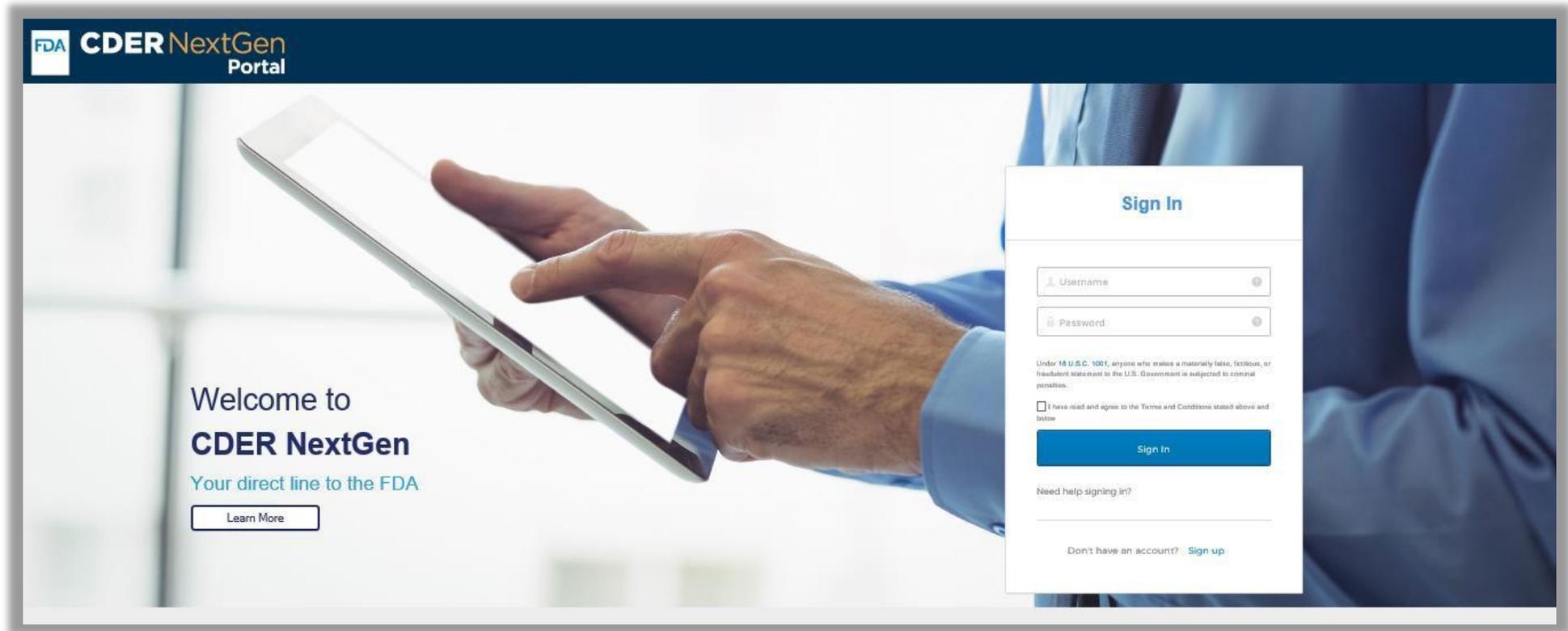


# CARES Act Amount Information Reporting

## Reference Guide



The screenshot shows the CDER NextGen Portal sign-in interface. The header includes the FDA logo and the text "CDER NextGen Portal". The main content area features a background image of a person in a blue suit using a tablet. On the left, there is a welcome message: "Welcome to CDER NextGen Your direct line to the FDA" with a "Learn More" button. On the right, there is a "Sign In" form with fields for "Username" and "Password", a checkbox for terms and conditions, a "Sign In" button, and a "Sign up" link for new users.

**FDA CDER NextGen Portal**

Welcome to  
**CDER NextGen**  
Your direct line to the FDA

[Learn More](#)

**Sign In**

Username

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subjected to criminal penalties.

I have read and agree to the Terms and Conditions stated above and below

**Sign In**

Need help signing in?

Don't have an account? [Sign up](#)

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# CARES Act Amount Information Reporting

## Introduction

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

This guide describes how to use the CDER NextGen Portal to **upload data from a comma-separated values (CSV) file** to create and submit a CARES Act Amount Information report to the FDA. 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 email the EDM Support Team ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)).

