CARES Act Amount Information Reporting: Entering Data Manually

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 **manually enter data** to create and submit a CARES Act Amount Information report to the FDA. It is an expanded version of the original **CARES Act Amount Information Reporting** guide posted on **the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Drug Shortage Mitigation Efforts** webpage (https://www.fda.gov/drugs/drug-shortages/coronavirus-aid-relief-and-economic-security-act-cares-act-drug-shortage-mitigation-efforts).

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

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

CARES Act Amount Information Reporting
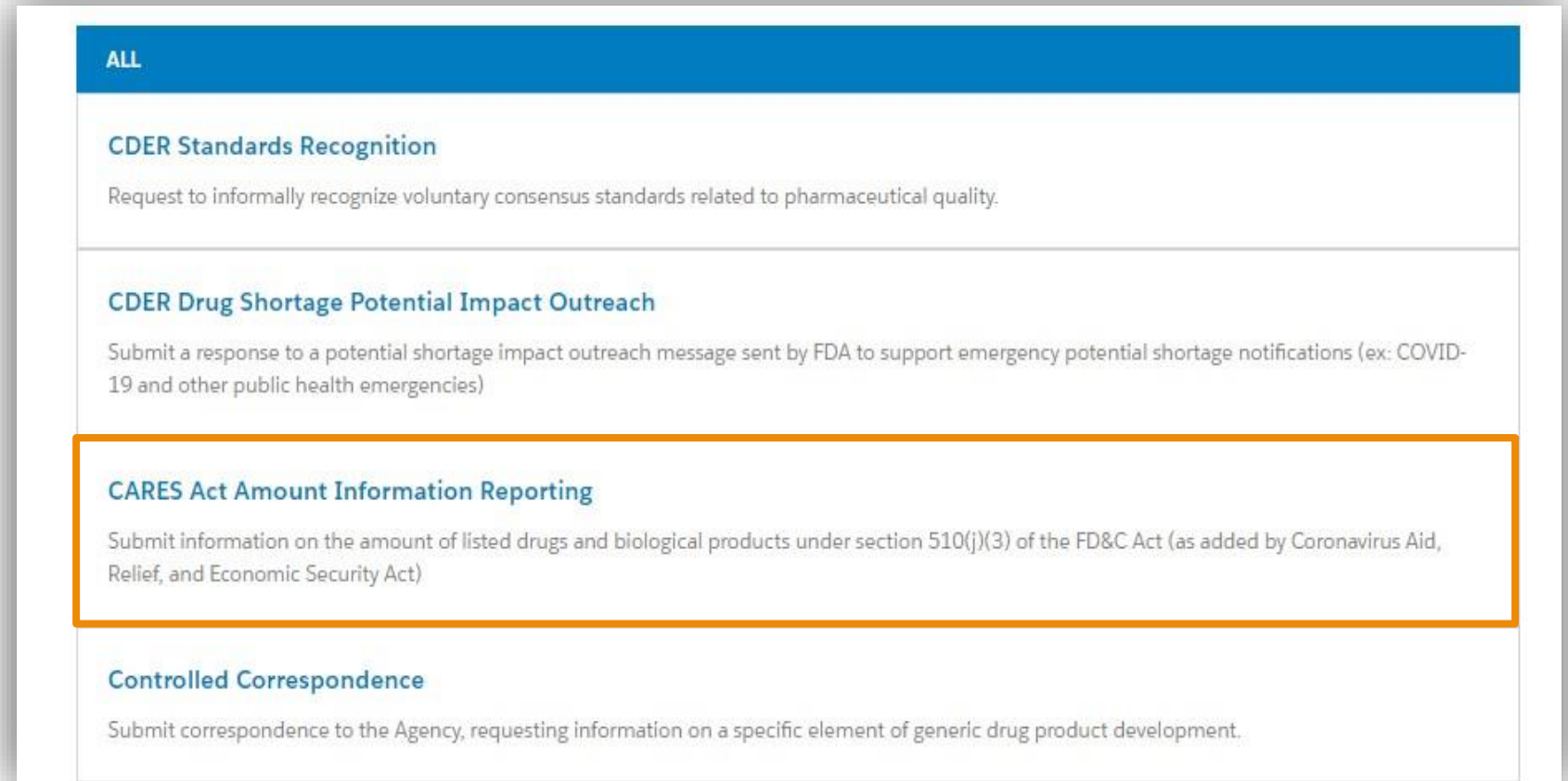
CDER NextGen Portal Homepage

