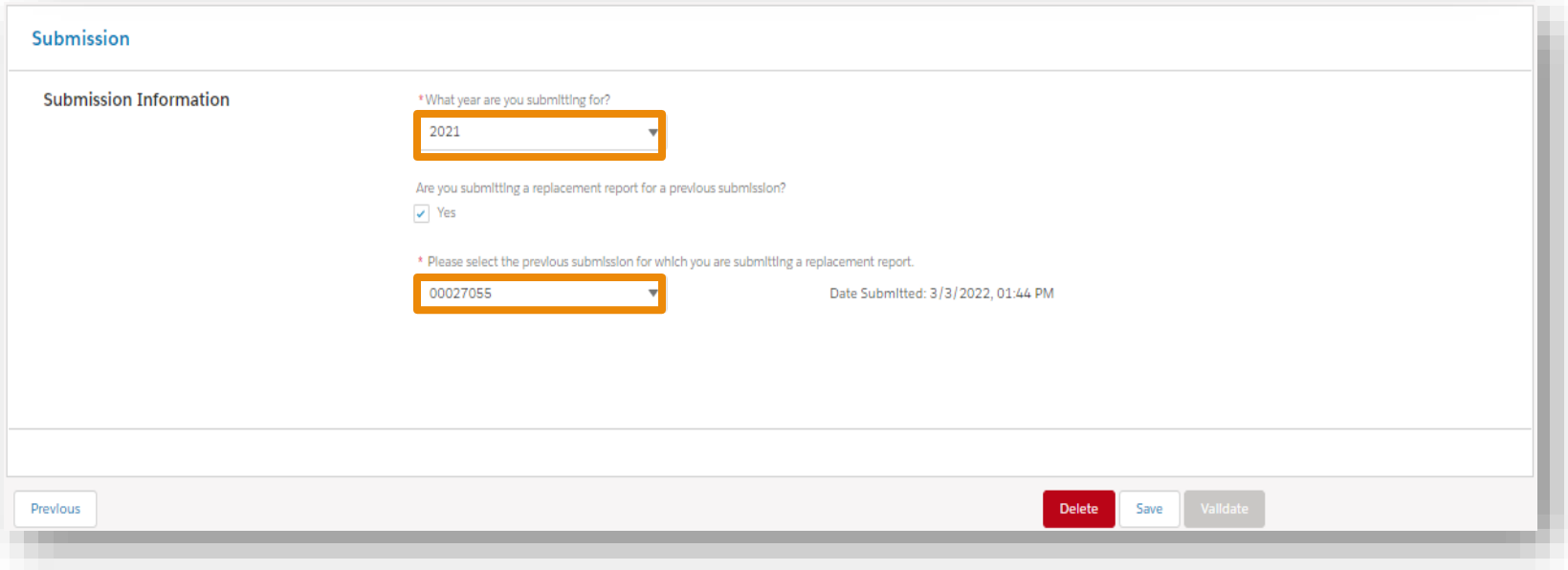
Manual Submission – API or API + Inactive Ingredients