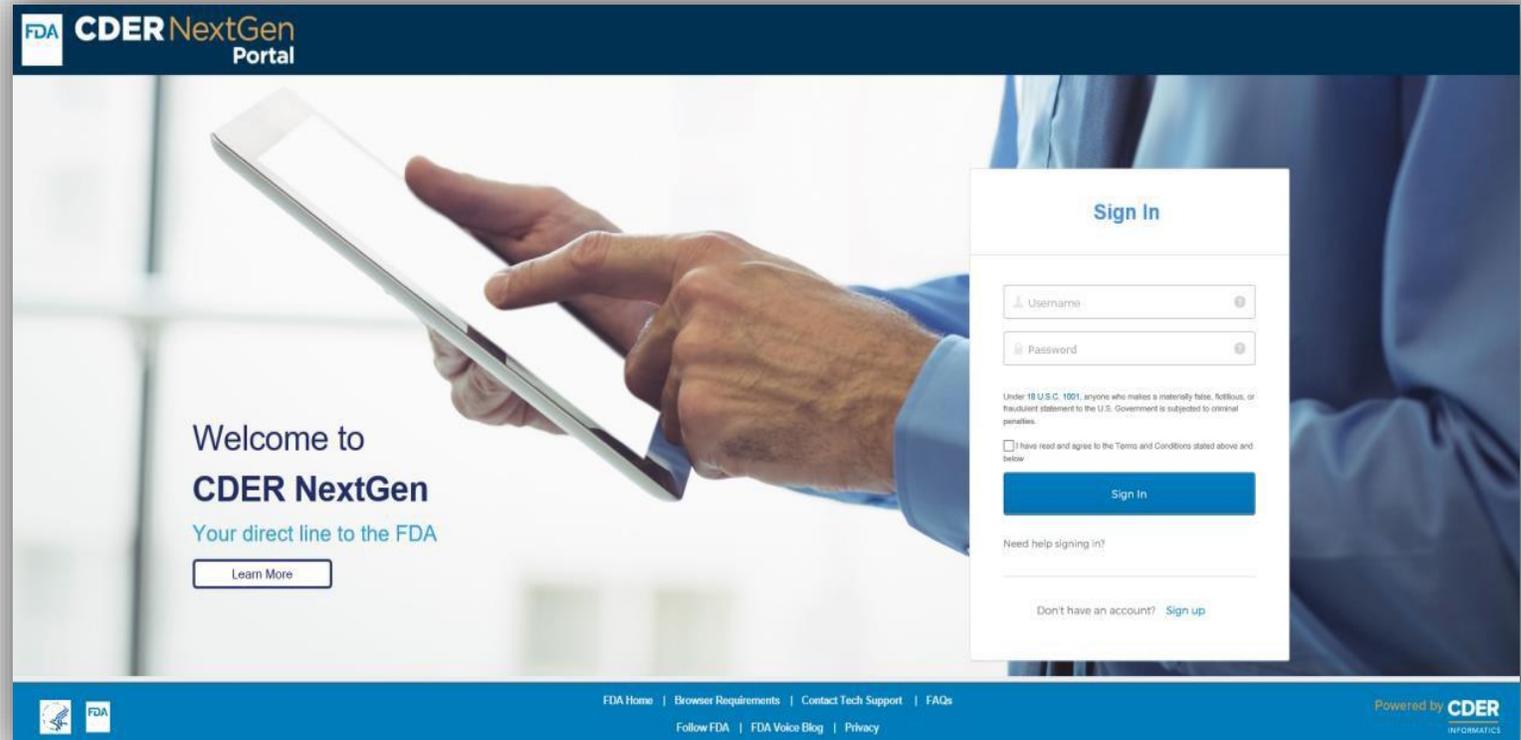
For questions on how to enter or upload data, please email the Drug Amount Reporting Team ([DrugAmountReporting@fda.hhs.gov](mailto:DrugAmountReporting@fda.hhs.gov)).

## CSV File Upload Submission

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

## CDER NextGen Portal Homepage

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



# CARES Act Amount Information Reporting

## 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

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

**CDER NextGen Portal**

**CARES Act Amount Information Reporting**

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

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# CARES Act Amount Information Reporting

## CARES Act Amount Information Report

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

**Step 5.** Click **Next**.

The screenshot shows a web interface for the CARES Act Amount Information Reporting Portal. At the top, there is a header with the word "Introduction" in blue. Below this, 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 sub-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 interface, there are two buttons: "Cancel" and "Next". The "Next" button is highlighted with an orange border, indicating it is the recommended action.

# CARES Act Amount Information Reporting

## Submitter Information

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

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

**Submitter Information**

---

**Submitter Information**

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

Registrant

Authorized Agent

---

**Profile Information**

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

## CSV File Upload Submission - Finished Package Form

# CARES Act Amount Information Reporting

## 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 Information' section of the 'Submission' form. A dropdown menu is open for the question 'What year are you submitting for:'. The menu lists '2021' and '2020'. The '2021' option is currently selected. Below the dropdown, there is a checkbox for 'Are you submitting a replacement report for a previous submission?' which is currently unchecked. At the bottom of the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

The screenshot shows the 'Submission Information' section of the 'Submission' form. The 'What year are you submitting for?' dropdown is now set to '2021'. The checkbox for 'Are you submitting a replacement report for a previous submission?' is now checked. Below this, a new dropdown menu is open for the question 'Please select the previous submission for which you are submitting a replacement report.', showing the report ID '00027055'. The 'Date Submitted' is shown as '3/3/2022, 01:44 PM'. At the bottom of the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

# CARES Act Amount Information Reporting

## 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.

# CARES Act Amount Information Reporting

## 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.

**Submission**

**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

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](#)

**Reference Materials**

Sample Data for CSV Upload  
[CARES SAMPLE Data for Finished Package.xlsx](#)  
 Instructions for Using the CSV Template  
[CARES CSV Template Instructions for Finished Package.pdf](#)  
 Instructions for Creating a Custom CSV File  
[CARES CSV Custom File Instructions for Finished Package.pdf](#)

Or drop files

# 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
	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	10	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

