



# How to Use the 506J Notification Spreadsheet Template

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Center for Devices and Radiological Health  
August 2021

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## Introduction

The purpose of this document is to provide step-by-step instructions on the use of the 506J Spreadsheet Template for the purposes of submitting multiple notifications of interruptions or permanent discontinuances of certain devices under section 506J of the Food, Drug, and Cosmetic Act (FD&C Act). This document provides information about the fields/cells in which information should be entered and troubleshooting potential issues. Please note that this Spreadsheet Template is one method for submission of a batch of 506J Notifications. While not all of the information in the Spreadsheet Template is required to submit a 506J notification, information that is marked with an asterisk (\*) in the Spreadsheet Template must be provided to the agency for it to be considered complete.

## Instructions

### **Instructions: Using This Template to Submit a Large Number of FEI-Product Code Combinations**

Under Section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act), manufacturers of the following devices must notify the FDA of an interruption or permanent discontinuance in manufacturing.

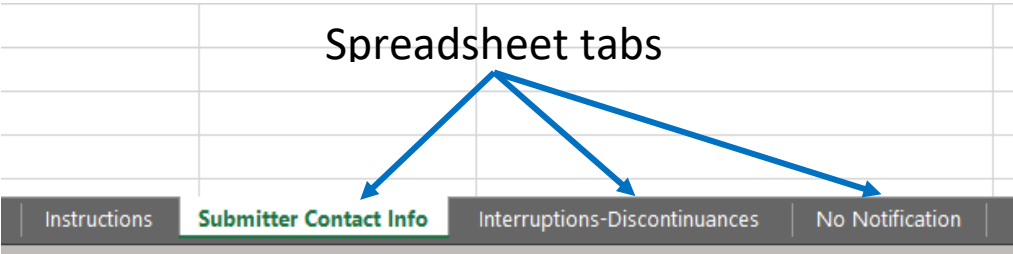
-Devices that are critical to public health during a public health emergency, including those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery.

-Devices for which the FDA determines information on potential meaningful supply disruptions is needed during a public health emergency.

### **Steps for Completing and Submitting This Spreadsheet:**

- Fully read the information on the “Instructions” tab

To input information in the template, use the tabs at the bottom of the spreadsheet.



### Submitter Contact Info

<b>Submitter Contact Info (* asterisk indicates information necessary for completeness)</b>				
*Submitter First Name	*Submitter Last Name	*Submitter E-Mail	*Submitter Phone Number	*Submitter Company Name
Jane (Example)	Doe	<a href="mailto:Jane.Doe@medicaldevices.inc">Jane.Doe@medicaldevices.inc</a>	+1 (123) 456-7890	Medical Devices, Inc. (Example)

- Submitter First Name – Enter submitter’s first name
- Submitter Last Name – Enter the submitter’s last name
- Submitter E-Mail – Enter the submitter’s email address
- Submitter Phone Number – Enter the submitter’s phone number
- Submitter Company Name – Enter the submitter’s manufacturer or company name

### Interruptions-Discontinuances

#### Medical Device Details

<b>Medical Device Details (* asterisk indicates information necessary for completeness)</b>											
*Notification Type	*FEI Number	*Product Code	Secondary or Subsequent Product Codes	Marketing Submission Holder	Marketing Submission Number	Device Trade Name	Unique Device Identifier (UDI)	Model/Catalog Number	SKU Number	Has the Interruption been resolved?	Is this a pediatric device or does it include pediatric sizes? (Yes/No)

- Notification Type – Type in the cell or select from the drop-down menu “Initial” or “Update” by selecting the drop-down arrow to the right of the field. “Initial” indicates that the submission is the FIRST from the Manufacturer about the specific devices; “Update” indicates that the Manufacturer has followed-up about a previous notification regarding the specific devices
- FEI number – Type in the cell or choose your Firm’s Establishment Identifier (FEI) number from the drop-down list by selecting the arrow to the right of the field

- Product Code – Type in the cell or choose the product code assigned to the device from the drop-down list by selecting the drop-down arrow to the right of the field
- Secondary or Subsequent Product Codes – If your device has been assigned multiple product codes, you can type the additional product codes assigned to the device here separated by a semicolon (;)
- Marketing Submission Holder – Enter the name of the holder of the marketing submission, in the case that the original submission has been transferred or sold
- Submission Number – Enter the submission number associated with the device, if applicable
- Device Trade Name – Enter the device trade name
- UDI – Enter the Unique Device Identifier (UDI). If you are entering multiple UDI, separate them with a semicolon (;)
- Model/Catalog Number – Enter the model or catalog number, if applicable. If you are entering multiple Model/Catalog numbers, separate them with a semicolon (;)
- SKU Number – Enter the Stock Keeping Unit (SKU) number, if applicable. If you are entering multiple SKU, separate them with a semicolon (;)
- Has the interruption been Resolved – For an interruption that has since been resolved, or if there is a change in status of a previously communicated discontinuance, type in the cell or choose “Yes” or “No” from the drop-down list by selecting the arrow to the right of the field. Blanks are considered “No”
- Is this a pediatric device or does it include pediatric sizes – Type in the cell or choose “Yes” or “No” from the drop-down list by selecting the arrow to the right of the field. Blanks are considered “No”

## Reasons for Discontinuance or Interruption

*Reasons for discontinuance or interruption (choose at least one of the reasons below)															
Requirements related to complying with good manufacturing practices (GMP) (Yes/No)	Regulatory delay (Yes/No)	Order to divert devices from other U.S. government entities (Yes/No)	Shortage or discontinuance of a component, part or accessory of the device (including specific supplies from diagnostic and serological specimen collection kits or reagents for extraction or PCR amplification) (Yes/No)	Discontinuance of the manufacture of the device (Yes/No)	Delay in shipping of the device (e.g. due to export or import challenges, or transportation challenges) (Yes/No)	Delay in sterilization of the device (Yes/No)	Increase in demand for the device (Yes/No)	Facility closure (Yes/No)	Device is currently in shortage (i.e., demand currently exceeds supply) (Yes/No)	Device is expected to be in shortage (i.e., projected demand exceeds projected supply) (Yes/No)	Device on backorder (i.e., temporarily out of stock) (Yes/No)	Device on allocation (i.e., limiting the quantity distributed to customers to extend the life of the existing supply) (Yes/No)	Device on export restriction (Yes/No)	Longer than usual delay from order to delivery (Yes/No)	Other Reasons not listed, description below

- Identify the reason for the discontinuance or interruption of your device. Type in the cell or choose “Yes” or “No” from the drop-down list by selecting the arrow to the right of the field. Blanks are considered “No”. If the reason for your discontinuance or interruption is not described by one of the reasons identified, use the “Other Reasons” field to type the reason for your discontinuance or interruption. This is a required field and a reason must be identified for the discontinuance or interruption either by indicating “Yes” in one of the fields or typing a reason in the “Other Reasons” field. Multiple reasons can be selected.