Step 1. First, sign in on the CDER NextGen Portal homepage.
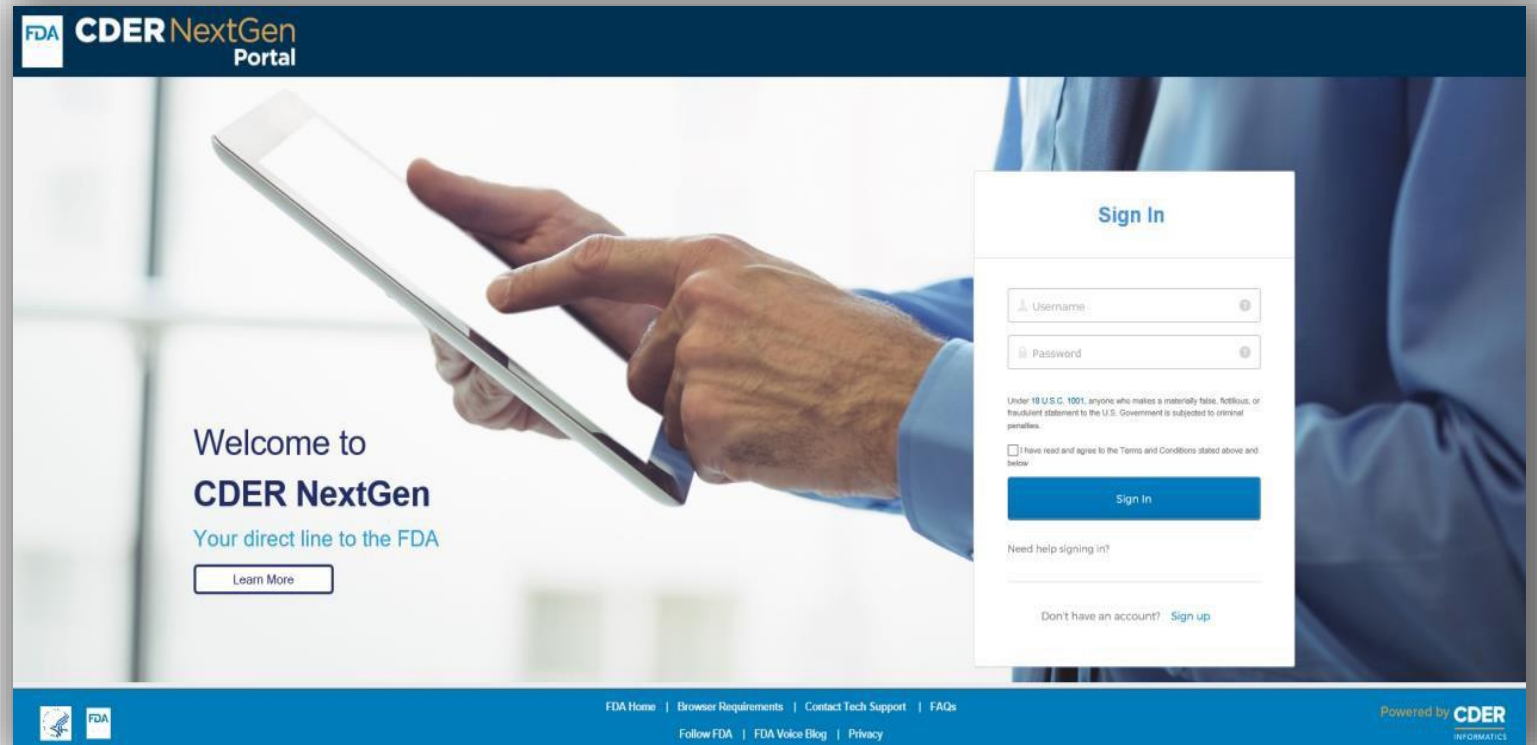
CARES Act Amount Information Reporting