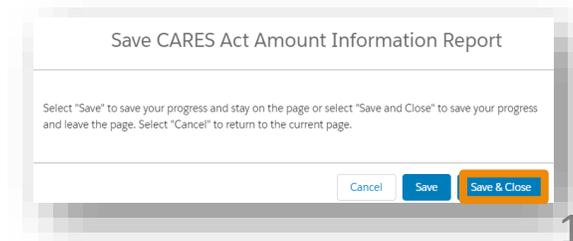
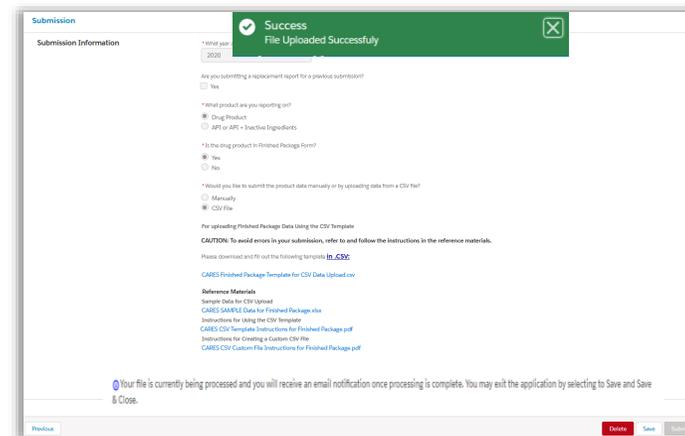
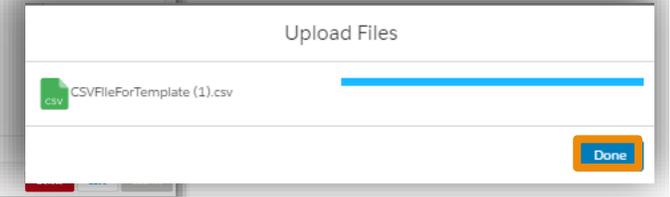
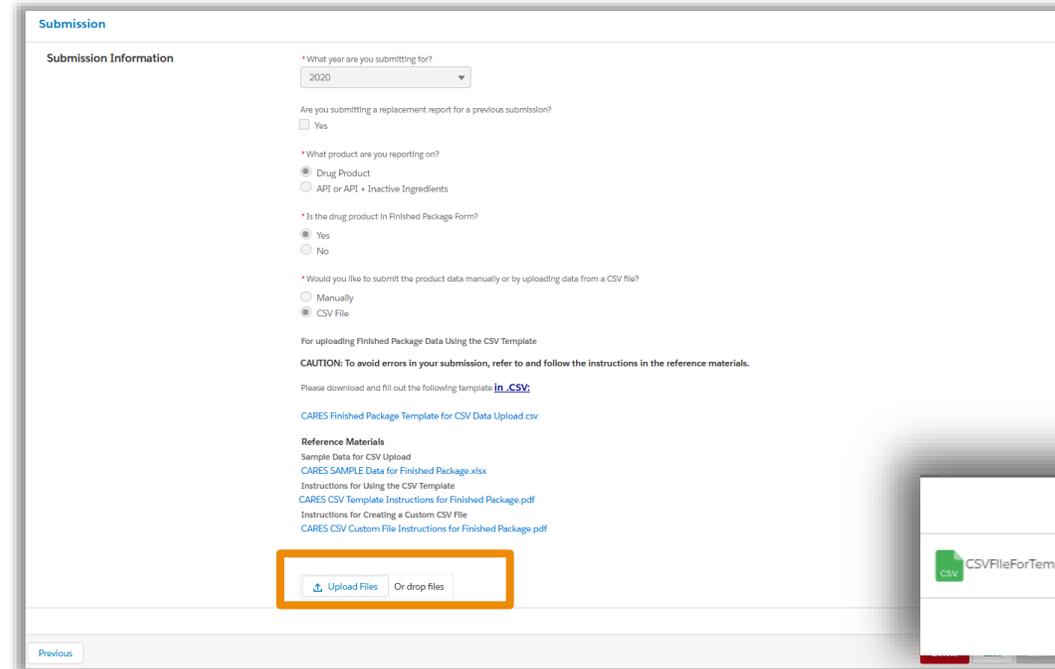
## CSV Submission – Finished Package Form

**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**.



# 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](mailto: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

[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.

# CARES Act Amount Information Reporting

## 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

# 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.

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](mailto: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](mailto:EDMSupport@fda.hhs.gov)).

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**CSV File Upload Submission - Not in Finished 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.

**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 lists '2021' and '2020'. The '2021' option is highlighted in blue. Below the dropdown, there is a checkbox for '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' form with the 'Submission Information' section. The 'What year are you submitting for?' dropdown is set to '2021'. Below this, there is a question 'Are you submitting a replacement report for a previous submission?' with a checked 'Yes' option. Underneath, there is a question 'Please select the previous submission for which you are submitting a replacement report.' with a dropdown menu showing '00027055'. To the right of this dropdown, it says '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.

# 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**.

**Submission**

**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

**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.

# CARES Act Amount Information Reporting

## 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 a web form titled "Submission" with the following sections and elements:

- Submission Information**
  - \* What year are you submitting for? (Dropdown menu: 2021)
  - Are you submitting a replacement report for a previous submission? (Radio buttons: Yes, No)
  - \* What product are you reporting on? (Radio buttons: Drug Product, API or API + Inactive Ingredients)
  - \* Is the drug product in Finished Package Form? (Radio buttons: Yes, No)
  - \* Would you like to submit the product data manually or by uploading data from a CSV file? (Radio buttons: Manually, CSV File)
- 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
- 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
  - Instructions for Creating a Custom CSV File
  - CARES CSV Custom File Instructions for Drug Product not in Finished Package Form.pdf
- Upload Files | Or drop files
- Navigation buttons: Previous, Delete, Save, Submit

# CARES Act Amount Information Reporting

## 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**.

**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

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

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

For uploading Drug Product not in Finished Package 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](#)

**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](#)  
[Instructions for Creating a Custom CSV File](#)  
[CARES CSV Custom File Instructions for Drug Product not in Finished Package Form.pdf](#)

[Previous](#)

**Upload Files**

CSVFileForTemplate (1).csv

**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

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

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

For uploading Drug Product not in Finished Package 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](#)

**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](#)  
[Instructions for Creating a Custom CSV File](#)  
[CARES CSV Custom File Instructions for Drug Product not in Finished Package Form.pdf](#)

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.