## Duration

Duration		
Estimated Duration Start Date	*Estimated Duration End Date	*Estimated Duration (Other)

- Estimated Duration Start Date – Enter the estimated duration start date, if the exact date of the month cannot be identified, enter the first of the month
- Estimated Duration End – Enter the estimated duration end date, if the exact date of the month cannot be identified, enter the end of the month. If a date cannot be identified and the end can be described in another way (for example, end of pandemic), use the “Other” field to type when the discontinuance or interruption will be resolved or if the date is unknown. An end date should be estimated by either entering a date or typing a duration in the “Other” field

## Impact on Manufacture or Distribution of your Devices

Impact on manufacture or distribution of your devices							
Has the COVID-19 pandemic further affected your ability to manufacture or distribute your device(s)? (Yes/No)	Labor shortages (Yes/No)	Lack of protective equipment for employees (Yes/No)	Shortage or delay in raw material supply (Yes/No)	Temporary plant closure (Yes/No)	Shipping or transportation challenges (Yes/No)	Export or import challenges (Yes/No)	Other Issues or Additional Details of Issues

- Answer the identified questions to explain the impact of the discontinuance or interruption on the manufacture or distribution of your devices. Type in the cell or choose “Yes” or “No” from the drop-down list by selecting the arrow to the right of the field. Blanks are considered “No”. If additional issues have occurred, use the “Other Issues” field to explain.

### Critical Suppliers

Critical Suppliers	
Are critical Suppliers Potentially Affected by COVID-19? (Yes/No)	Critical Supplier Information Provided

- Type in the cell or choose “Yes” or “No” from the drop-down list by selecting the arrow to the right of the field. Blanks are considered “No”. Use the “Supplier Information” field to identify and critical suppliers that might affect your device

### Additional Information, Including Possible Mitigations

Additional Information, including possible mitigations					
Is the device manufactured on multiple lines? (Yes/No)	Is the device manufactured at multiple facilities? (Yes/No)	Have you provided, or will you provide, public information for your stakeholders and patients regarding this actual or potential shortage? (Yes/No)	Proposal to expedite availability of device or for FDA to help prevent or mitigate a supply disruption.	Do you have shortage mitigation plans in place that could be shared with the FDA? (Yes/No)	If yes, describe your shortage mitigation plan

- Type in the cell or choose “Yes” or “No” from the drop-down list by selecting the arrow to the right of the field. Blanks are considered “No”. If you have a proposal to expedite the availability of device type it in the “Proposal to expedite availability” field. If you have a shortage mitigation plan, type it in the “Describe your shortage mitigation” field.

## Production Capacity and Market Share

Production Capacity and Market Share						
Estimated US market share (%).	Average Historic Production Volume [# / month].	Average Historic US distribution [# / month].	Current Production Volume [# / month].	Current US distribution [# / month].	Maximum Production Volume [# / month].	How much device inventory do you have? [Enter in eaches (individual units)].

- Estimated US Market Share – Enter an estimate of your facility’s percent US market share for the specific device. This is the percentage of the market share at the identified FEI produces when compared to other facilities and manufacturers
- Average Historic Production Volume – Enter your average historic production volume per month
- Average Historic US distribution – Enter your average historic US distribution per month
- Current Production Volume – Enter your current production volume per month
- Current US distribution – Enter your current US distribution per month
- Maximum Production Volume – Enter your maximum production volume per month
- Current Device Inventory – Enter your current device inventory in individual units (eaches)

## No Notification

Please note that if you are currently not experiencing an interruption or permanent discontinuance in manufacturing that requires the submission of a 506J notification, you may also complete the Voluntary Online Notification form on the online webform. Select “Voluntarily Indicate No Current Interruption or Permanent Discontinuance” on the webform. If you have a large volume to voluntarily report, you may use the spreadsheet template.

## Identifier Information

Identifier Information		
*FEI Number	*Product Code	Secondary or Subsequent Product Codes

- FEI number – Type in the cell or choose your Firm’s Establishment Identifier (FEI) number from the drop-down list by selecting the arrow to the right of the field

- Product Code – Type in the cell or choose the product code assigned to the device from the drop-down list by selecting the drop-down arrow to the right of the field
- Secondary/Subsequent Product Codes – If your device has been assigned multiple product codes, you can type the additional product codes assigned to the device here separated by a semicolon (;)

Voluntarily Indicate Currently No Notification under 506J

<b>*Voluntarily indicate currently no notification under 506J</b>		
<b>No interruption or permanent discontinuance in manufacturing of product (Yes/No)</b>	<b>Other reasons not listed (Yes/No)</b>	<b>Other Reasons not listed, description below</b>
Yes	Yes	Example text: add any other reasons why a notification is not needed.

- Type in the cell or choose “Yes” or “No” from the drop-down list by selecting the arrow to the right of the field. Blanks are considered “No”. If additional reasons are needed, use the “Other Reasons” field to explain.





# How to Use the FDA 506J Notification Webform

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Center for Devices and Radiological Health  
August 2021

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## Introduction

The purpose of this document is to provide step-by-step instructions on how to input information into the 506J Notification Webform for the purposes of submitting a notification of interruption or permanent discontinuance of certain devices under section 506J of the Food, Drug, and Cosmetic Act (FD&C Act). This document provides information about the fields in which information should be entered, troubleshooting issues, and potential error messages which may be displayed. Please note that the 506J Notification Webform is one method to submit a 506J notification to FDA. While not all of the information in the webform is required to submit a 506J notification, information that is marked with an asterisk (\*) must be provided in the webform for it to be transmitted to the agency.

Please use Chrome, Microsoft Edge, or Firefox to fill out the webform. The webform is incompatible Internet Explorer.

## Notification Information

### Notification Information

<p>* Submitter First Name</p> <input type="text"/>	<p>* Submitter Last Name</p> <input type="text"/>
<p>* Submitter Email Address</p> <input type="text"/>	<p>* Submitter Phone</p> <input type="text"/>
<p>* Submitter Company Name</p> <input style="height: 50px;" type="text"/>	

- Submitter First Name – Type your first name into this field (character limit: 25)
- Submitter Last Name – Type your last name into this field (character limit: 25)
- Submitter Email Address – Type your email address into this field (character limit: 80)
- Submitter Phone – Type phone number into this field (character limit: 40)
- Submitter Company Name – Type full Owner/Operator name into this field. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit 255)

# Identifier Information

## Identifier Information

\* Notification Type  
 --None--

\* FEI Number (Begin typing the number and select it from the dropdown list)  
 FEI Number

\* Product Code (Begin typing the product code and select it from the dropdown list)  
 Product Code

If device is associated with more than one product code, select the 'Add Secondary/Subsequent Product Code' button below to add each product code.  
 Add Secondary Product Code

Marketing Submission Holder

Marketing Submission Number (if more than one, use semicolons to separate the numbers)

Device Trade Name (if more than one, use semicolons to separate the names)

Unique Device Identifier (UDI) (if more than one, use semicolons to separate each identifier)

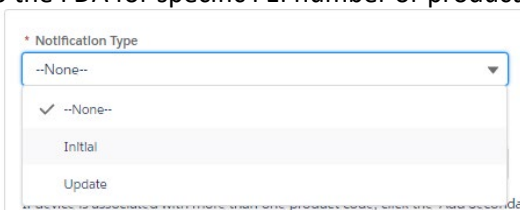
Model/Catalog Numbers (if more than one, use semicolons to separate the numbers)

SKU Numbers (if more than one, use semicolons to separate the numbers)