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

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

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



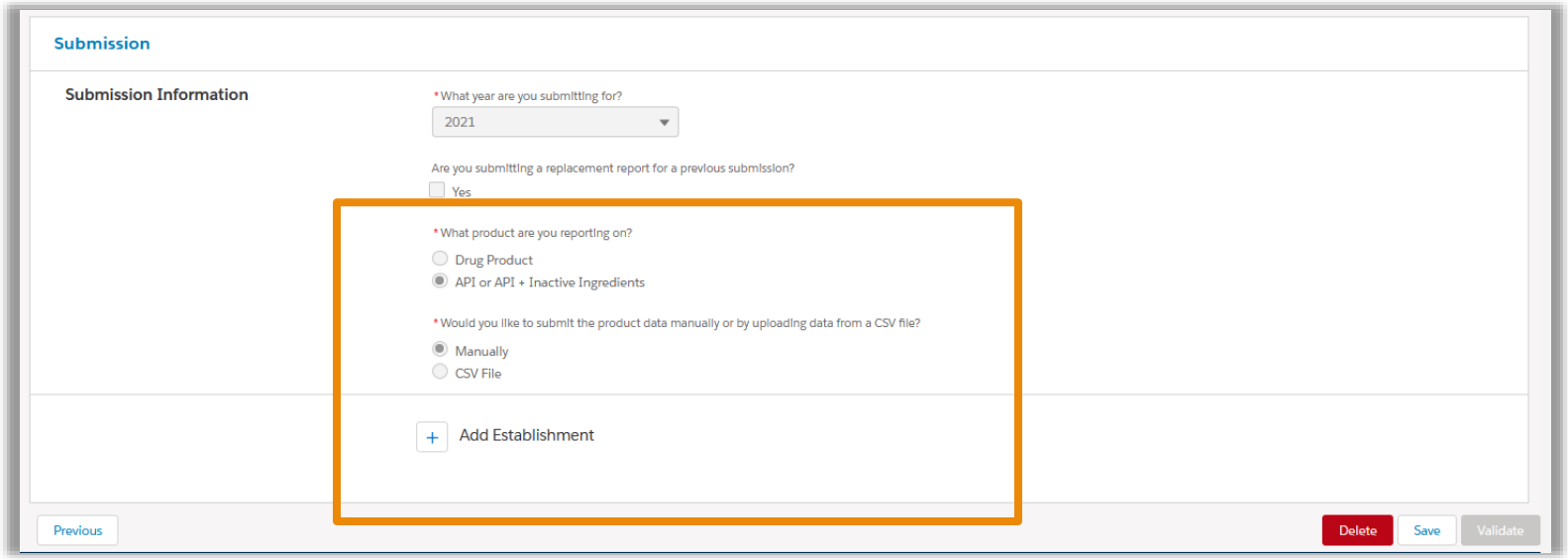


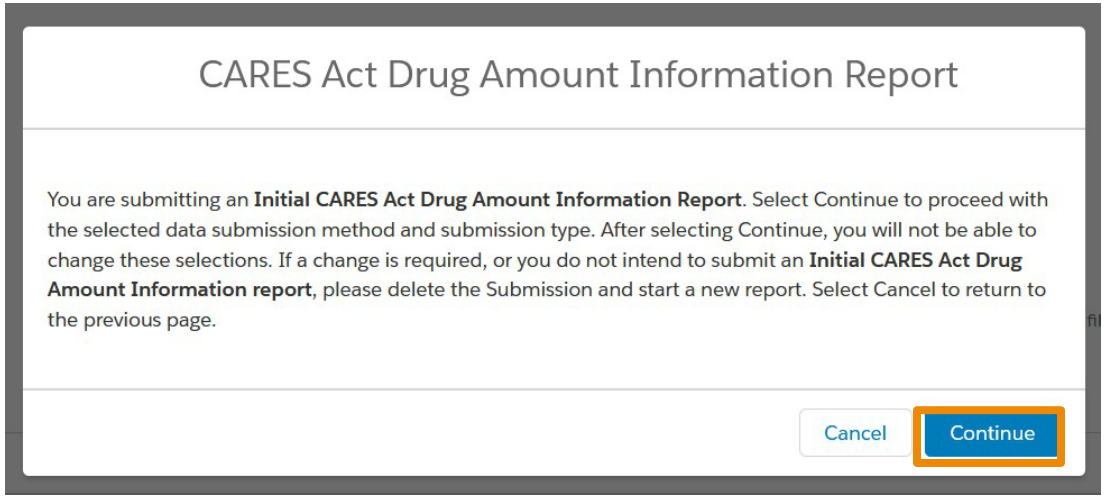
Manual Submission – API or API + Inactive Ingredients

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

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

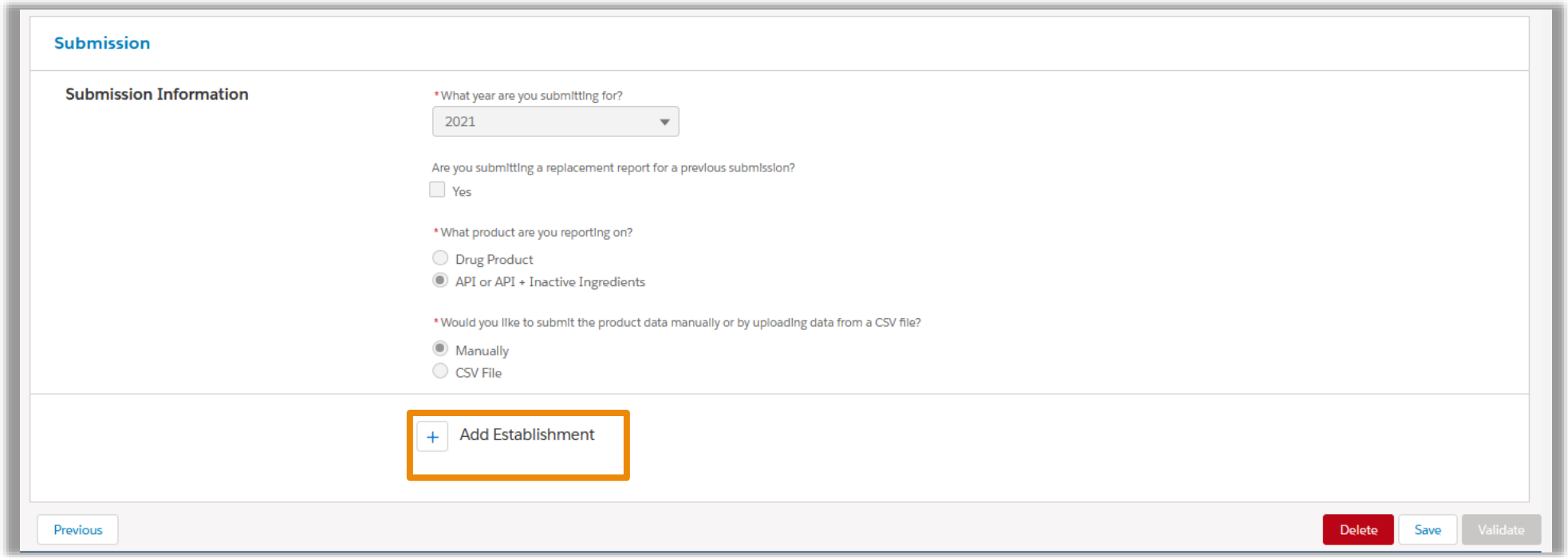
Step 12. In the confirmation screen, click **Continue.**





Manual Submission – API or API + Inactive Ingredients

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



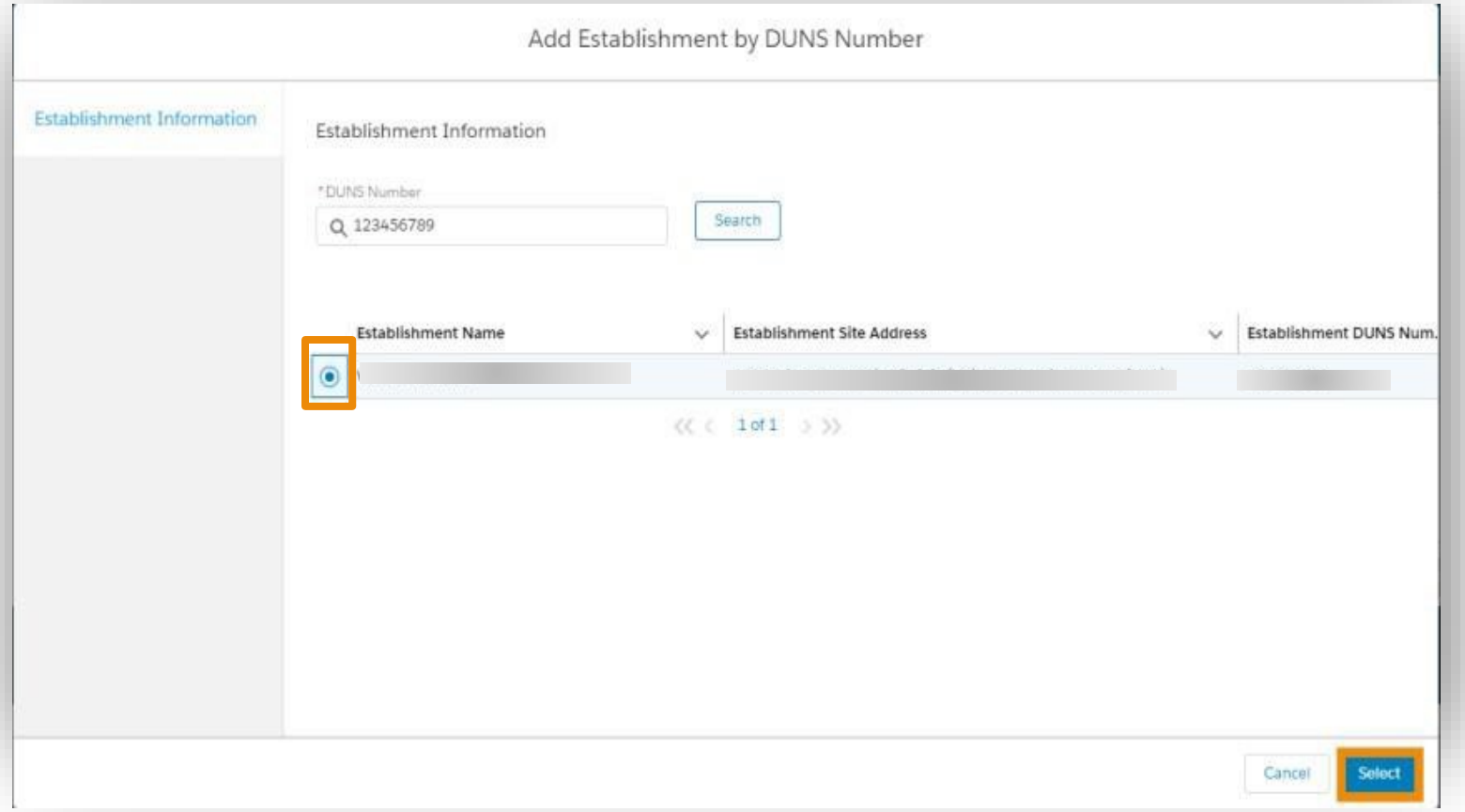
Manual Submission – API or API + Inactive Ingredients