[Previous](#)

**Save CARES Act Amount Information Report**

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.

# 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](mailto: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.

# CARES Act Amount Information Reporting

## CSV Submission – Not In 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

# 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.

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](mailto: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](mailto:EDMSupport@fda.hhs.gov)).

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INFORMATICS

## CSV File Upload Submission - API or API + Inactive Ingredients

# CARES Act Amount Information Reporting

## 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 field 'What year are you submitting for?'. The menu lists '2021' and '2020'. The '2021' option is highlighted in blue. Below the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

The screenshot shows the 'Submission' form with the 'Submission Information' section. The field 'What year are you submitting for?' is set to '2021'. Below it, the question 'Are you submitting a replacement report for a previous submission?' is checked 'Yes'. The field 'Please select the previous submission for which you are submitting a replacement report.' is set to '00027055'. The 'Date Submitted' is '3/3/2022, 01:44 PM'. Below the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

# 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**.

# CARES Act Amount Information Reporting

## 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.

The screenshot shows a web form titled "Submission" with a section for "Submission Information".

- What year are you submitting for?** A dropdown menu is set to "2021".
- Are you submitting a replacement report for a previous submission?** A checkbox labeled "Yes" is unchecked.
- What product are you reporting on?** Radio buttons are present for "Drug Product" (unchecked) and "API or API + Inactive Ingredients" (checked).
- Would you like to submit the product data manually or by uploading data from a CSV file?** Radio buttons are present for "Manually" (unchecked) and "CSV File" (checked).

Below these options, there is a "CAUTION" note and a link to a CSV template. Three links are highlighted with orange boxes:

- CARES API or API with Activity Template for CSV Data Upload.csv
- CARES CSV Template Instructions for API or API with Activity.pdf
- CARES CSV Custom File Instructions for API or API with Activity.pdf

At the bottom of the form, there is an "Upload Files" button with a dashed box for dropping files, and a "Previous" button on the left and "Delete", "Save", and "Submit" buttons on the right.

# 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 <sup>U</sup> /mg	140	100
16	222222222	Manufacture	12345-678-91	February	150	mg	USP <sup>U</sup> /mg	80	100
17	222222222	Manufacture	12345-678-91	March	150	mg	USP <sup>U</sup> /mg	80	100
18	222222222	Manufacture	12345-678-91	April	260	mg	USP <sup>U</sup> /mg	120	80
19	222222222	Manufacture	12345-678-91	May	150	mg	USP <sup>U</sup> /mg	120	80
20	222222222	Manufacture	12345-678-91	June	150	mg	USP <sup>U</sup> /mg	80	100
21	222222222	Manufacture	12345-678-91	July	150	mg	USP <sup>U</sup> /mg	100	100
22	222222222	Manufacture	12345-678-91	August	150	mg	USP <sup>U</sup> /mg	100	100
23	222222222	Manufacture	12345-678-91	September	150	mg	USP <sup>U</sup> /mg	80	100
24	222222222	Manufacture	12345-678-91	October	220	mg	USP <sup>U</sup> /mg	100	80
25	222222222	Manufacture	12345-678-91	November	150	mg	USP <sup>U</sup> /mg	100	100
26	222222222	Manufacture	12345-678-91	December	150	mg	USP <sup>U</sup> /mg	100	100
27	222222222	Manufacture	12345-678-91	Annual Total	2130	mg	USP <sup>U</sup> /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”

