U.S. FOOD & DRUG ADMINISTRATION

How to Use the 506J Notification Webform

Center for Devices and Radiological Health

Updated May 2023

Contents

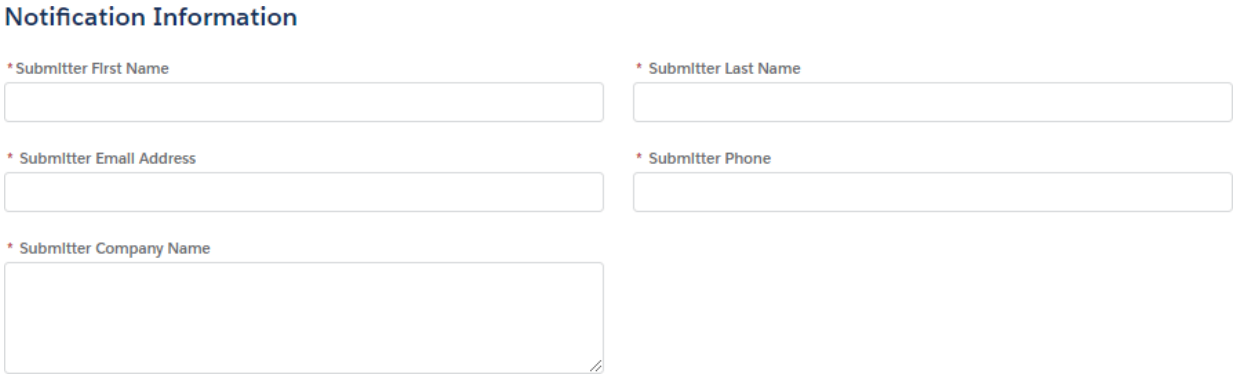
May 2023

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.

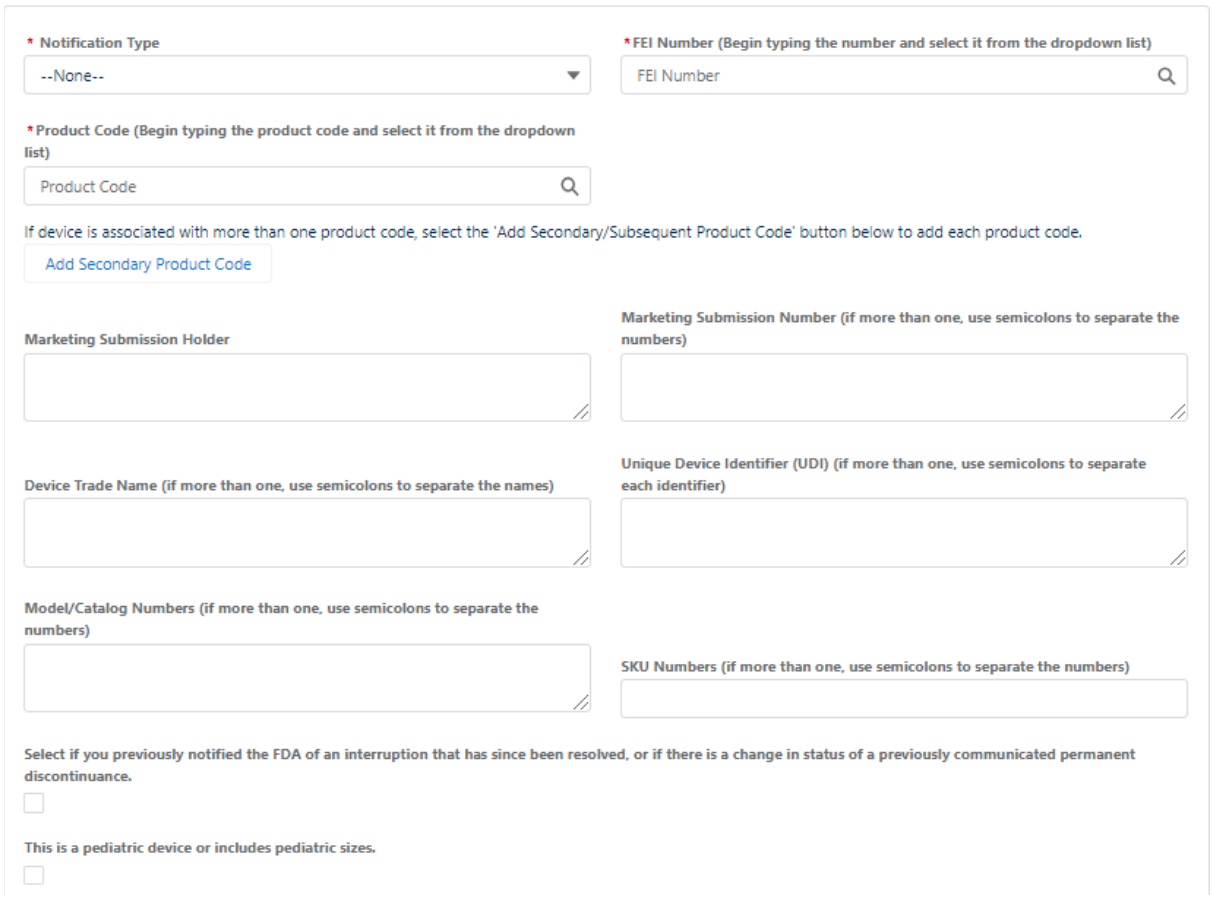
Please use Chrome, Microsoft Edge, or Firefox to fill out the webform.