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 Reporting
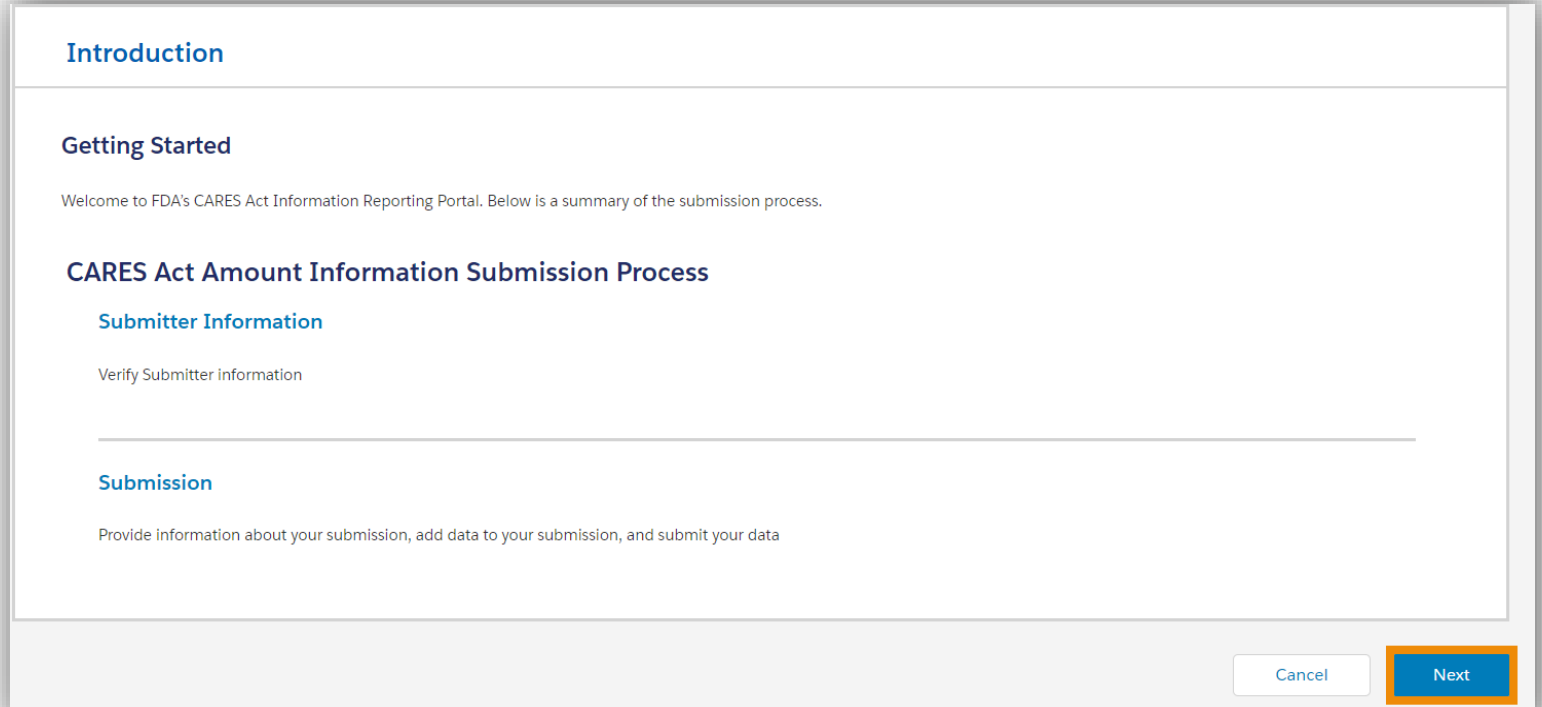
CARES Act Amount Information Report