# CARES Act Amount Information Reporting

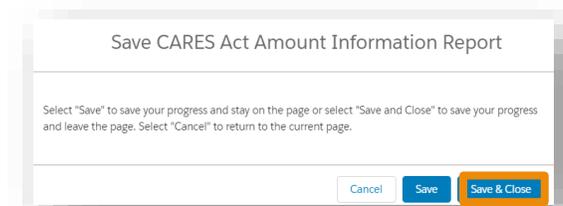
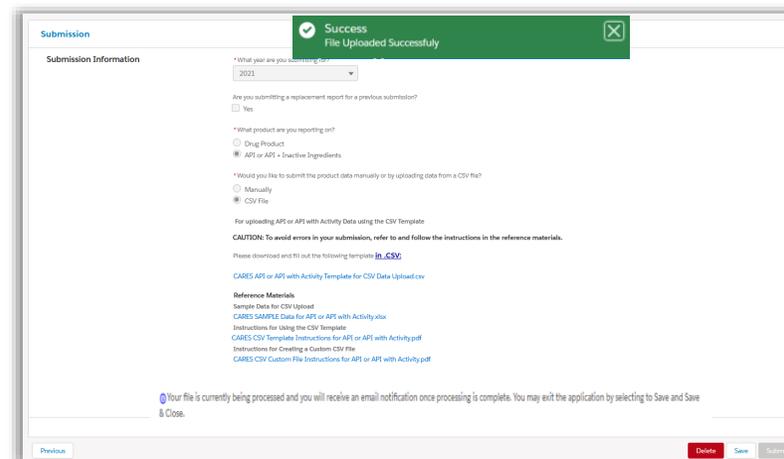
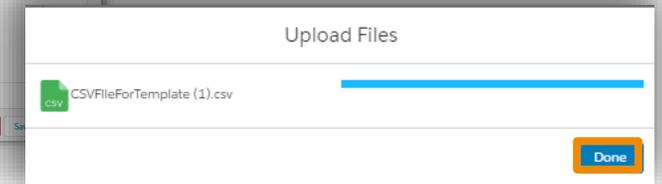
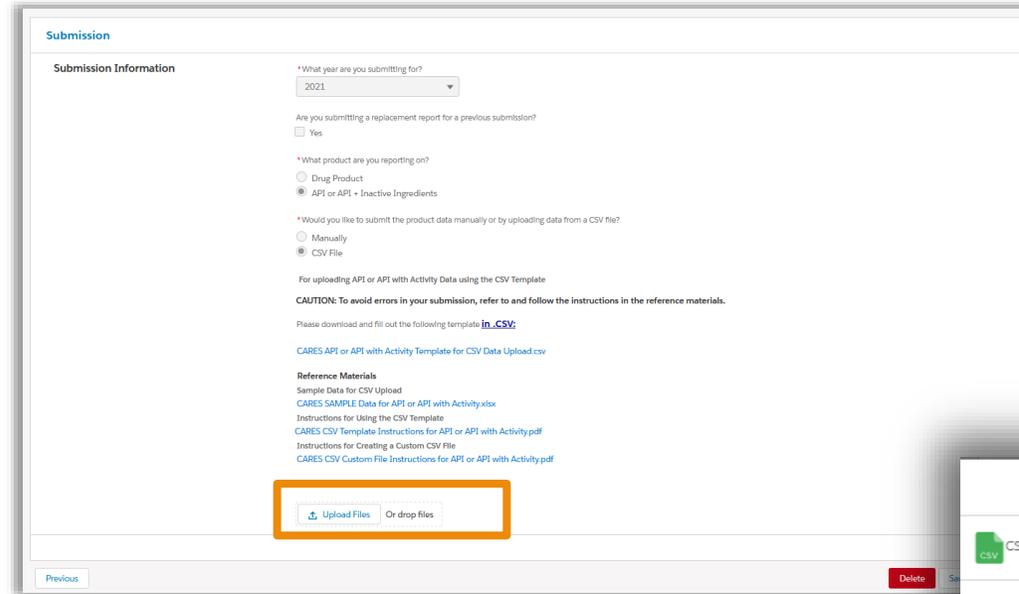
## CSV Submission – API or API + Inactive Ingredients

**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**.



# 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](mailto: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   ▼

[00027123](#)  
Draft  
Last Modified: 03/04/2022, 12:47 PM  
Reporting Year: 2021  
Correction to Report: 00026981

**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

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

# CARES Act Amount Information Reporting

## CSV Submission – API or API + Inactive Ingredients

**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 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.

Complete & Submit CARES ACT Amount  
Information Report

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

Cancel Submit

# CARES Act Amount Information Reporting

## 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](mailto: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](mailto:EDMSupport@fda.hhs.gov)).

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## CSV File Submission Errors

# CARES Act Amount Information Reporting

## Submission Errors

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

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

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

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

The screenshot shows the 'CARES Act Amount Information Reporting' web application. At the top, there is a search bar and a '+ New Report' button. Below this, a list of submissions is shown, with one draft submission highlighted in orange, labeled '0002713'. The main content area displays the 'Submission Information' form for this draft. The form includes several questions with radio button options:

- \* What year are you submitting for? (Dropdown menu 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)
- \* Would you like to submit the product data manually or by uploading data from a CSV file? (Manually, CSV File)

Below the form, there is a 'Reference Materials' section highlighted in orange, containing links to sample data, instructions for using the CSV template, and instructions for creating a custom CSV file. At the bottom of the submission page, a 'Validation Error\_Path 2.csv' message is visible, and a 'View Results' button is highlighted in orange.

# 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

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.**

To correct errors in your submission, 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](mailto: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](mailto: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.