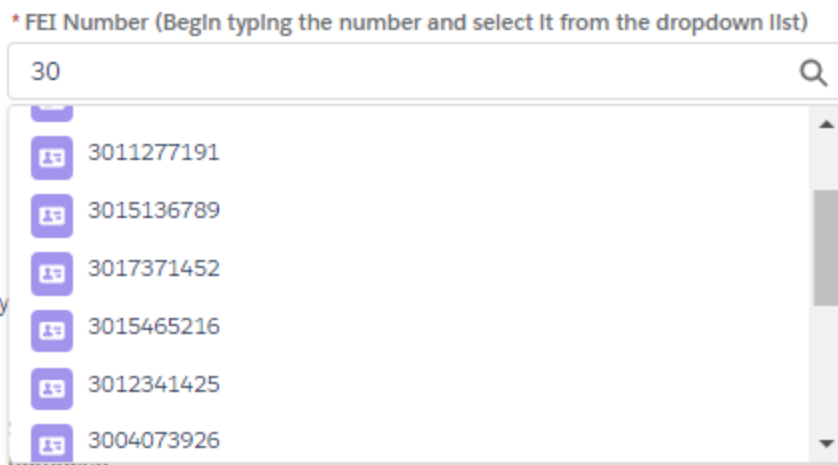
Select if you previously notified the FDA of an interruption that has since been resolved, or if there is a change in status of a previously communicated permanent discontinuance.

This is a pediatric device or includes pediatric sizes.

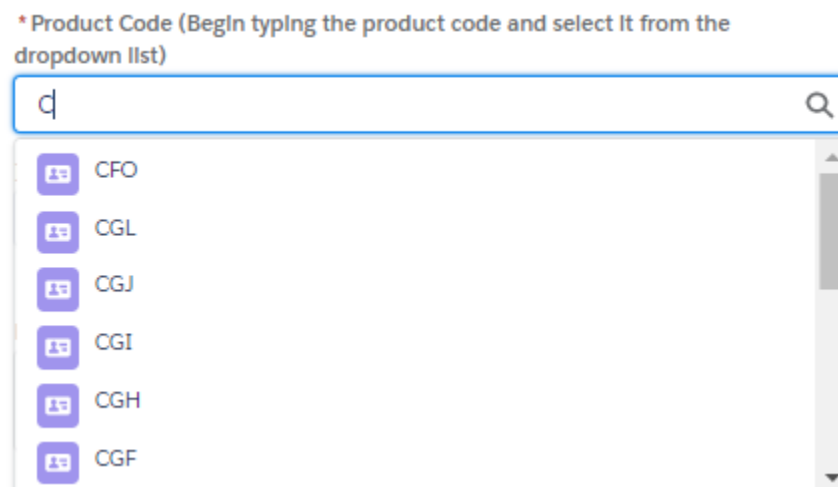
- Notification Type –Select the drop-down arrow and select “Initial” or “Update.” “Initial” indicates the submission is the FIRST from the Manufacturer for the specific FEI number or product code. “Update” indicates that the Manufacturer has followed-up on the first submission to the FDA for specific FEI number or product code.



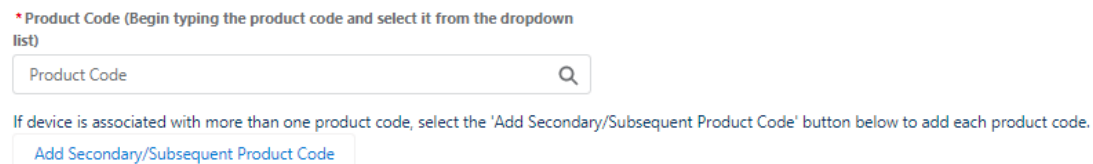
- FEI Number – Begin typing your FEI number and then select it from the dropdown list by Selecting in the list. Once selected the FEI number will display with the icon next to the number.



- If your FEI number does not appear, verify that you have the correct FEI number with the Establishment Registration and Device Listing database or the FEI Portal, see FAQs for more details
- If you have verified you have the correct FEI number and it is still not appearing in the list contact the Agency at [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) and include “Question” in the subject line of the email
- Product Code – Begin typing your product code and select it from the dropdown list. Once selected, the product code will display with the icon next to the number.



- If you do not know your product code, you can find that information in the [Establishment Registration and Device Listing database](#).
- If your device has subsequent/secondary product codes, select “Add Secondary/subsequent Product Code” and follow the steps above



- If you have entered subsequent/secondary product codes in error, select the trash can icon to the right of the extra Product Code fields (this icon only appears for subsequent/secondary product codes)

- If your product code is not available, please contact the FDA for further instruction at [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) and include “Product Code” in the subject line. Include your name, organization, and contact information and an FDA team member will contact you with instructions on how to submit your notification.
- Marketing Submission Holder – In the case that the original submission has been transferred or sold, type the name of the marketing submission holder. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

Marketing Submission Holder

- Marketing Submission Number – Type the submission number for the product. If there is more than one submission number associated with your product, separate them with semicolons (;). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 255)

Marketing Submission Number (if more than one, use semicolons to separate the numbers)

- Device Trade Name – Type the device trade name. If there is more than one, separate them with semicolons (;). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

Device Trade Name (If more than one, use semicolons to separate the names)

- UDI– Type the Unique Device Identifier (UDI). If there is more than one, separate them with semicolons (;). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 5,000)

Unique Device Identifier (UDI) (if more than one, use semicolons to separate each identifier)

- Model/Catalog Numbers – Type the model or catalog numbers. If there is more than one, separate them with semicolons (;). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

Model/Catalog Numbers (If more than one, use semicolons to separate the numbers)

- SKU Numbers – Type the SKU numbers. If there is more than one, separate them with semicolons (;). (character limit: 255)

SKU Numbers (If more than one, use semicolons to separate the numbers)

- For an interruption that has since been resolved, or if there is a change in status of a previously communicated permanent discontinuance, select the box under the question. Selecting this box will end the form and give you the option to add another entry, submit and close, or add files

Select if you previously notified the FDA of an interruption that has since been resolved, or if there is a change in status of a previously communicated permanent discontinuance.

Add another entry

Submit and close

Submit and add attachments

- For a pediatric device –Select the box under the question if the device is a pediatric device or comes in a pediatric size

This is a pediatric device or Includes pediatric sizes.

## Reason(s) for discontinuance or interruption

### Reason(s) for discontinuance or interruption

Reason(s) for discontinuance or Interruption

Available

- Requirements related to complying with good manufacturing prac...
- Regulatory delay
- Order to divert devices from other U.S government entities
- Shortage or discontinuance of a component, part or accessory of t...

Chosen

Other reasons not listed

- Reason(s) for discontinuance or interruption – Select the reason(s) for the discontinuance or interruption by selecting the reason from the list available and selecting the right arrow between the “Available” and “Chosen” boxes. Multiple reasons can be moved at once by holding the control (Ctrl) key while selecting. You can scroll through all the options by using the small scroll bar on the right of the “Available” box.

Reason(s) for discontinuance or interruption

Available

- Regulatory delay
- Discontinuance or disruption of the manufacture of the device
- Delay in shipping of the device (e.g., due to export or import challe...
- Delay in sterilization of the device

Chosen

Requirements related to complying with good manufacturing practices

Move selection to Chosen from other U.S government entities

Shortage or discontinuance of a component, part or accessory of the ...

- If a reason is incorrectly selected, it can be removed by selecting the reason and then selecting the left arrow between the “Available” and “Chosen” boxes.