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

Step 5. Click **Next.**

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

CARES Act Amount Information Reporting

Submitter Information

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

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

Submitter Information

Submitter Information

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

Profile Information

First Name

Last Name

Email Address

Phone Number

Extension

Organization Name

Address Line 1

Address Line 2

City

State / Province

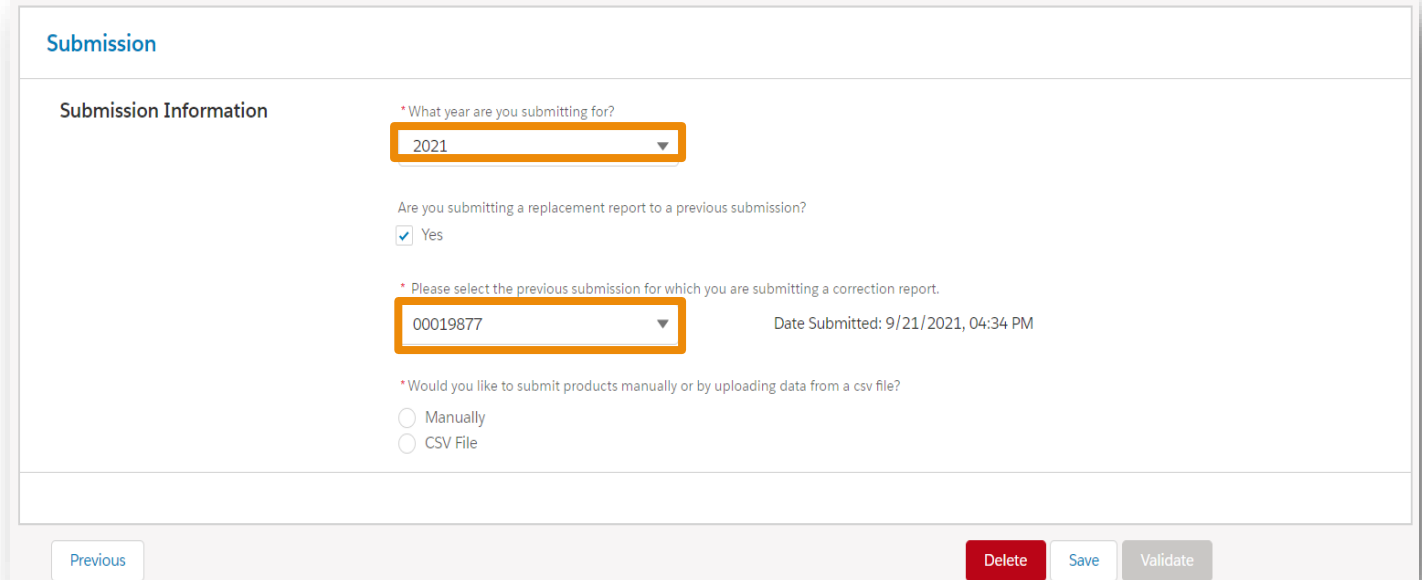Zip Code

Country

Save   Next

Submission

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

Step 9. If you are submitting a replacement report to a previous submission, check **Yes**. Then, select the report ID of the previous submission from the drop-down menu.
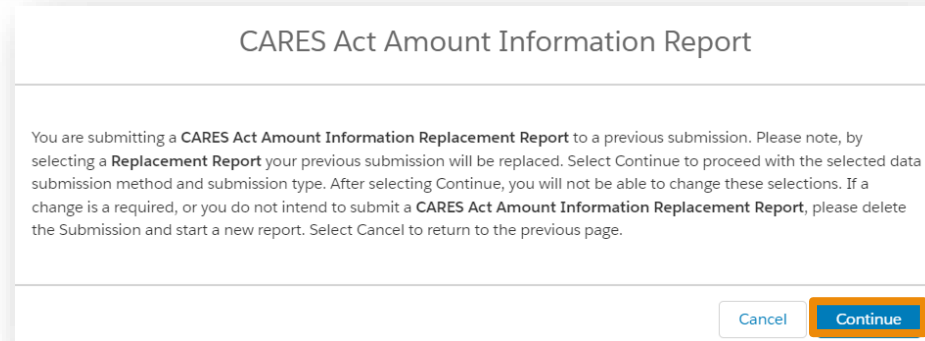
Step 10. Select that you would like to submit product data **Manually**.