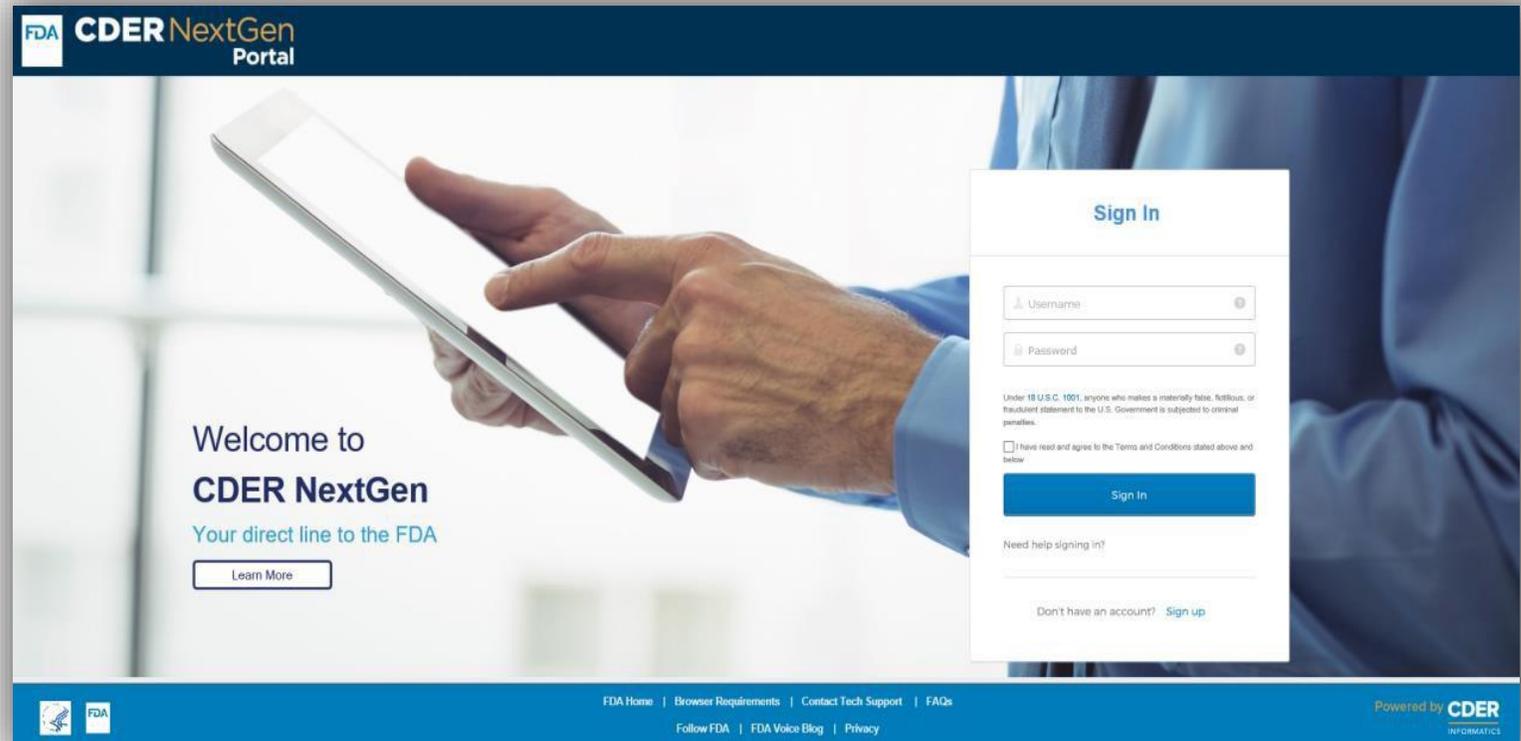
In the case you encounter any issues, please contact EDM Support at [EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)

## 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.



# CARES Act Amount Information Reporting

## 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 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

<a href="#">00020506</a> Draft Last Modified: 11/29/2021, 04:48 PM Reporting Year: 2020 <span style="background-color: #666; color: white; padding: 2px;">✎ Unsubmitted Draft</span>	<a href="#">00020357</a> Draft Last Modified: 11/29/2021, 04:48 PM Reporting Year: 2021 <span style="background-color: #666; color: white; padding: 2px;">✎ Unsubmitted Draft</span>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

CDER NextGen Portal

## CARES Act Amount Information Reporting

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

FDA Home | Browser Requirements | Contact Tech Support | FAQs

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# CARES Act Amount Information Reporting

## CARES Act Amount Information Report

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

**Step 5.** Click **Next**.

The screenshot shows a web interface for the CARES Act Amount Information Reporting Portal. The page is titled "Introduction" and is divided into sections. The "Getting Started" section contains a welcome message and a summary of the submission process. The "CARES Act Amount Information Submission Process" section is currently active and contains two sub-sections: "Submitter Information" and "Submission". The "Submitter Information" sub-section includes the text "Verify Submitter information" and a horizontal line. The "Submission" sub-section includes the text "Provide information about your submission, add data to your submission, and submit your data". At the bottom right of the page, 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

# CARES Act Amount Information Reporting

## Submitter Information

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

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

**Submitter Information**

---

**Submitter Information**

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

Registrant

Authorized Agent

---

**Profile Information**

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

## Manual Submission - Finished Package Form

# CARES Act Amount Information Reporting

## 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 Information' section of the 'Submission' form. A dropdown menu is open for the question 'What year are you submitting for:'. The menu options are 'Select one', '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?' which is currently unchecked. At the bottom of the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

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

# CARES Act Amount Information Reporting

## Manual Submission – Finished Package Form

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

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

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

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

**Submission**

**Submission Information**

\*What year are you submitting for?  
2022

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

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

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

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

**CARES Act Drug Amount Information Report**

You are submitting an **Initial CARES Act Drug Amount Information Report**. Select Continue to proceed with the selected data submission method and submission type. After selecting Continue, you will not be able to change these selections. If a change is required, or you do not intend to submit an **Initial CARES Act Drug Amount Information report**, please delete the Submission and start a new report. Select Cancel to return to the previous page.

Cancel **Continue**

# CARES Act Amount Information Reporting

## Manual Submission – 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?

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

# CARES Act Amount Information Reporting

## Manual Submission – Finished Package Form

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

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

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

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

Add Establishment by DUNS Number

Establishment Information

\*DUNS Number  
Q 123456789 Search

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

<< < 1 of 1 > >>

Cancel Select

# 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, there is a vertical sidebar with the text "Establishment Information". The main content area is also titled "Establishment Information" and contains a search field labeled "\* DUNS Number" with the value "111111111" and a "Search" button. Below the search field, a red error message reads "DUNS Not found. Please search a different DUNS or add manually." Below the error message, a button labeled "+ Add Manually" is highlighted with an orange box. At the bottom right of the form, there 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**.