- If none of the reasons listed under the “Available” box describe the reason for your discontinuance or interruption, a text box is available for you to type a different reason that fits your situation. Select “Other reasons not listed above, description below” and then enter information into the provided text box. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

## Duration of discontinuance or interruption

### Duration of discontinuance or interruption

Enter a value for either "Estimated Duration End Date" OR "Estimated Duration Other"

- Estimated Duration Start Date –Select this field and use the calendar that appears and select the approximate start date of your discontinuance or interruption. The month can be changed by selecting the left and right arrows at the top; the year can be changed by selecting the field and selecting the correct year. If the exact start date is not known, but the month/year is known, enter the first day of the month.



Estimated Duration Start Date

\*Estimated Duration Other

**COVID-19 pandemic**

Has the COVID-19 pandemic fully impacted your device(s)?

Available

No

Labor shortages

Lack of protective equipment

Shortage or delay in raw material supply

January							2021
Sun	Mon	Tue	Wed	Thu	Fri	Sat	
27	28	29	30	31	1	2	
3	4	5	6	7	8	9	
10	11	12	13	14	15	16	
17	18	19	20	21	22	23	
24	25	26	27	28	29	30	
31	1	2	3	4	5	6	

Today

- **Estimated Duration End Date** –Select this field and use the calendar that appears and select the approximate end date of your discontinuance or interruption. The month can be changed by selecting the left and right arrows at the top; the year can be changed by selecting the field and selecting the correct year. If the end date is not known, but the month/year is known, enter the last day of the month. The estimated end date must be after the estimated start date if one is provided.

\*Estimated Duration End Date

January							2021
Sun	Mon	Tue	Wed	Thu	Fri	Sat	
27	28	29	30	31	1	2	
3	4	5	6	7	8	9	
10	11	12	13	14	15	16	
17	18	19	20	21	22	23	
24	25	26	27	28	29	30	
31	1	2	3	4	5	6	

Today

What device(s) have you chosen?

Chosen

- **Estimated Duration Other** – If the duration of your discontinuance or interruption cannot be estimated to a date, this field can be utilized to type a response to describe the estimated duration. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

\*Estimated Duration Other

## COVID-19 pandemic-specific inquiries

### COVID-19 pandemic-specific inquiries

Has the COVID-19 pandemic further affected your ability to manufacture or distribute your device(s)?

<p>Available</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>No</p> <p>Labor shortages</p> <p>Lack of protective equipment for employees</p> <p>Shortage or delay in raw material supply</p> </div>	▶	<p>Chosen</p> <div style="border: 1px solid #ccc; height: 80px;"></div>
--	---	---

Additional details of issue(s).

If yes, describe the impact and supplier(s), including how reliance on critical suppliers affected by the COVID-19 pandemic might adversely impact your ability to manufacture device(s), and names of your critical supplier(s). If your information will not fit in this text box, provide the information as an attachment.

Do you rely on any critical suppliers that might be affected by the COVID-19 pandemic?

--None--

- Has the COVID-19 pandemic further affected your ability to manufacture or distribute your device(s)? – Select the reason(s) that have impacted your ability to manufacture or distribute your device(s) by selecting the reason from the list available and selecting the right arrow between the “Available” and “Chosen” boxes. Multiple reasons can be moved at once by holding the control (Ctrl) key while selecting. You can scroll through all the options by utilizing the small scroll bar on the right of the “Available” box.

Has the COVID-19 pandemic further affected your ability to manufacture or distribute your device(s)?

<p>Available</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Temporary plant closure</p> <p>Shipping/transportation challenges</p> <p>Export/import challenges</p> <p>Other reasons not listed above, description below.</p> </div>	▶	<p>Chosen</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Shortage or delay in raw material supply</p> </div>
--	---	--

Move selection to Chosen

- If a reason is chosen accidentally, use the left arrow between the “Available” and “Chosen” boxes to remove a chosen reason.

Has the COVID-19 pandemic further affected your ability to manufacture or distribute your device(s)?

<p>Available</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Labor shortages</p> <p>Lack of protective equipment for employees</p> <p>Shipping/transportation challenges</p> <p>Other reasons not listed above, description below.</p> </div>	▶	<p>Chosen</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Shortage or delay in raw material supply</p> <p>Temporary plant closure</p> <p>Export/import challenges</p> </div>
--	---	---

Move selection to Available

- If none of the reasons listed under “Available” describe the reason for your discontinuance or interruption, a text box is available for you to type a different reason that fits your situation. Select “Other reasons not listed above, description below” if you are going to use this text box.

This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

Has the COVID-19 pandemic further affected your ability to manufacture or distribute your device(s)?

Available

- Shortage or delay in raw material supply
- Temporary plant closure
- Shipping/transportation challenges
- Export/import challenges

Chosen

Other reasons not listed above, description below.

Additional details of Issues(s).

- Do you rely on any critical suppliers that might be affected by the COVID-19 pandemic? – The default answer for this question is “None”; to select “Yes” or “No,” use the drop-down menu.

**Do you rely on any critical suppliers that might be affected by the COVID-19 pandemic?**

--None--

---

✓ --None--

YES

NO

- If “Yes” is selected, provide a description in the text field to the right of this question. If your answer does not fit in the text field, provide information as an attachment. There is an “Add files” button at the bottom of this form to upload files as attachments. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 32,768)

Do you rely on any critical suppliers that might be affected by the COVID-19 pandemic?

If yes, describe the impact and supplier(s), including how reliance on critical suppliers affected by the COVID-19 pandemic might adversely impact your ability to manufacture device(s), and names of your critical supplier(s). If your information will not fit in this text box, provide the information as an attachment.

## Additional Information, including possible mitigations

### Additional Information, including possible mitigations

Is this device manufactured on multiple lines?

--None--

Is this device manufactured in multiple facilities?

--None--

Have you provided, or will you provide, public information for your stakeholders and patients regarding this actual or potential shortage?

--None--

Do you have a proposal for FDA to review to expedite availability of your device? What else do you think FDA can do to help prevent or mitigate a supply disruption?

--None--

Proposal to expedite availability of device and/or for FDA to help prevent or mitigate a supply distribution.

Do you have shortage mitigation plans in place that could be shared with the FDA?

--None--

If yes, describe your shortage mitigation plans or add attachment.

- Is this device manufactured on multiple lines – The default answer for this question is “None”; to select “Yes” or “No,” use the drop-down menu.

Is this device manufactured on multiple lines?

--None--

✓ --None--

YES

NO

- Is this device manufactured in multiple facilities – The default answer for this question is “None;” to select “Yes” or “No,” use the drop-down menu.

Is this device manufactured in multiple facilities?

--None--

✓ --None--

YES

NO

- Have you provided, or will you provide public information to your stakeholders and patients regarding this actual or potential shortage? – The default answer for this question is “None;” to select “Yes” or “No,” use the drop-down menu.

Have you provided, or will you provide, public information for your stakeholders and patients regarding this actual or potential shortage?

--None--

✓ --None--

YES

NO

- Do you have a proposal for FDA to review to expedite availability of your device? – The default answer for this question is “None;” to select “Yes” or “No,” use the drop-down menu.

Do you have a proposal for FDA to review to expedite availability of your device? What else do you think FDA can do to help prevent or mitigate a supply disruption?