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

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Submission

Step 12. To begin to submit product data manually, select **Add Establishment** to enter a DUNS Number.
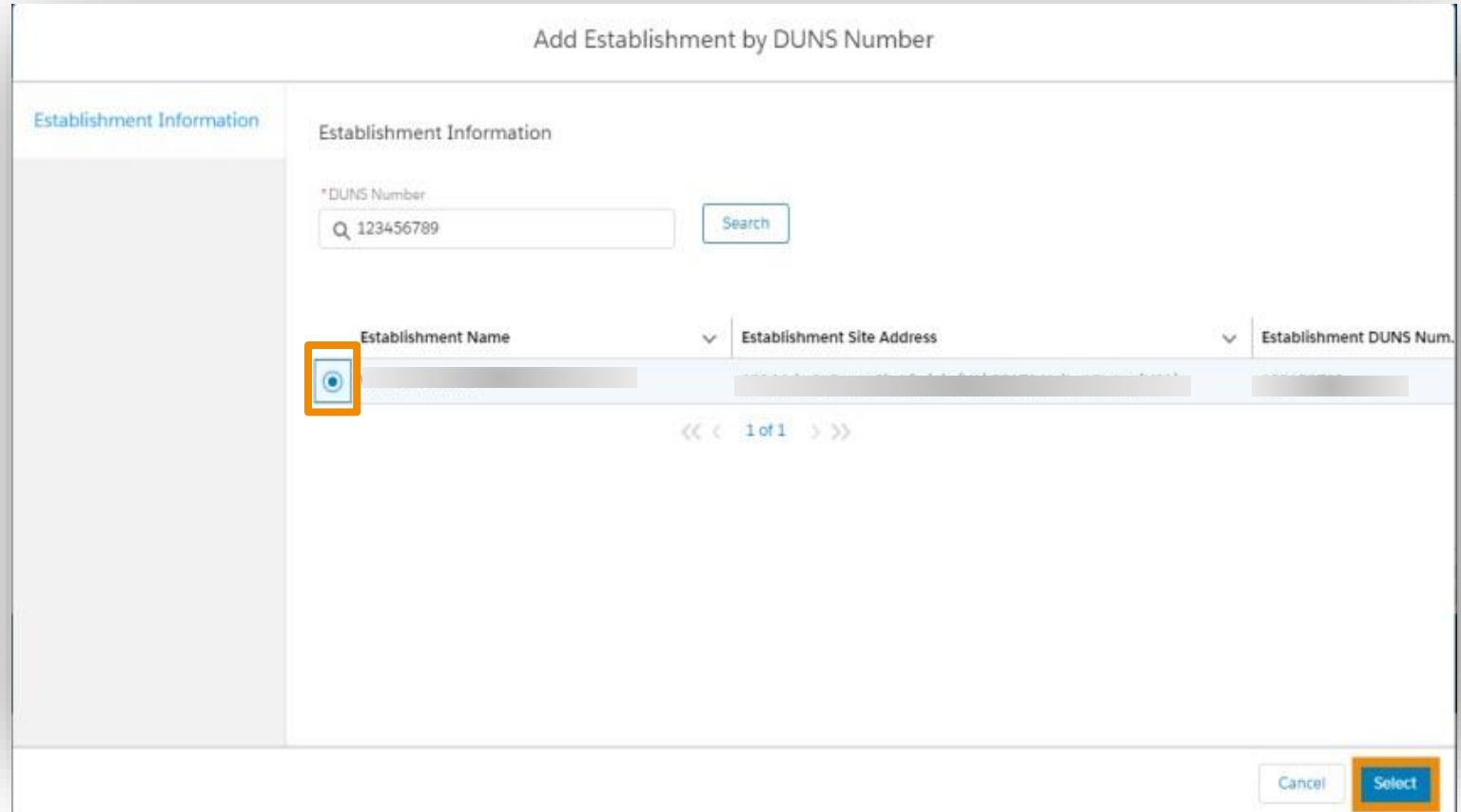
Submission