### Add Establishment by DUNS Number

Establishment Information

Manually Add Establishment Information

\* Establishment DUNS Number  Back to Search

\* Establishment Name

\* Address Line 1  Address Line 2

\* City  \* Country

State/Province  \* Zip Code

Cancel
Save

# CARES Act Amount Information Reporting

## 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.

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

Manually  
 CSV File

---

**Submission Details**

+ Add Establishment

Establishment Name	Establishment Address	Establishment DUNS Number	
[redacted]	[redacted]	[redacted]	Remove
<a href="#">Add New Business Operation</a>			

Previous
Delete Save & Close Validate

# CARES Act Amount Information Reporting

## 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, there is a '+ Add Establishment' button. Below this, a 'DUNS:' label is followed by a blurred input field. A table with three columns is shown: 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. The first row contains blurred data and a 'Remove' button. Below the table, a dropdown menu is open, 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 of the form, there are 'Delete', 'Save', and 'Validate' buttons.

# 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**.

# 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

# CARES Act Amount Information Reporting

## 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"/>	

**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.

# CARES Act Amount Information Reporting

## 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.

NDC	Source NDC	Outermost Package			Innermost Package			Intended to Fulfill 21 CFR 314.81	Select Arrow to Enter Monthly Amounts
		Quantity Manufactured	Quantity Distributed(Non-US)	Package Type	Quantity Manufactured	Quantity Distributed(Non-US)	Package Type		
<input type="checkbox"/>		142.00 <i>Annual Total</i>	40.00 <i>Annual Total</i>		30 <i>Annual Total</i>	95 <i>Annual Total</i>		<input type="checkbox"/>	▲
January		12.00	10.00		2	10			
February		15.00	15.00		16	17			
March		115.00	15.00		12	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

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.

Previous Cancel **Submit**

Delete Save **Submit**

# CARES Act Amount Information Reporting

## 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.

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](mailto: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](mailto:EDMSupport@fda.hhs.gov)).

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**Manual Submission - Not in Finished Package Form**

# CARES Act Amount Information Reporting

## 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.

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?' which is currently unchecked. At the bottom of the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

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

**Submission**

**Submission Information**

- \* What year are you submitting for?  
2022
- Are you submitting a replacement report for a previous submission?  
 Yes
- \* What product are you reporting on?  
 Drug Product  
 API or API + Inactive Ingredients
- \* Is the drug product in Finished Package Form?  
 Yes  
 No
- \* Would you like to submit the product data manually or by uploading data from a CSV file?  
 Manually  
 CSV File

**CARES Act Drug Amount Information Report**

You are submitting an **Initial CARES Act Drug Amount Information Report**. Select Continue to proceed with the selected data submission method and submission type. After selecting Continue, you will not be able to change these selections. If a change is required, or you do not intend to submit an **Initial CARES Act Drug Amount Information report**, please delete the Submission and start a new report. Select Cancel to return to the previous page.

Cancel **Continue**

# 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?

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

# CARES Act Amount Information Reporting

## 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.

The screenshot shows a web form titled "Add Establishment by DUNS Number". The form is divided into two main sections. The top section, "Establishment Information", contains a search field labeled "\*DUNS Number" with the value "123456789" and a "Search" button. Below this is a table with three columns: "Establishment Name", "Establishment Site Address", and "Establishment DUNS Num.". The table contains one row of data, and a radio button in the first column of this row is selected and highlighted with an orange box. Below the table are navigation arrows and the text "1 of 1". At the bottom right of the form are "Cancel" and "Select" buttons, with the "Select" button highlighted in orange.

# 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 displays a web form titled "Add Establishment by DUNS Number". On the left, there is a vertical sidebar with the heading "Establishment Information". The main content area also has a heading "Establishment Information" and contains a search field labeled "\* DUNS Number" with the value "111111111" and a "Search" button. Below the search field, a red error message reads "DUNS Not found. Please search a different DUNS or add manually." A "+ Add Manually" button is positioned below the error message. At the bottom right of the form, there are "Cancel" and "Select" buttons. Orange boxes highlight the "Search" button, the "+ Add Manually" button, and the error message.

# CARES Act Amount Information Reporting

## Manual Submission – Not in Finished Package Form

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

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

Add Establishment by DUNS Number

---

Establishment Information

Manually Add Establishment Information

\* Establishment DUNS Number

Back to Search

\* Establishment Name

\* Address Line 1
Address Line 2

\* City
\* Country

--None--

State/Province
\* Zip Code

Cancel

Save

# CARES Act Amount Information Reporting

## 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
<span style="border: 1px solid orange; padding: 2px 5px;"><a href="#">Add New Business Operation</a></span>			

Previous
Delete
Save & Close
Validate

# CARES Act Amount Information Reporting

## 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 displays the 'Submission Details' interface. At the top right, there is a '+ Add Establishment' button. Below this is a table with columns for 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. A 'Remove' button is located to the right of the first row. Below the table, a dropdown menu is open, showing options: 'Select one', 'Manufacture', 'Repack', 'Relabel', 'Transfill', and 'Positron Emission Tomography Drug Production'. A 'Remove' button is next to the dropdown. At the bottom right, there is a '+Add Product' button. At the very bottom, there are 'Delete', 'Save', and 'Validate' buttons.