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.

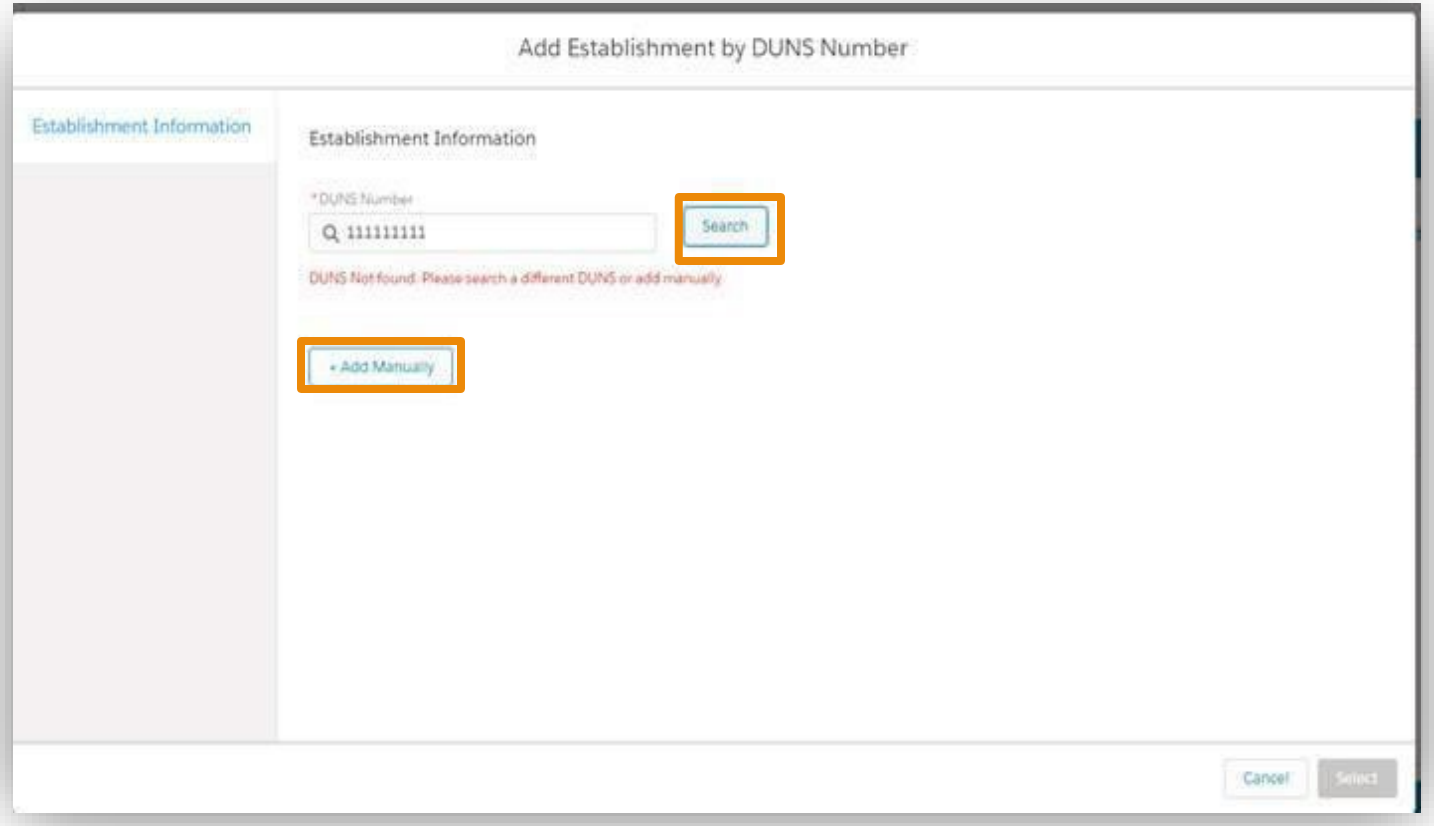
If this is the correct establishment, click in the radio button on the left and then click **Select**.