--None--

✓ --None--

YES

NO

- If “Yes” is selected, you may provide a description in the text field to the right of this question with your proposal to expedite availability of the device and/or for FDA to help prevent or mitigate a supply distribution. If your answer does not fit in the text field, provide information as an attachment. There is an “Add files” button at the bottom of this form to upload files as attachments. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 32,768)

Do you have a proposal for FDA to review to expedite availability of your device? What else do you think FDA can do to help prevent or mitigate a supply disruption?

YES

Proposal to expedite availability of device and/or for FDA to help prevent or mitigate a supply distribution.

- Do you have shortage mitigation plans in place that could be shared with FDA – The default answer for this question is “None;” to select “Yes” or “No,” use the drop-down menu.

Do you have shortage mitigation plans in place that could be shared with the FDA?

--None--

✓ --None--

YES

NO

- If “Yes” is selected, provide a description in the text field below this question. If your answer does not fit in the text field, provide information as an attachment. There is an “Add files” button at the bottom of this form to upload files as attachments. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 32,768)

Do you have shortage mitigation plans in place that could be shared with the FDA?

YES

If yes, describe your shortage mitigation plans or add attachment.

|

## Production Capacity and Market Share for this FEI and product code

### Production Capacity and Market Share for this FEI and product code

Estimated US market share (%) for this device

Average Historic Production Volume per Month

Average Historic US Distribution per Month

Current Production Volume per Month

Current US Distribution per Month

Maximum Production Volume per Month

How much device inventory do you have? Enter in individual units (eaches).

- Estimated US market share (%) for this device – Enter a number between 0 – 100 (character limit: unlimited but numerical values only)
- Average Historic Production Volume per Month – Enter a number (character limit: 14 numbers)
- Average Historic US Distribution per Month – Enter a number (character limit: 14 numbers)
- Current Production Volume per Month – Enter a number (character limit: 14 numbers)
- Current US Distribution per Month – Enter a number (character limit: 14 numbers)
- Maximum Product Volume per Month – Enter a number (character limit: 14 numbers)
- How much device inventory do you have? –Enter a number that approximates how much inventory you currently have in individual units (eaches). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

## End of Form and Attachments

Add another entry

Submit and close

Submit and add attachments

### Add Attachments

Once the form has been submitted, you will be able to upload files as attachments.

\* Upload files using the PDF, Word or Excel formats. The file attachment size should be 5 MB or less.

Upload Files Or drop files

Finish

- At the end of this form, there are three options:
  - Add another entry – if you have another interruption or discontinuance to report, for a different product code or a different FEI number, select this option to enter this form and create another, with some fields pre-populated
  - Submit and close – if you are done entering interruptions or discontinuances, select this option to submit the form to FDA and close the window
  - Submit and add attachments – if you would like to provide more information that was not captured in the form or a section of the form did not have enough space for you to provide your full answer, select “Submit and add files add attachments” and the Add Attachments section will become available. You can upload a PDF, Word, or Excel file,

the file size cannot exceed 5 MB per file. When you are done uploading files, select the “Finish” button

### Submitting a Spreadsheet

- To submit notification with a spreadsheet, fill out the [spreadsheet template](#). See: [How to Use the 506J Notification Spreadsheet Template](#) for help.
- Select add files.

Select the template spreadsheet you filled with your information

- Files successfully uploaded with appear below the Upload Files button and a green banner will appear

### If voluntarily indicating no interruption or permanent discontinuance

- Voluntarily Indicate Currently No Notification Under 506J – You may wish to voluntarily indicate that you are not currently experiencing an interruption or permanent discontinuance in manufacturing for a device that requires the submission of a 506J notification. Information that is marked with an asterisk (\*) must be provided for it to be transmitted to the agency. Indicate whether you are not experiencing an interruption or permanent discontinuance by selecting the reason from the list and selecting the right arrow between the “Available” and “Chosen” boxes. Multiple reasons can be moved at once by holding the control (Ctrl) key while selecting. You can scroll through all the options by utilizing the small scroll bar on the right of the “Available” box.

### Reason(s) no Notification is needed

\* Reason(s) no Notification is needed (May choose one or more)

- If a reason is incorrectly selected, it can be removed by selecting the reason and then selecting the left arrow between the “Available” and “Chosen” boxes.

## Error Messages

Enter a valid value

- This error occurs when text is entered into a field that is expecting a numerical value. These fields are mainly in the Production Capacity and Market Share and FEI field.

Average Historic US Distribution per Month

Enter a valid value.

Product Code not found see FAQ

- This error occurs when the product code that is being entered is not one of the [device types that currently require notification under section 506J](#) of the FD&C Act.

\* Product Code (Begin typing the product code and select it from the dropdown list)

Product Code not found please see FAQ

FEI number not found see FAQ

- This error occurs when the FEI number entered is either not entered correctly or is not registered as a device establishment in the webform. You can [look up your FEI number in the Establishment Registration and Device Listing database](#) or the [FEI Search portal](#).



\* FEI Number (Begin typing the number and select it from the dropdown list)

FEI number not found please see FAQ

Enter a value

- This error occurs when a required field has not been completed.

\* Submitter First Name

Enter a value.

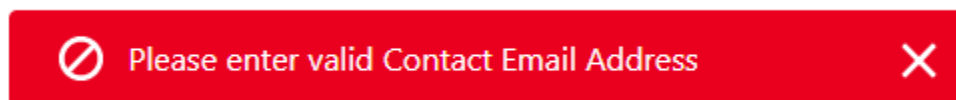
You have entered an invalid format

- This error occurs when a valid email address is not entered. The email address should include the @ symbol with text before and after.

\* Submitter Email Address

You have entered an invalid format.

- This error also occurs when a valid email address is not entered. The email address should include a domain name (.com, .gov, .edu, etc.)



Upload errors

- The size of the file exceeded 5 MB or is an incompatible file type

1 files couldn't be uploaded
✕

**Add Attachments**

Submit information. Once the details has been saved, you will be able to upload files.

\* Upload allowed files (PDF, Word or Excel). The file attachment size cannot exceed 5 MB.

Upload Files
Or drop files

Binder1.pdf

Finish

Your entry does not match the allowed format MMM d, yyyy

- This error occurs when a date is typed into the start date or end date fields instead of utilizing the pop-up calendar and selecting the appropriate date. Use the pop-up calendar to select the date.

\*Estimated Duration End Date

Your entry does not match the allowed format MMM d, yyyy.

Estimated duration start date should be less than estimated duration end date

- This error occurs when an end date is reported at a time prior to the reported start date.

⊘
Estimated Duration Start Date should be less than Estimated Duration End Date. ✕

Required field errors

- These errors occur when required fields have not been completed.

⊘

 Please enter Contact First Name  
 Please enter Contact Last Name  
 Please enter Contact Email Address  
 Please enter Contact Phone  
 Please enter Manufacturer  
 Please enter Notification Type  
 Either estimated duration end date or duration other should be completed.  
 Reason(s) for discontinuance or interruption should be completed.  
 Please enter a valid FEI Number. Please see the FAQ if the number you entered is not listed.  
 Please enter a valid product code. Please see the FAQ if the product code you entered is not listed.
 ✕

# Online 506J Notification Submission Methods: Frequently Asked Questions

This page responds to common questions on **online 506J notification submission methods, including the webform and spreadsheet template**, under section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act during the COVID-19 pandemic.