# 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**.

# 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.

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

# CARES Act Amount Information Reporting

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

**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.

# CARES Act Amount Information Reporting

## Manual Submission – Not in Finished Package Form

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

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

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

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

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  
 No

\*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

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**

Complete & Submit CARES ACT Amount Information Report

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

Cancel **Submit**

# CARES Act Amount Information Reporting

## 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.

CARES Act Drug Amount Information Report Submitted to the FDA

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**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](mailto: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](mailto:EDMSupport@fda.hhs.gov)).

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## Manual Submission - API or API + Inactive Ingredients

# CARES Act Amount Information Reporting

## 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.

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 lists '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?' which is currently unchecked. At the bottom of the form, there are buttons for 'Previous', 'Delete', 'Save', and 'Validate'.

The screenshot shows the 'Submission' form with the 'Submission Information' section. The dropdown menu for 'What year are you submitting for:' is now closed and shows '2021'. The checkbox for 'Are you submitting a replacement report for a previous submission?' is now checked. Below this, there is a dropdown menu for 'Please select the previous submission for which you are submitting a replacement report.' which shows '00027055'. To the right of this dropdown, the text 'Date Submitted: 3/3/2022, 01:44 PM' is visible. At the bottom of the form, there are buttons for 'Previous', 'Delete', 'Save', and '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 a web form titled "Submission" with a "Submission Information" section. The form includes the following elements:

- A dropdown menu for "What year are you submitting for?" with "2021" selected.
- A checkbox for "Are you submitting a replacement report for a previous submission?" with "Yes" selected.
- A radio button selection for "What product are you reporting on?" with "API or API + Inactive Ingredients" selected.
- A radio button selection for "Would you like to submit the product data manually or by uploading data from a CSV file?" with "Manually" selected.
- An "Add Establishment" button with a plus sign icon.
- Navigation buttons at the bottom: "Previous", "Delete", "Save", and "Validate".

The screenshot shows a confirmation screen titled "CARES Act Drug Amount Information Report". The text on the screen 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 of the screen, there are two buttons: "Cancel" and "Continue". The "Continue" button is highlighted with an orange border.

# 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?

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](#)

# CARES Act Amount Information Reporting

## 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.

The screenshot shows a web interface titled "Add Establishment by DUNS Number". It features a search bar with the text "123456789" and a "Search" button. Below the search bar is a table with columns for "Establishment Name", "Establishment Site Address", and "Establishment DUNS Num.". A single row of data is displayed, and a radio button in the left column of this row is selected and highlighted with an orange box. At the bottom right of the interface, there are "Cancel" and "Select" buttons, with the "Select" button also highlighted with an orange box.

# 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 displays a web interface titled "Add Establishment by DUNS Number". On the left, there is a vertical sidebar with the heading "Establishment Information". The main content area also has the heading "Establishment Information" and contains a search form. The form includes a text input field labeled "\* DUNS Number" with the value "111111111" and a "Search" button. Below the search field, a red error message reads "DUNS Not found. Please search a different DUNS or add manually." Below the error message is a button labeled "+ Add Manually". At the bottom right of the interface, there are "Cancel" and "Select" buttons. Orange boxes highlight the "Search" button, the "+ Add Manually" button, and the error message.

# 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, there is a sidebar with the text "Establishment Information". The main content area is titled "Manually Add Establishment Information" and contains several input fields and buttons:

- \* Establishment DUNS Number: A text input field with a "Back to Search" button to its right.
- \* Establishment Name: A text input field.
- \* Address Line 1: A text input field.
- Address Line 2: A text input field.
- \* City: A text input field.
- \* Country: A dropdown menu with "--None--" selected.
- State/Province: A text input field.
- \* Zip Code: A text input field.

At the bottom right of the form, there are two buttons: "Cancel" and "Save". The "Save" button is highlighted with an orange border.

# CARES Act Amount Information Reporting

## 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: [blurred]

Establishment Name	Establishment Address	Establishment DUNS Number	
[blurred]	[blurred]	[blurred]	Remove
<span style="border: 1px solid orange; padding: 2px 5px;"><a href="#">Add New Business Operation</a></span>			

Previous
Delete
Save & Close
Validate

# CARES Act Amount Information Reporting

## 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' interface. At the top right, there is a '+ Add Establishment' button. Below this, a dropdown menu is open for 'DUNS: 123456789'. The table below has three columns: 'Establishment Name', 'Establishment Address', and 'Establishment DUNS Number'. A 'Remove' button is highlighted in orange next to the first row. Below the table, a dropdown menu for 'Business Operation' is open, showing options: 'Select one', '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 highlighted in orange. At the bottom right, there are 'Delete', 'Save', and 'Validate' buttons. A 'Previous' button is partially visible on the left.

# 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**.

# 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

# CARES Act Amount Information Reporting

## 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>	▼

**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.

# CARES Act Amount Information Reporting

## 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

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 Amount Information Reporting

## 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.

CARES Act Drug Amount Information Report Submitted to the FDA

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**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](mailto: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](mailto:EDMSupport@fda.hhs.gov)).

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## Technical Support and Resources

# CDER NextGen Portal Support & Resources

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

## CDER NextGen Portal Announcements

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



## Learn More Information

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

## Technical Support

For all technical support, contact **CDER Platform Support Team** at [EDMSupport@fda.hhs.gov](mailto: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.