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



Manual Submission – API or API + Inactive Ingredients

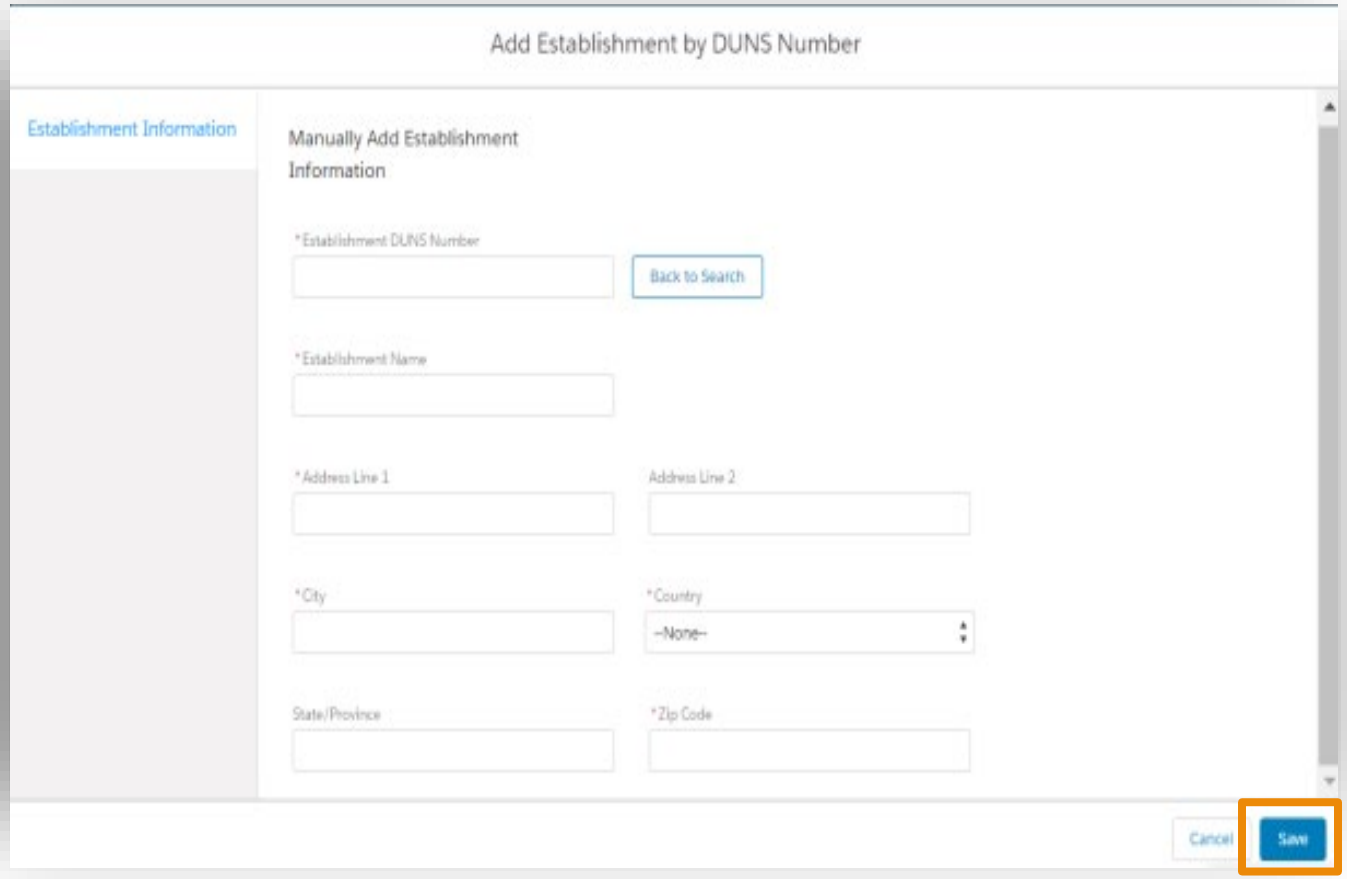
Step 15. If the search for a DUNS number fails, an error message and an +**Add Manually** button will appear. Click the button to enter establishment information.



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.**



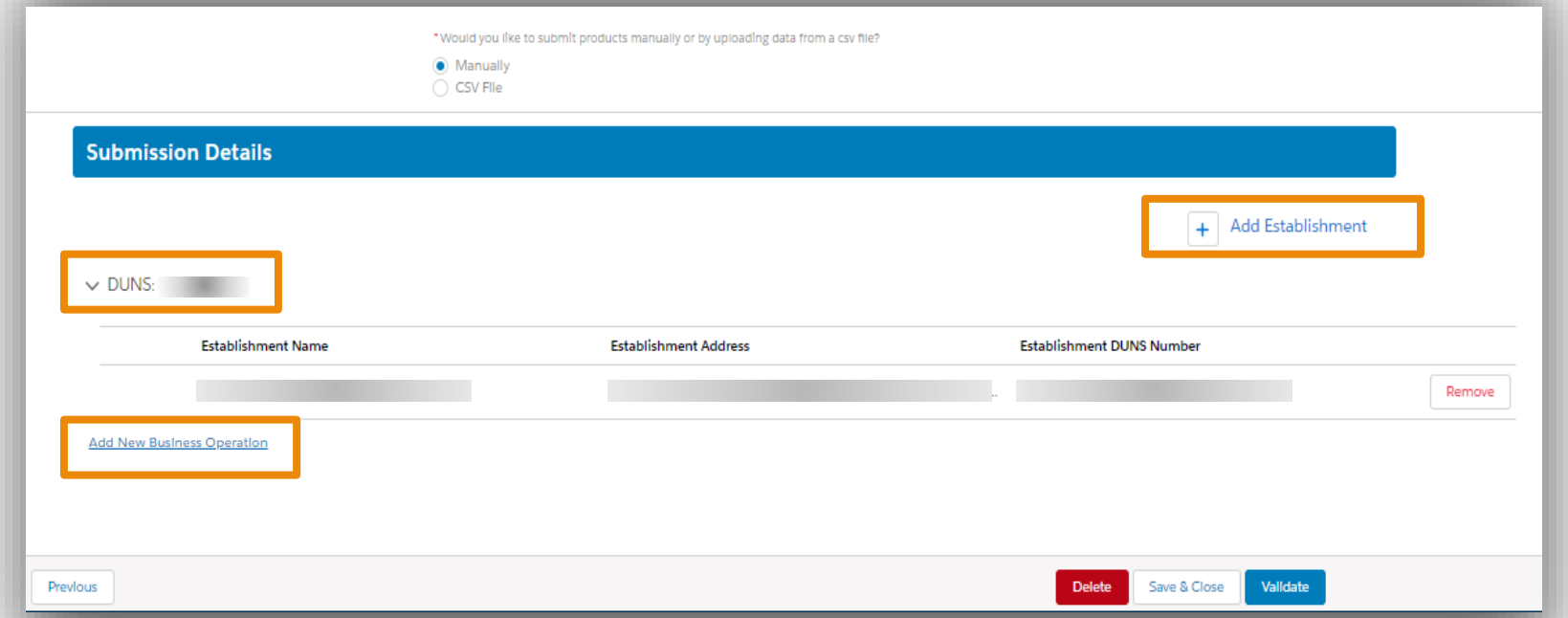
Manual Submission – API or API + Inactive Ingredients

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**.