On this page:

- [Webform FAQs](#)
- [Spreadsheet Template FAQs](#)

## Webform FAQs

**Q. How do I submit notifications using the webform? Where can I find help if I have trouble using the webform?**

A. Please see the [How to Use the FDA 506J Notification Webform \(/media/151055/download\)](/media/151055/download) for more information on submitting information through the webform, troubleshooting, and answers to frequently asked questions on the webform.

**Q. Is the information I submit using the webform secure?**

A. The FDA [506J Notification webform \(https://fdaproduct.force.com/shortages\)](https://fdaproduct.force.com/shortages) [\(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) complies with Hypertext Transfer Protocol Secure (HTTPS) messaging standards and uses digital certificates for secure communication.

**Q: What is the purpose of the “Voluntarily Indicate No Current Interruption or Permanent Discontinuance” option on the online webform?**

A: If a manufacturer is currently not experiencing an interruption or permanent discontinuance in manufacturing, they may voluntarily indicate this to the FDA selecting this option and filling out the form.

**Q. Are there other ways than the webform to submit a 506J Notification?**

A. The FDA recommends using the [webform \(https://fdaproduct.force.com/shortages\)](https://fdaproduct.force.com/shortages) [\(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) to submit your notification. However, there are alternate methods to submit a 506J notification. For example, if you do not utilize the webform, manufacturers may email their information to

[CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) (<mailto:CDRHManufacturerShortage@fda.hhs.gov?subject=Notification>) and begin the email subject line with the word "Notification." Section V of the guidance, [Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency \(Revised\)](#) (</regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc>), provides an [example 506J notification](#) (<https://www.fda.gov/media/137712/download#page=13>) intended to illustrate the type of information that the FDA recommends be included in a notification.

**Q. I'm having trouble loading the form in my web browser. Are there certain web browsers that work better than others?**

A. Please use Chrome, Microsoft Edge, or Firefox to fill out the webform. The webform does not support Internet Explorer.

**Q. Can I see what information I have submitted previously?**

A. No, once the webform is submitted, the information is sent to the FDA and is not saved within the webform. If you have a question about the information you submitted, please email [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) (<mailto:CDRHManufacturerShortage@fda.hhs.gov>) and include "Question" in the subject line of the email.

**Q. Can I use multiple methods to submit information using the webform?**

A. Yes, you can submit notifications through any or all of the three methods in the webform (for example, webform, spreadsheet, voluntary notification). Once you've completed and submitted notification using one method, you will be redirected to the [webform home page](#) (<https://fdaproduct.force.com/shortages>). [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer), where you can select a different method.

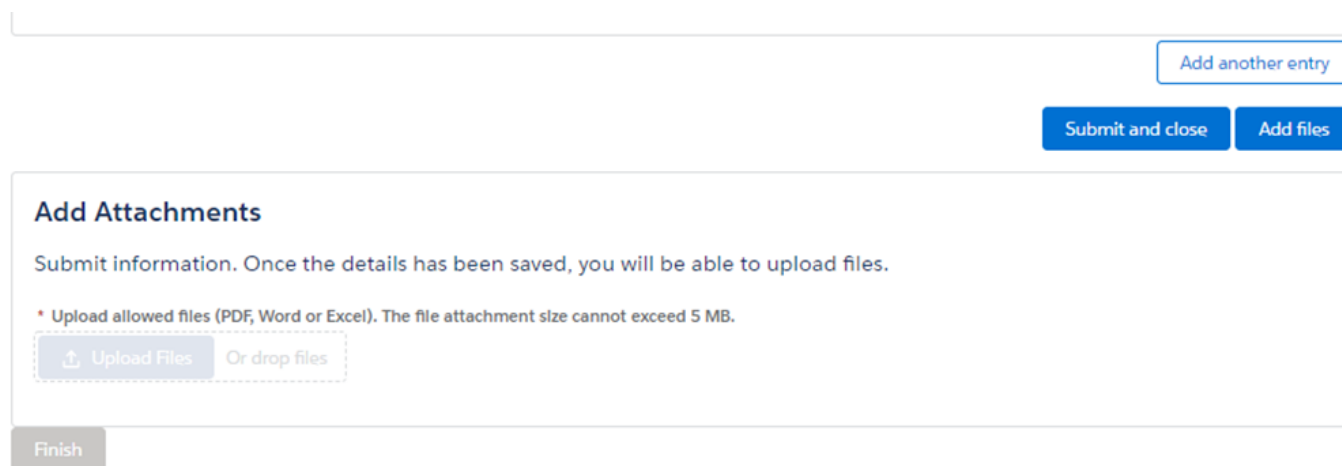
**Q. How do I know if the FDA received my webform submission?**

A. Once you have submitted a 506J notification through the webform, a confirmation email will be sent to the identified contact's email address. To inform possible mitigation efforts, the FDA may follow up with manufacturers or conduct targeted outreach where an interruption is cross-cutting or may have the potential to impact users. However, you will **not** routinely hear from the FDA once the FDA has analyzed the information.

The FDA will publicly communicate updates to the device shortage list and device discontinuance list. Any information that is trade secret or confidential information will be treated as such, consistent with section 552(b)(4) of title 5, United States Code, section 1905 of title 18, United States Code, section 520(c) of 21 USC 360J(c), and other applicable laws.

**Q. What if I want to provide the FDA with additional information than is required or requested? How can I submit that information?**

A. When using the [webform \(https://fdaproduct.force.com/shortages\)](https://fdaproduct.force.com/shortages)  [\(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer), you may attach additional documents if there is additional information you wish to provide to the FDA. Select “Add files” at the bottom of the page and the option to add attachments will become available.



**Q. How do I submit a 506J notification for a product code that is not available on the webform?**

A. If your product code is not available, please contact the FDA for further instruction at [CDRHManufacturerShortage@fda.hhs.gov \(mailto:CDRHManufacturerShortage@fda.hhs.gov\)](mailto:CDRHManufacturerShortage@fda.hhs.gov) and include “Product Code” in the subject line. Include your name, organization, and contact information and an FDA team member will contact you with instructions on how to submit your notification.

**Q. How do I submit a 506J notification for an FEI that is not available on the webform?**

A. If you are having trouble locating your FEI number, see [How to Determine FEI, product code, and submission number \(https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login\)](https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login) for information on how to locate your firm’s establishment information. If you are still unable to locate your establishment’s FEI number in the webform, please email [CDRHManufacturerShortage@fda.hhs.gov \(mailto:CDRHManufacturerShortage@fda.hhs.gov\)](mailto:CDRHManufacturerShortage@fda.hhs.gov) and include “Question” in the subject line.

**Q. There are three different notification options on the webform. How do I know if I have a “small” or “large” amount of FEI-product codes to enter?**

A. The FDA recommends submitting 506J notifications using the method that is most convenient for you.

Generally, for a manufacturer having between 5 and 10 FEI-product code combinations, submitting 506J notifications directly through the webform may be easiest.

For a manufacturer having over 10 FEI-product code combinations, the spreadsheet template may be a more convenient method to submit a 506J notification. You can then submit it to the FDA in your initial notification, as well as use it to collect any revised information for update notifications.

