



**U.S. FOOD & DRUG
ADMINISTRATION**

How to Use the 506J Notification Webform

Center for Devices and Radiological Health

Updated May 2023

Contents

- Introduction 3
- Notification Information..... 3
- Identifier Information..... 4
- Reason(s) for discontinuance or interruption..... 7
- Duration of discontinuance or interruption..... 8
- Manufacturing-specific inquiries 10
- Additional Information, including possible mitigations 11
- Production Capacity and Market Share for this FEI and product code 13
- End of Form and Attachments..... 13
 - Submitting a Spreadsheet 14
 - If indicating no interruption or permanent discontinuance 14
- Error Messages..... 15

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.

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> <div style="border: 1px solid #ccc; height: 40px; width: 100%; position: relative;"> <div style="position: absolute; bottom: 0; right: 0; width: 15px; height: 15px; border-top: 1px solid #ccc; border-right: 1px solid #ccc;"></div> </div>	

- 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 drop-down list by selecting in the list. Once selected the FEI number will display with the icon next to the number.

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

A search input field containing the text '30' with a magnifying glass icon on the right. Below the input field is a dropdown menu with a scroll bar on the right. The dropdown menu contains seven items, each consisting of a purple icon with a white 'E' and a number: 3011277191, 3015136789, 3017371452, 3015465216, 3012341425, and 3004073926.

- 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 and include “Question” in the subject line of the email.
- Product Code – Begin typing your product code and select it from the drop-down list. Once selected, the product code will display with the icon next to the number.

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

A search input field containing the text 'd' with a magnifying glass icon on the right. Below the input field is a dropdown menu with a scroll bar on the right. The dropdown menu contains six items, each consisting of a purple icon with a white 'E' and a code: CFO, CGL, CGJ, CGI, CGH, and CGF.

- 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.

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

A search input field with the placeholder text 'Product Code' and a magnifying glass icon on the right. Below the input field is a button with the text 'Add Secondary/Subsequent 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.

- 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 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
- Order to divert devices from other U.S government entities
- Shortage or discontinuance of a component, part or accessory of the ...

Move selection to Chosen

- 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

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

ite your device(s)?

Chosen

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 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

Manufacturing-specific inquiries

- Has your ability to manufacture or distribute your device(s) been affected? – 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.

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

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)

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

- 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)

Additional Information, including possible mitigations

Additional Information, including possible mitigations

Is this device manufactured on multiple lines?

Is this device manufactured in multiple facilities?

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

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?

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?

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--
 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--
 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--
 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 disruption.

- 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 <input type="text"/>	Average Historic Production Volume per Month <input type="text"/>
Average Historic US Distribution per Month <input type="text"/>	Current Production Volume per Month <input type="text"/>
Current US Distribution per Month <input type="text"/>	Maximum Production Volume per Month <input type="text"/>
How much device inventory do you have? Enter in individual units (eaches). <input type="text"/>	

- 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)

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.

Or drop files

Finish

End of Form

and Attachments

- 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

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

Finish

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.

File name:

Custom Files (*.pdf;*.docx)

- Custom Files (*.pdf;*.docx)
- All 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

✔ 1 files has been uploaded successfully. ✕

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

506J Submission Template.xlsx

Finish

If indicating no interruption or permanent discontinuance

- Indicate Currently No Notification Under 506J – You may wish to 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.
 ✕