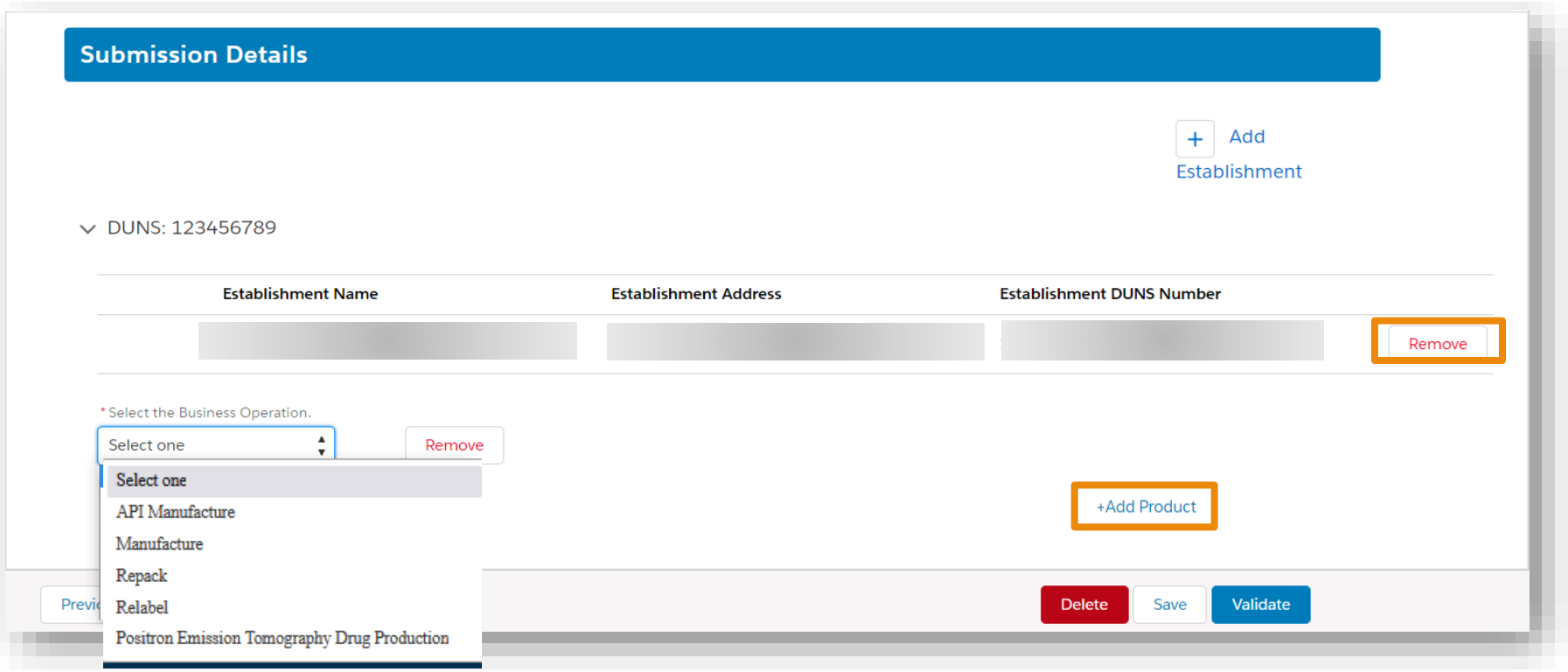
To enter data for another DUNS number, click on **Add Establishment** and repeat the process of adding a DUNS number.



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.