Notification Information



- 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

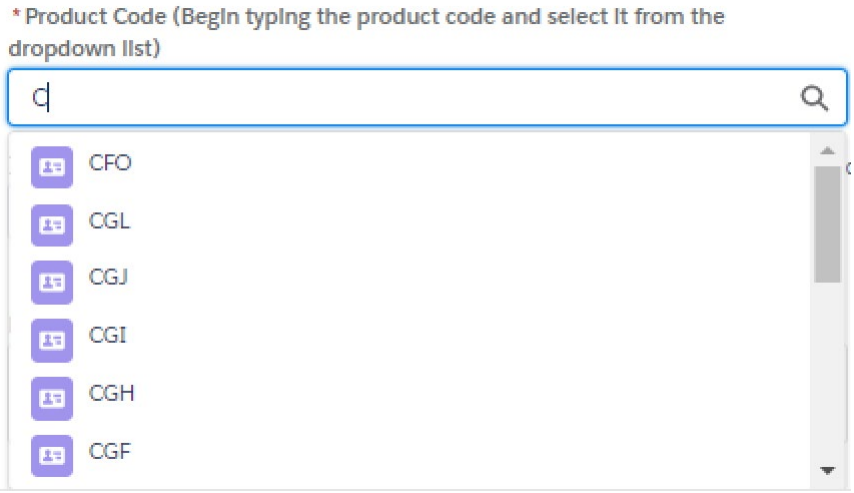


- Notification Type –Select the drop-down arrow and select “Initial” or “Update.” “Initial” indicates the submission is the FIRST from the Manufacturer for the specific FEI number or product code. “Update” indicates that the Manufacturer has followed-up on the first submission to the FDA for specific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

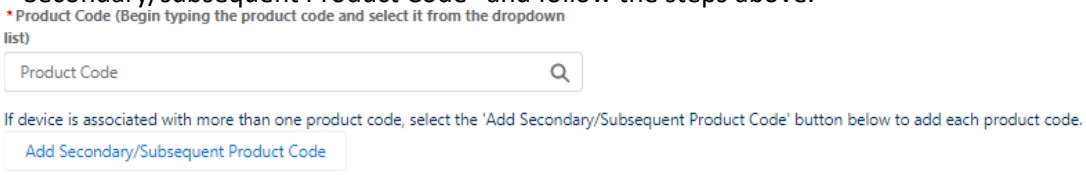
- FEI Number – Begin typing your FEI number and then select it from the drop-down list by Selecting in the list. Once selected the FEI number will display with the icon next to the number.

- 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.



- 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.

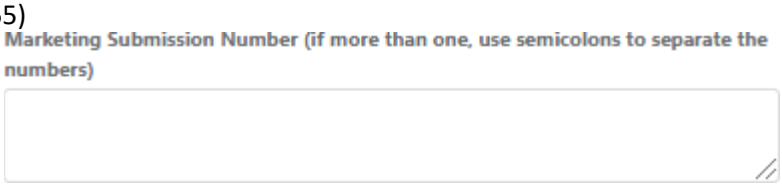


- If you have entered subsequent/secondary product codes in error, select the trash can icon to the right of the extra Product Code fields (this icon only appears for subsequent/secondary product codes).

- If your product code is not available, please contact the FDA for further instruction at CDRHManufacturerShortage@fda.hhs.gov 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.

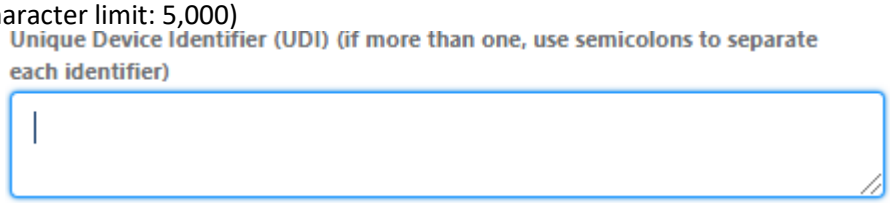
- Marketing Submission Holder – In the case that the original submission has been transferred or sold, type the name of the marketing submission holder. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

- Marketing Submission 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)

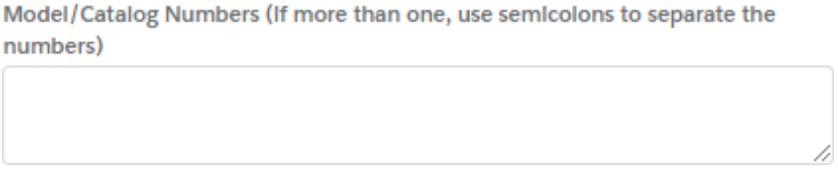


- Device Trade Name – Type the device trade name. If there is more than one, separate them with semicolons (;). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)

