



Use Chrome, Microsoft Edge, or Firefox to fill out the webform.

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

This page provides an electronic method for manufacturers of certain medical devices to submit 506J notifications to notify the FDA of an interruption or permanent discontinuance in manufacturing during or in advance of a public health emergency. Manufacturers should submit 506J notifications in the method that is most convenient. The webform is updated to include new information from Establishment Registration and Device 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)
- [Online 506J Notification Submission Methods: Frequently Asked Questions \(https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/online-506j-notification-submission-methods-frequently-asked-questions\)](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/online-506j-notification-submission-methods-frequently-asked-questions)
- [Common error messages when using the 506J Notification webform \(https://www.fda.gov/media/151055/download#page=16\)](https://www.fda.gov/media/151055/download#page=16)

### 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

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 indicate no current interruption or permanent discontinuance.

Indicate No Current Interruption or  
Permanent Discontinuance

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

- **[Notify 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)**
- **Guidance:**
  - **[Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act \(https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc\)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc)**

## Questions?

For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act, refer to **[Supply and Shortages of Medical Devices: Frequently Asked Questions. \(https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/supply-and-shortages-medical-devices-frequently-asked-questions\)](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/supply-and-shortages-medical-devices-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)** and include “Question” in the subject line of the email.

**[Website Policies /Privacy \(https://www.fda.gov/about-fda/about-website/website-policies\)](https://www.fda.gov/about-fda/about-website/website-policies)**||**[Vulnerability Disclosure Policy \(https://www.hhs.gov/vulnerability-disclosure-policy/index.html\)](https://www.hhs.gov/vulnerability-disclosure-policy/index.html)**



# 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 \(https://www.fda.gov/media/151055/download\)](https://www.fda.gov/media/151055/download)

[506J Notification Submission Methods: Frequently Asked Questions \(https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/online-506j-notification-submission-methods-frequently-asked-questions\)](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/online-506j-notification-submission-methods-frequently-asked-questions)

For more information on the methods for submitting notifications to FDA, as well as links to additional resources on section 506J of the FD&C Act, see [FDA About a Medical Device Supply Chain Issue. \(https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/notify-fda-about-medical-device-supply-issue\)](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/notify-fda-about-medical-device-supply-issue)

## 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 ...

Reasons not listed

Chosen

## Estimated 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

## Manufacturing-specific inquiries

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

File

Material shortages

Chosen

: of protective equipment for employees



rtage or delay in raw material supply

onal details of issue(s).

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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 attachment.

rely on any critical suppliers that might be affected by the interruption?

### ditional Information, including possible mitigations

device manufactured on multiple lines?

Is this device manufactured in multiple facilities?

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

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

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

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

describe your shortage mitigation plans or add attachment.

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

ted US market share (%) for this device

Average Historic Production Volume per Month

ge Historic US Distribution per Month

Current Production Volume per Month

it US Distribution per Month

Maximum Production Volume per Month

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

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Add another

Submit and close

Submit and add attachment

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## 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

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## Questions?

For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FDCA) Act, see **Supply and Shortages of Medical Devices: Frequently Asked Questions**. (<https://www.fda.gov/medical-devices/medical-device-shortages/supply-and-shortages-medical-devices-frequently-asked-questions>) If your question is not answered, you can email [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov) (mailto: [CDRHManufacturerShortage@fda.hhs.gov](mailto:CDRHManufacturerShortage@fda.hhs.gov)) and include "506J" in the subject line of the email.

For more information, see **Website Policies / Privacy** (<https://www.fda.gov/about-fda/about-website/website-policies>) | **Vulnerability Disclosure Policy** (<https://www.hhs.gov/vulnerability-disclosure-policy/index.html>).



# 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)
- [Online 506J Notification Submission Methods: Frequently Asked Questions \(https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/online-506j-notification-submission-methods-frequently-asked-questions\)](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/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 a Medical Device Supply Chain Issue. \(https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/notify-fda-about-medical-device-supply-issue\)](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/notify-fda-about-medical-device-supply-issue)

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

## Questions?

For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act, refer to [Supply and Shortages of Medical Devices: Frequently Asked Questions](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/supply-and-shortages-medical-devices-frequently-asked-questions). (<https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/supply-and-shortages-medical-devices-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.

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# 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 public health emerge...
- 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

## Questions?

For questions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FD&C) Act, refer to [Supply and Shortages of Medical Devices: Frequently Asked Questions](https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/supply-and-shortages-medical-devices-frequently-asked-questions). (<https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/supply-and-shortages-medical-devices-frequently-asked-questions>) If your question is not answered by the FAQ, you can email

**CDRHManufacturerShortage@fda.hhs.gov (mailto: CDRHManufacturerShortage@fda.hhs.gov)**  
and include "Question" in the subject line of the email.

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