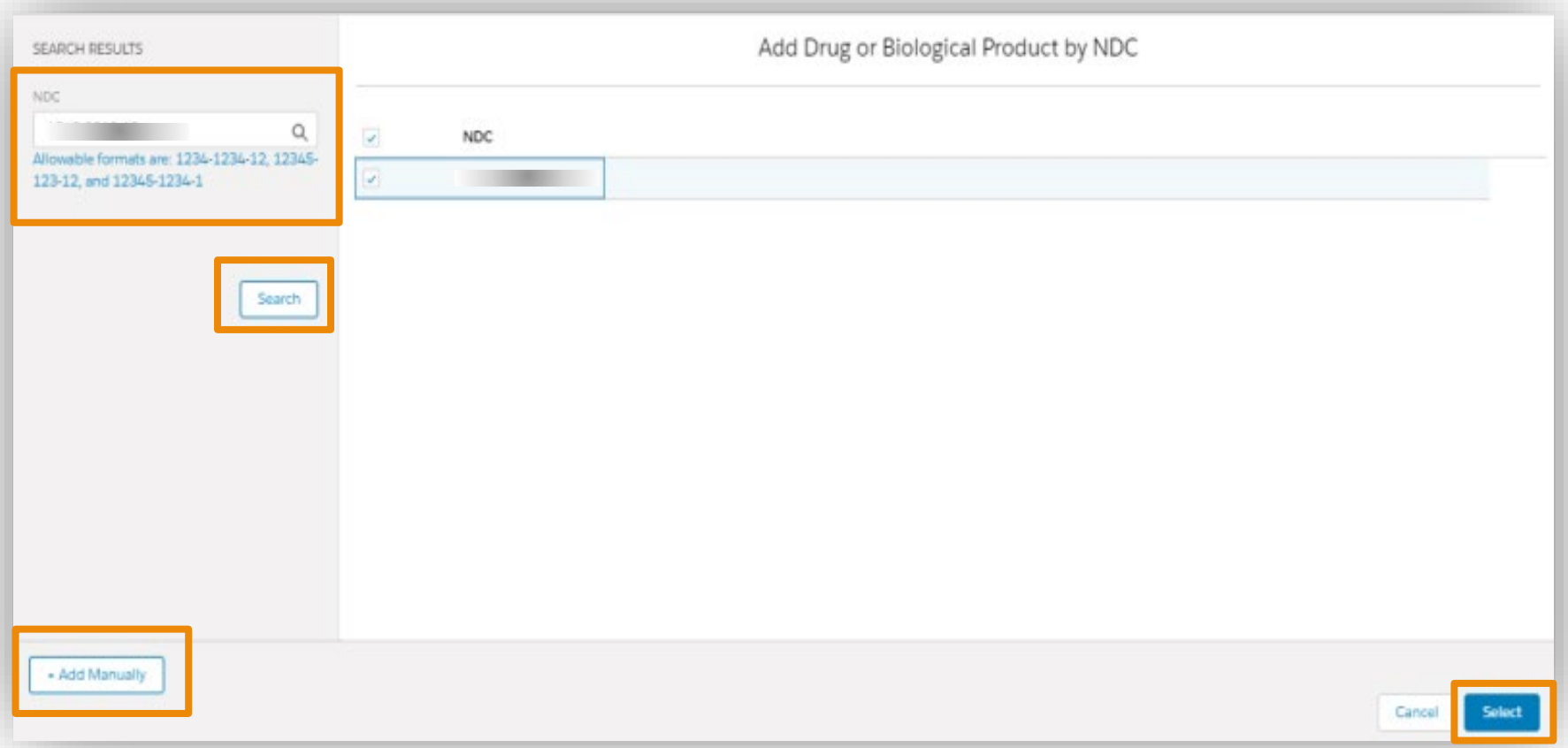


Manual Submission – API or API + Inactive Ingredients

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

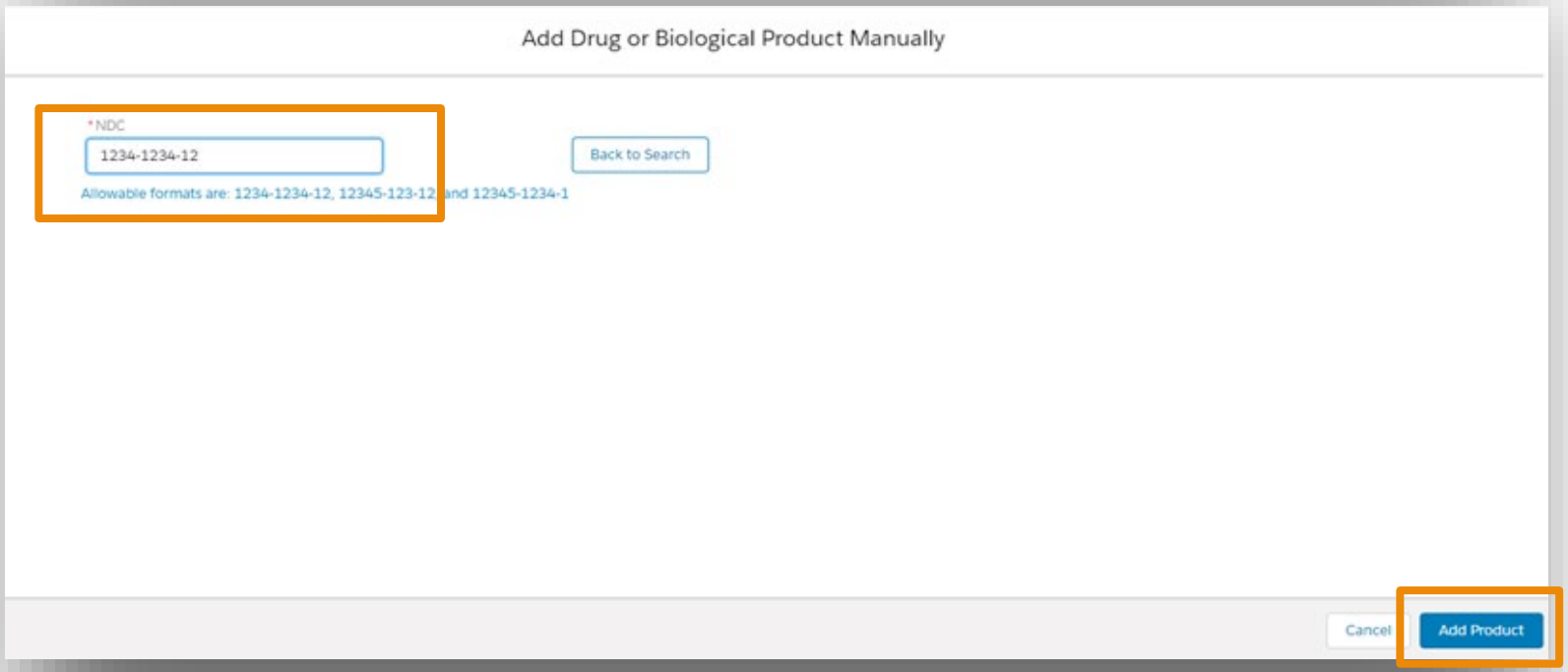
If the NDC appears on the right, check the box next to it and then click **Select**, which will return you to the **Submission** screen.