The webform is updated weekly to include new information from Registration & Listing; however, the format of the spreadsheet will not change.


**Q. I ran out of character space in a box. How can I add more context to my answer?**

A. If you have exceeded the character limit in a text box field, an additional file can be attached to your submission that contains any additional information. Please find the option to attach a file at the bottom of the form.

**Q. What if the options for the reason for interruption don't fully explain my situation?**

A. You have the option to select several reasons for the discontinuance or interruption as well as an option of "Other." An open text field is below this question where you can explain the reason for the discontinuance or interruption if you feel the options don't explain your situation. Additionally, there is an option to attach a file at the end of your submission.

**Q. Is there a way of notifying the FDA that I do not currently have an interruption or permanent discontinuance?**

A. Yes. If you are not currently experiencing an interruption or discontinuance in manufacturing, you may voluntarily notify the FDA using the "[Voluntarily Indicate No Current Interruption or Permanent Discontinuance](https://fdaproduct.force.com/shortages) (<https://fdaproduct.force.com/shortages>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)" option on the webform.

**Q. Where can I find more information about 506J notifications?**

A. See [Medical Device Supply Chain Notifications During the COVID-19 Pandemic](/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-supply-chain-notifications-during-covid-19-pandemic) (</medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-supply-chain-notifications-during-covid-19-pandemic>) for more information about 506J notifications. For answers to frequently asked questions about the device shortage list, who to contact, or 506J Notifications in general, please see [Supplies of Medical Devices for COVID-19: Frequently Asked Questions](/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions) (</medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions>).

# Spreadsheet Template FAQs

**Q. How do I submit large numbers of notifications using the spreadsheet? Where can I find help if I have trouble entering information in the spreadsheet?**

A. Please see the *[How to Use the 506J Notification Spreadsheet Template \(/media/151056/download\)](/media/151056/download)* for more information on submitting information through the webform, troubleshooting, and answers to frequently asked questions on the webform.

**Q. Can I submit a spreadsheet that does not use the FDA spreadsheet template using the webform?**

A. No. Spreadsheet files that are not formatted in the [FDA spreadsheet template \(/media/151057/download\)](/media/151057/download) will not be able to be processed correctly. If you are experiencing problems with the FDA template spreadsheet, email [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) (<mailto:CDRHManufacturerShortage@fda.hhs.gov>) and include “Question” in the subject line.



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Use Chrome, Microsoft Edge, or Firefox to fill out the webform. The webform does not support Internet Explorer.

## **Notify the FDA About an Interruption or Permanent Discontinuance in Device Manufacturing (506J Notification)**

Under Section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act), manufacturers of the following devices must notify the FDA of an interruption or permanent discontinuance in manufacturing during or in advance of a public health emergency.

- Devices that are critical to public health during a public health emergency, including those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery.
- Devices for which the FDA determines information on potential meaningful supply disruptions is needed during a public health emergency.

This page provides an electronic method for submitting 506J notifications, as well as other voluntary notifications, to FDA. The FDA recommends submitting 506J notifications in the method that is most convenient for you. The webform is updated to include new information from Registration & Listings.

OMB # 0910-0491, exp. 06/30/2024

For help using the notification options below, refer to the following How To documents:

- [How to use the FDA 506J Notification Webform \(https://www.fda.gov/media/151055/download\)](https://www.fda.gov/media/151055/download)
- [How to use the 506J Notification Spreadsheet Template \(https://www.fda.gov/media/151056/download\)](https://www.fda.gov/media/151056/download)
- [FAQs on FDA's online 506J Notification submissions methods \(https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/online-506j-notification-submission-methods-frequently-asked-questions\)](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/online-506j-notification-submission-methods-frequently-asked-questions)
- [Common error messages when using the 506J Notification webform \(https://www.fda.gov/media/151055/download#page=13\)](https://www.fda.gov/media/151055/download#page=13)

**Note:** If you are experiencing an interruption or discontinuance of a device that may not be related to a public health emergency response, but you would still like to voluntarily notify FDA, you may submit

that information using either the webform or spreadsheet.

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## Notify FDA using webform:

Complete the Online Notification using this form, you can submit individual notifications.

[Submit Notifications Online](#)

## Notify FDA using a spreadsheet:

Complete the Online Notification and submit a spreadsheet with a batch of notifications.

[Submit Notifications Using a Spreadsheet](#)

## Voluntarily indicate there is not an interruption or permanent discontinuance:

If you are currently not experiencing an interruption or permanent discontinuance in manufacturing that requires the submission of a 506J notification, you may complete the Voluntary Online Notification form.

[Voluntarily Indicate No Current Interruption or Permanent Discontinuance](#)

For more information about section 506J of the FD&C Act, see:

- [Contact the FDA About a Medical Device Supply Chain Issue \(https://www.fda.gov/medical-devices/medical-device-safety/contact-fda-about-medical-device-supply-chain-issue\)](https://www.fda.gov/medical-devices/medical-device-safety/contact-fda-about-medical-device-supply-chain-issue)
- [Medical Device Types to Help Determine Section 506J Notification Obligations \(https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-types-help-determine-section-506j-notification-obligations\)](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-types-help-determine-section-506j-notification-obligations)

For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act during the COVID-19 pandemic, refer to Supplies of Medical Devices for COVID-19: Frequently Asked Questions. (<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions>) If your question is not answered by the FAQ, you can email [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) (mailto: [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov)) and include "Question" in the subject line of the email.





# Submit Notifications Online

Form is one method for submission of a 506J Notification. Using this form, you can submit individual notifications for interruption or discontinuance. While not all of the information in the webform is required to submit a 506J notification, information marked with an asterisk (\*) must be provided in the webform for it to be transmitted to the agency.

If more than one FEI-product code combination, complete the form and select the "Add another interruption or discontinuance" button at the bottom of the form to add the next FEI-product code combination.

Using the webform, refer to the following How To documents:

- How to use the FDA 506J Notification Webform (<https://www.fda.gov/media/151055/download>)
- Learn more on FDA's online 506J Notification submissions methods (<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/online-506j-notification-submission-methods-frequently-asked-questions>)

For more information on methods for submitting notifications to FDA, as well as links to additional resources on section 506J of the FD&C Act, please see [FDA About an Interruption or Permanent Discontinuance in Device Manufacturing \(506J Notification\)](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-supply-chain-notifications-covid-19-pandemic#notifying).

## Submitter Information

Required Submitter First Name

\* (required) Submitter Last Name

Required Submitter Email Address

\* (required) Submitter Phone

Required Submitter Company Name

## Product Information

Required Notification Type

\* (required) FEI Number (Begin typing the number and select it from the dropdown list)

Required Product Code (Begin typing the product code and select it from the dropdown list)

If a notification is associated with more than one product code, select the 'Add Secondary/Subsequent Product Code' button below to add each product code.

Add Secondary/Subsequent Product Code

Marketing Submission Holder

Marketing Submission Number (if more than one, use semicolons to separate numbers)

Trade Name (if more than one, use semicolons to separate the names)

Unique Device Identifier (UDI) (if more than one, use semicolons to separate each identifier)

Catalog Numbers (if more than one, use semicolons to separate the numbers)

SKU Numbers (if more than one, use semicolons to separate the numbers)

if you previously notified the FDA of an interruption that has since been resolved, or if there is a change in status of a previously communicated permanent discontinuance.

a pediatric device or includes pediatric sizes.