Step 13. 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.

Submission

Step 14. 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.

CARES Act Amount Information Reporting

Submission

Step 15. When +**Add Manually** is clicked, a screen for manually entering establishment information appears.

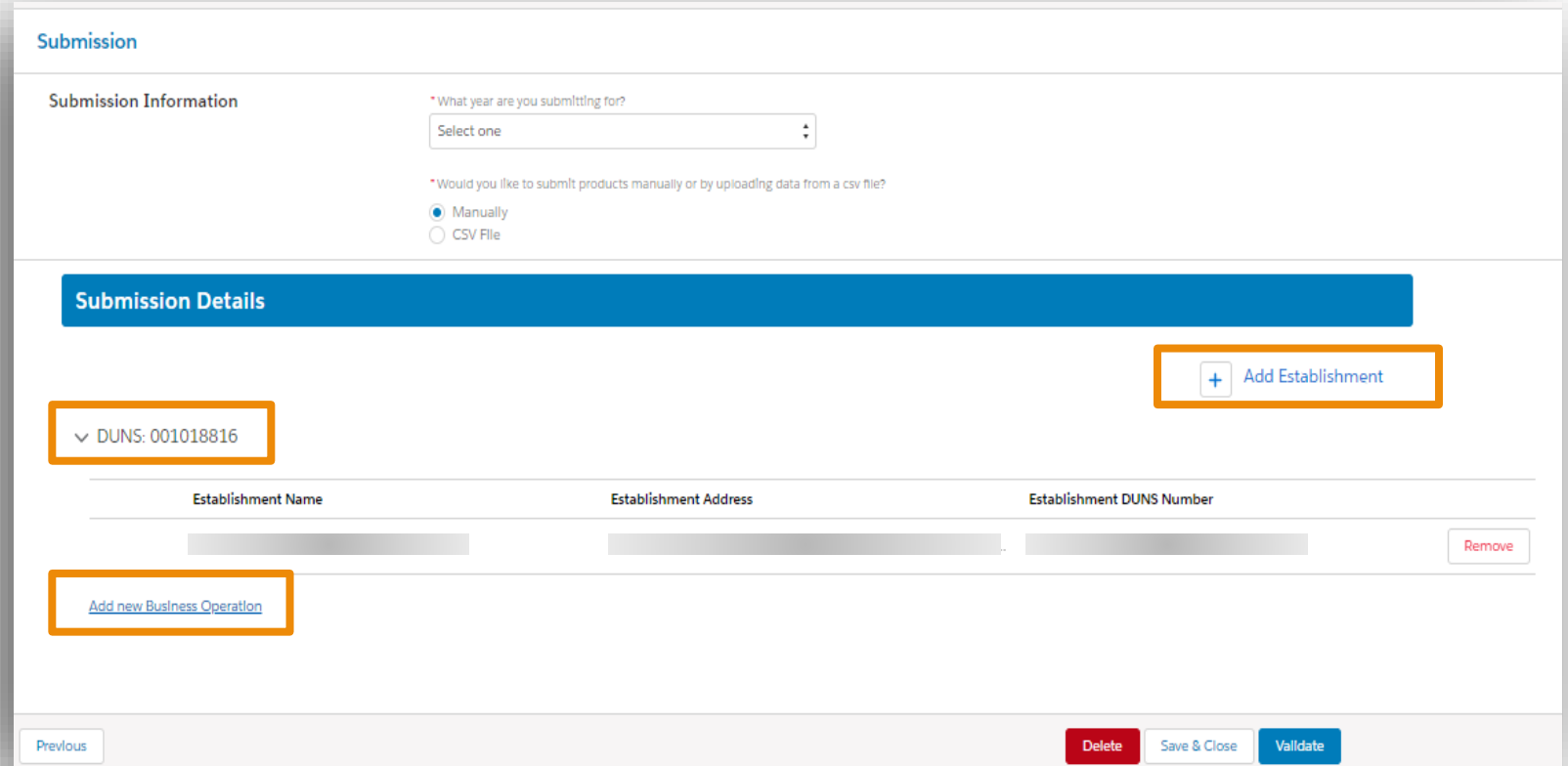Enter the requested information and then click **Save.**

