U.S. FOOD & DRUG ADMINISTRATION

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)**
- **How to use the 506J Notification Spreadsheet Template (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)**
- **Common error messages when using the 506J Notification webform (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)**
- **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)**

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) 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.

Submit Notifications Online

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

ve more than one FEI-product code combination, complete the form and select the "Add another interruption or
uance" 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:

o use the FDA 506J Notification Webform (https://www.fda.gov/media/151055/download)
e 506J Notification Submission Methods: Frequently Asked Questions (https://www.fda.gov/medical-devices/medical-
y-chain-and-shortages/online-506j-notification-submission-methods-frequently-asked-questions)

methods for submitting notifications to FDA, as well as links to additional resources on section 506J of the FD&C Act,
e FDA About a Medical Device Supply Chain Issue. (https://www.fda.gov/medical-devices/medical-device-supply-chai
s/notify-fda-about-medical-device-supply-issue)

cation Information

ed) Submitter First Name

*** (required) Submitter Last Name**

ed) Submitter Email Address

*** (required) Submitter Phone**

ed) Submitter Company Name

fier Information

uired) Notification Type

one--

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

FEI Number

uired) Product Code (Begin typing the product code and select it from the own list)

duct Code

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

d Secondary/Subsequent Product Code

ting Submission Holder

Marketing Submission Number (if more than one, use semicolons to separat 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 ers)

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 tinuance.

a pediatric device or includes pediatric sizes.

son(s) for discontinuance or interruption

uired) Reason(s) for discontinuance or interruption

ble

Chosen

uirements related to complying with good manufacturing practices

ulatory delay

er to divert devices from other US government entities

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

reasons not listed

ation of discontinuance or interruption

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

ted Duration Start Date

***Estimated Duration End Date**

ated Duration Other

nufacturing-specific inquiries

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

ble

Chosen

or shortages

: of protective equipment for employees

rtage or delay in raw material supply

onal details of issue(s).

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.

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

one--

litional Information, including possible mitigations

device manufactured on multiple lines?

one--

Is this device manufactured in multiple facilities?

--None--

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

one--

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

one--

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

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

one--

describe your shortage mitigation plans or add attachment.

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

t US Distribution per Month

Maximum Production Volume per Month

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

Add anothe

Submit and close | Submit and add attach

Attachments

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

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

Upload Files

tions?

ions about medical device shortages and notifications under section 506J of the Federal Food, Drug, and Cosmetic (FD upply and Shortages of Medical Devices: Frequently Asked Questions. (https://www.fda.gov/medical-devices/medical ain-and-shortages/supply-and-shortages-medical-devices-frequently-asked-questions) If your question is not answe you can email CDRHManufacturerShortage@fda.hhs.gov (mailto: CDRHManufacturerShortage@fda.hhs.gov) and incl n" 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) to submit a batch of 506J notifications.

Instructions: The Spreadsheet Template (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) 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) 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). Once you enter your data into the Spreadsheet Template (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)**
- **How to use the 506J Notification Spreadsheet Template (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)**

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)

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) 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.

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)**

FEI Number

*** (required) 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/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) 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.