## Reason(s) for discontinuance or interruption

Selected Reason(s) for discontinuance or interruption

File

- Requirements related to complying with good manufacturing practices
- Regulatory delay
- Effort to divert devices from other US government entities
- Damage or discontinuance of a component, part or accessory of the ...

Chosen

Reasons not listed

## Duration of discontinuance or interruption

Provide a value for either "Estimated Duration End Date" OR "Estimated Duration Other"

Estimated Duration Start Date

\*Estimated Duration End Date

Estimated Duration Other

## COVID-19 pandemic-specific inquiries

Did the COVID-19 pandemic further affect your ability to manufacture or distribute your device(s)?

File

Chosen

or shortages

: of protective equipment for employees

rtage or delay in raw material supply



onal details of issue(s).

If yes, describe the impact and supplier(s), including how reliance on critical suppliers affected by the COVID-19 pandemic might adversely impact your ability to manufacture device(s), and names of your critical supplier(s). If your information will not fit in this text box, provide the information as an attachment.

Do you rely on any critical suppliers that might be affected by the COVID-19 pandemic?

None--

### Additional Information, including possible mitigations

Is this device manufactured on multiple lines?

None--

Is this device manufactured in multiple facilities?

--None--

Have you provided, or will you provide, public information for your stakeholders or patients regarding this actual or potential shortage?

None--

Do you have a proposal for FDA to review to expedite availability of your device? Please also do you think FDA can do to help prevent or mitigate a supply shortage?

None--

Proposal to expedite availability of device and/or for FDA to help prevent or mitigate a supply distribution.

Do you have shortage mitigation plans in place that could be shared with the FDA?

None--

Describe your shortage mitigation plans or add attachment.

### Production Capacity and Market Share for this FEI and product code

Estimated US market share (%) for this device

Average Historic Production Volume per Month

Historic US Distribution per Month

Current Production Volume per Month

Estimated US Distribution per Month

Maximum Production Volume per Month

How much device inventory do you have? Enter in individual units (eaches).

Add another

Submit and close

Submit and add attachment

## Attachments

After the form has been submitted, you will be able to upload files as attachments.

**Required) Upload files using the PDF, Word or Excel formats. The file attachment size should be 5 MB or less.**

Upload Files

For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FDCA) Act during the COVID-19 pandemic, refer to [Supplies of Medical Devices for COVID-19: Frequently Asked Questions](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions). [www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions)). If your question is not answered by the FAQ, email [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) (mailto: [ManufacturerShortage@fda.hhs.gov](mailto:ManufacturerShortage@fda.hhs.gov)) and include "Question" in the subject line of the email.



# Submit Notifications Using a Spreadsheet

You may use the [Spreadsheet Template \(https://www.fda.gov/media/151057/download\)](https://www.fda.gov/media/151057/download) to submit a batch of 506J notifications.

Instructions: The [Spreadsheet Template \(https://www.fda.gov/media/151057/download\)](https://www.fda.gov/media/151057/download) is one method for submission of a batch of 506J Notifications. While not all of the information in the [Spreadsheet Template \(https://www.fda.gov/media/151057/download\)](https://www.fda.gov/media/151057/download) is required to submit a 506J notification, information that is marked with an asterisk (\*) in the [Spreadsheet Template \(https://www.fda.gov/media/151057/download\)](https://www.fda.gov/media/151057/download) must be provided to the agency for it to be considered complete. Enter each FEI-product code combination on a separate row of the [Spreadsheet Template \(https://www.fda.gov/media/151057/download\)](https://www.fda.gov/media/151057/download). Once you enter your data into the [Spreadsheet Template \(https://www.fda.gov/media/151057/download\)](https://www.fda.gov/media/151057/download) you can upload it by selecting the “add attachments” button below.

For help using the spreadsheet, refer to the following documents:

- [How to use the FDA 506J Notification Webform \(https://www.fda.gov/media/151055/download\)](https://www.fda.gov/media/151055/download)
- [How to use the 506J Notification Spreadsheet Template \(https://www.fda.gov/media/151056/download\)](https://www.fda.gov/media/151056/download)
- [FAQs on FDA’s online 506J Notification submissions methods \(https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/online-506j-notification-submission-methods-frequently-asked-questions\)](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/online-506j-notification-submission-methods-frequently-asked-questions)

For other methods for submitting notifications to FDA, as well as links to additional resources on section 506J of the FD&C Act, see [Notify the FDA About an Interruption or Permanent Discontinuance in Device Manufacturing \(506J Notification\). \(https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-supply-chain-notifications-during-covid-19-pandemic#notifying\)](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-supply-chain-notifications-during-covid-19-pandemic#notifying)

Note: There is a 5 MB limit for the uploaded files.

## Notification Information

\* (required) Submitter First Name

\* (required) Submitter Last Name

\* (required) Submitter Email Address

\* (required) Submitter Phone

\* (required) Submitter Company Name

Submit and add attachments

## Add Attachments

Once the form has been submitted, you will be able to upload files as attachments.

\* (required) Upload files using the PDF, Word or Excel formats. The file attachment size should be 5 MB or less.

 Upload Files

Finish

**For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act during the COVID-19 pandemic, refer to [Supplies of Medical Devices for COVID-19: Frequently Asked Questions](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions). (<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions>) If your question is not answered by the FAQ, email [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) (mailto: [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov)) and include "Question" in the subject line of the email.**





# Voluntarily Indicate No Current Interruption or Permanent Discontinuance

This form may be used if you wish to voluntarily indicate that you are not currently experiencing an interruption or permanent discontinuance in manufacturing for a device that requires the submission of a 506J notification. Information that is marked with an asterisk (\*) must be provided for it to be transmitted to the agency.

If you have more than one FEI-product code combination, you may complete the form and select the "Add another entry" button at the bottom of the form to add the next FEI-product code combination.

## Notification Information

\* (required) Submitter First Name

\* (required) Submitter Last Name

\* (required) Submitter Email Address

\* (required) Submitter Phone

\* (required) Submitter Company Name

## Reason(s) no Notification is needed

\* (required) Reason(s) no Notification is needed (May choose one or more)

Available


- No longer manufacturing product
- No interruption in manufacturing of product
- Product is not used towards COVID-19 treatment ...
- Other reasons not listed above, description below.

Chosen

Other reasons not listed

## Identifier Information

**\* (required) FEI Number (Begin typing the number and select it from the dropdown list)**

**\* (required) Product Code (Begin typing the product code and select it from the dropdown list)**

If device is associated with more than one product code, select the 'Add Secondary/Subsequent Product Code' button below to add each product code.

Add Secondary/Subsequent Product Code

Add another entry

Submit and close

Submit and add attachments

## Add Attachments

Once the form has been submitted, you will be able to upload files as attachments.

**\* (required) Upload files using the PDF, Word or Excel formats. The file attachment size should be 5 MB or less.**

 Upload Files

Finish

**For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act during the COVID-19 pandemic, refer to [Supplies of Medical Devices for COVID-19: Frequently Asked Questions](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions). (<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/supplies-medical-devices-covid-19-frequently-asked-questions>) If your question is not answered by the FAQ, email [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) ([mailto: CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov)) and include "Question" in the subject line of the email.**