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

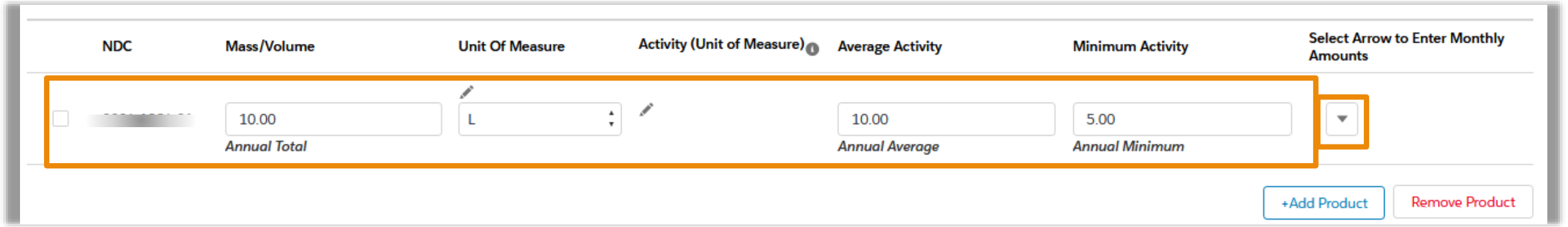


Manual Submission – API or API + Inactive Ingredients

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



Manual Submission – API or API + Inactive Ingredients



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

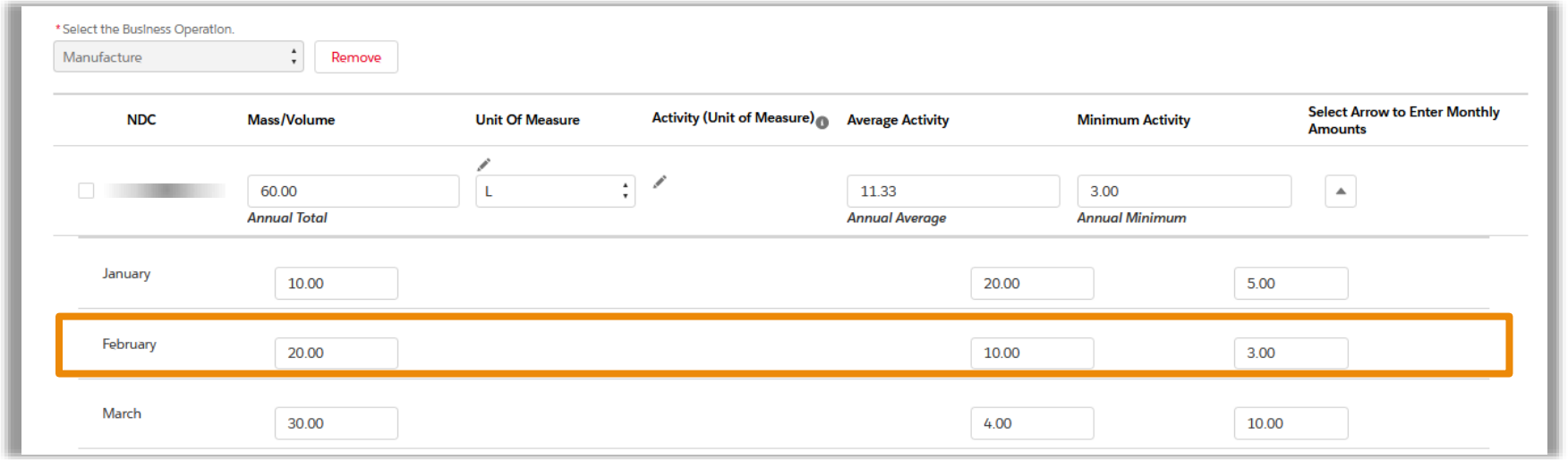
Click **+Add Product and/or Remove Product** as needed.

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.



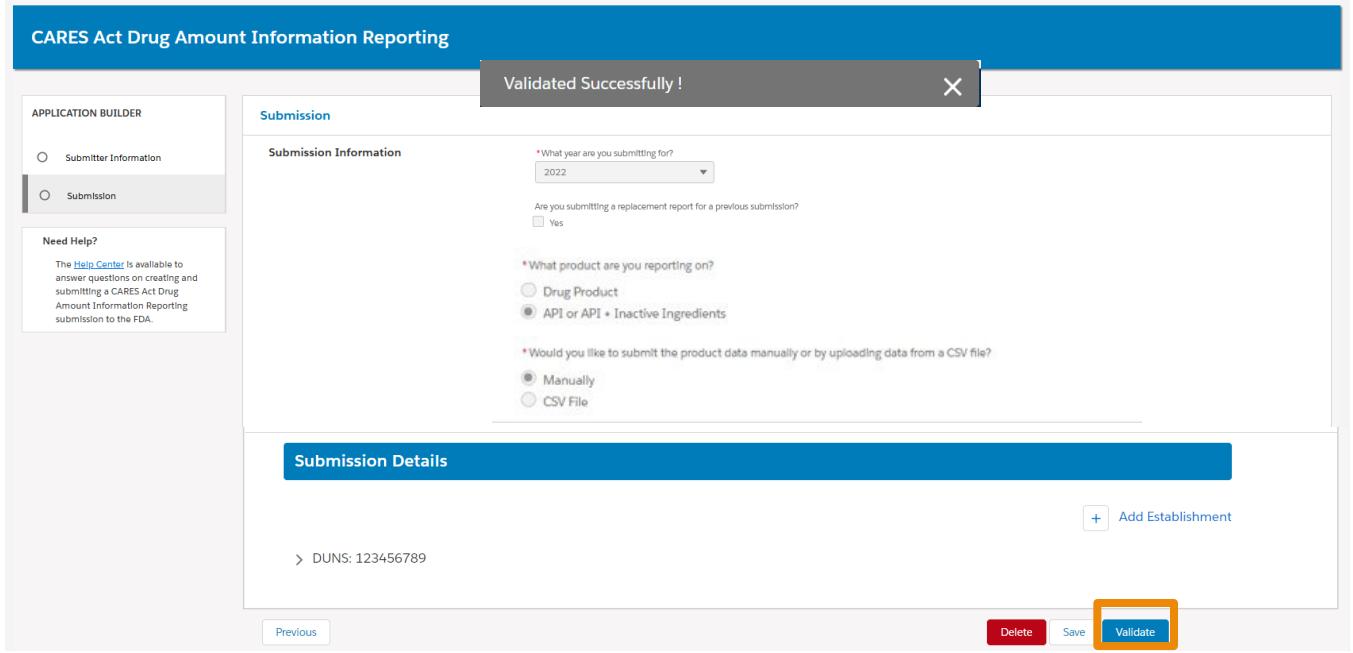
Manual Submission – API or API + Inactive Ingredients