Submission

Step 16. 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.

Submission

Step 17. 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 18. Click **+Add Product** to add a product. Each Business Operation can have one product or multiple products.

Submission Details

+ Add Establishment

⌄ DUNS: 123456789

Establishment Name	Establishment Address	Establishment DUNS Number	
			Remove

* Select the Business Operation.

Select one ⬍   Remove

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

+Add Product

Previ...   Delete   Save   Validate

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Submission

Step 19. 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**.

Submission

Step 20. After clicking on **+Add Manually,** enter the NDC number and then click **Add Product**, which will return you to the **Submission** screen.

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CARES Act Amount Information Reporting

Submission

Step 21. In the Submission screen, enter the requested amount information of the product and click each **pencil** to enter the package types. If a product has single-level packaging, use only the "Outermost Package" fields. Click **+Add Product** and/or **Remove Product** as needed. Select the checkbox under **Market Unknown**, if applicable**.**

Scroll to the right and click the arrow to expand the record so that data can be entered by month.

Submission

Step 22. For each month, enter the amounts released or distributed. Use only whole numbers, no decimals or fractions.

Fields can be left blank for months during which the product was not released 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.

Submission

Step 23. Data will be validated before a report can be submitted.

When all data has been entered, click **Save**. The system requires saving the report at least once before validation.

Step 24. In the confirmation window, click **Save** to stay on the Submission page or click **Save & Close** to go to the landing page.

On the landing page, select the newly created and saved report to return to it.

The "Validated Successfully!" message means that validation occurred, not that all the data was found to be valid.

Submission

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 Amount Information Reporting

Submission

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 or **New Report** to submit a new report.

CARES Act Amount Information Report Submitted to the FDA

Congratulations!

00005218

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

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

Return Home   New Report

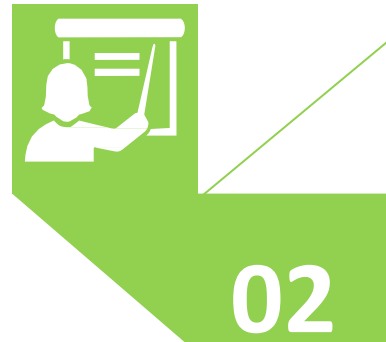For technical support, please contact the CDER platform support team (EDMSupport@fda.hhs.gov).

Technical Support and Resources

CDER NextGen Portal Support & Resources

FDA

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.

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02

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

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Technical Support
For all technical support, contact **CDER Platform Support Team** at EDMSupport@fda.hhs.gov.
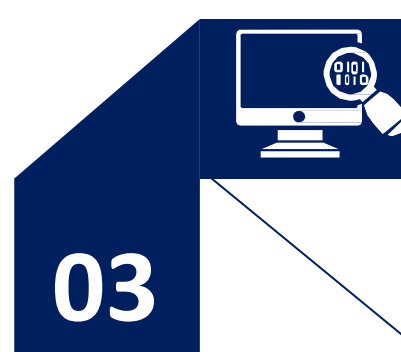
CDER NextGen Portal Video Tutorial
The "**Video Tutorial**" contains **1-4 minute video clips** on how to complete submissions for events on the portal.