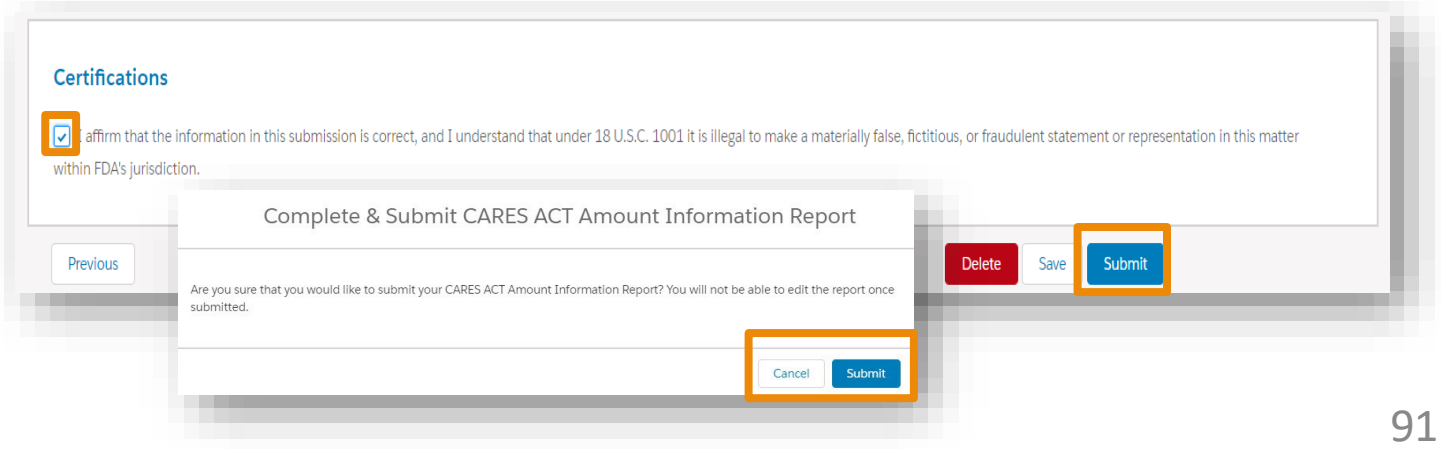
Step 24. Click the **Validate** button at the bottom of the page.

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.

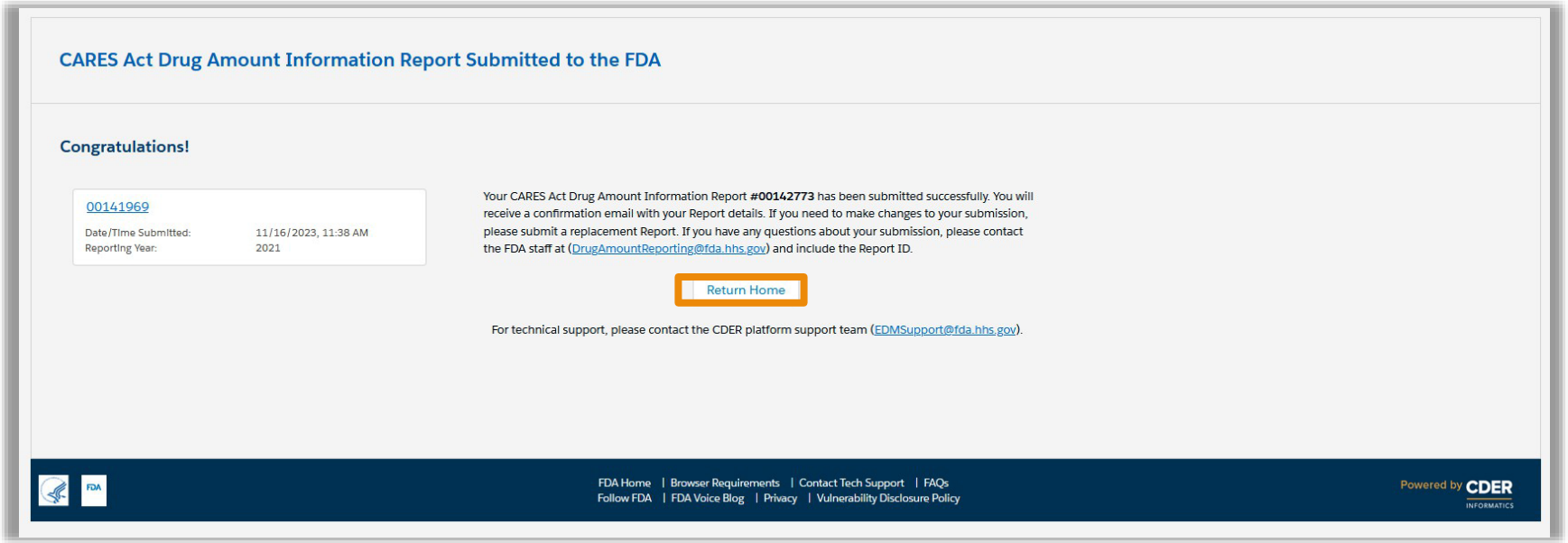




Manual Submission – API or API + Inactive Ingredients

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

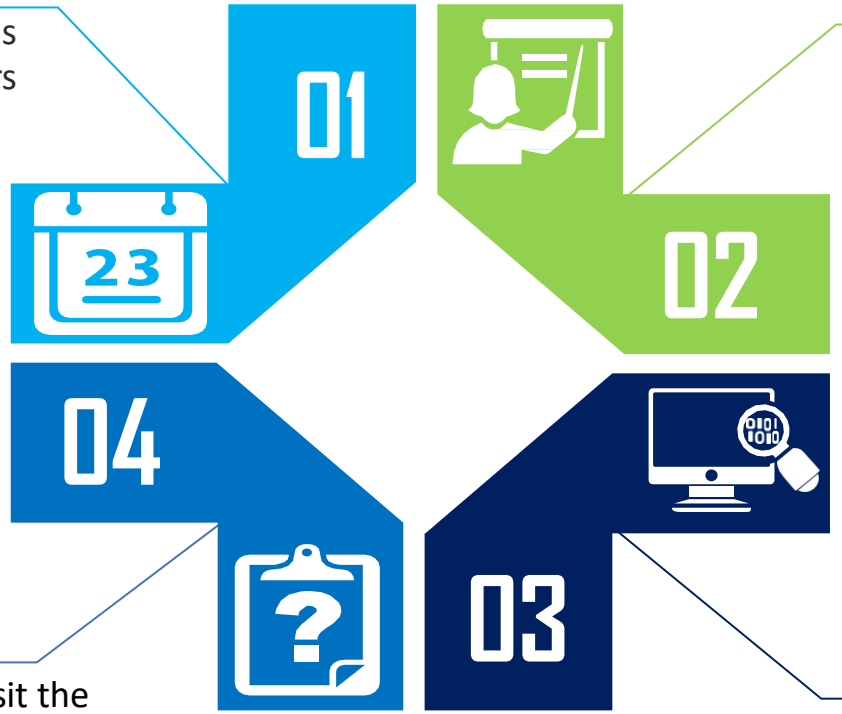
The CDER NextGen Portal has many resources for support.

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.