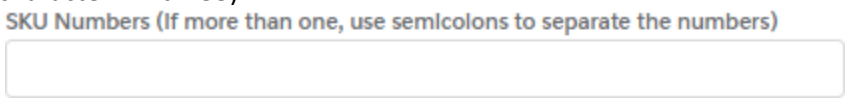
- UDI– Type the Unique Device Identifier (UDI). If there is more than one, separate them with semicolons (;). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 5,000)



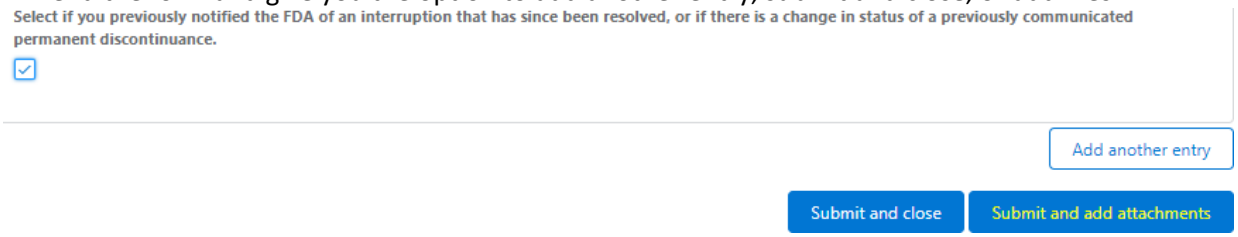
- Model/Catalog Numbers – Type the model or catalog numbers. If there is more than one, separate them with semicolons (;). This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: 20,000)



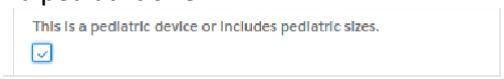
- SKU Numbers – Type the SKU numbers. If there is more than one, separate them with semicolons (;). (character limit: 255)



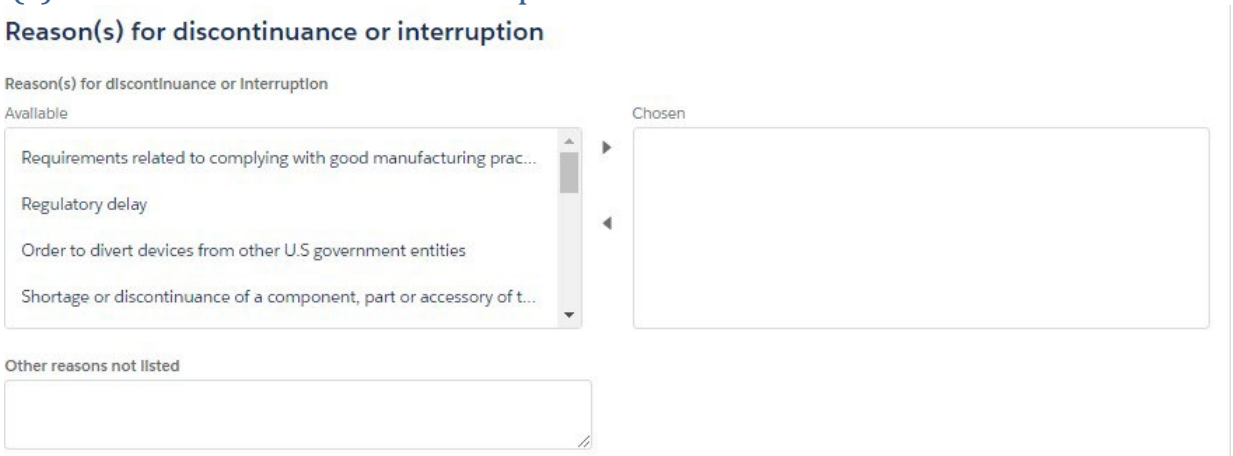
- For an interruption that has since been resolved, or if there is a change in status of a previously communicated permanent discontinuance, select the box under the question. Selecting this box will end the form and give you the option to add another entry, submit and close, or add files



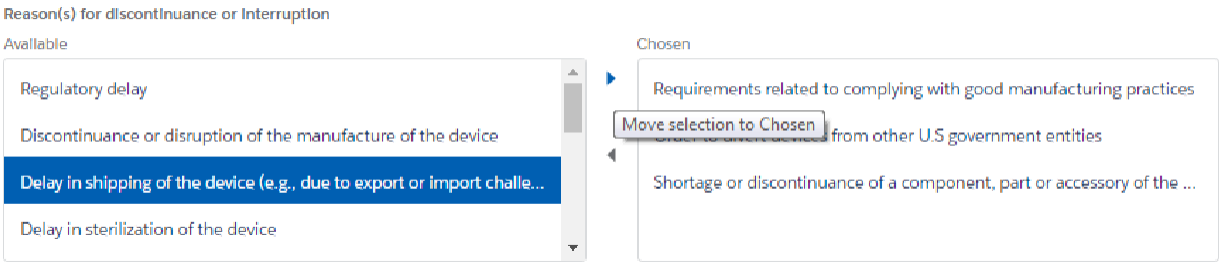
- For a pediatric device –Select the box under the question if the device is a pediatric device or comes in a pediatric size



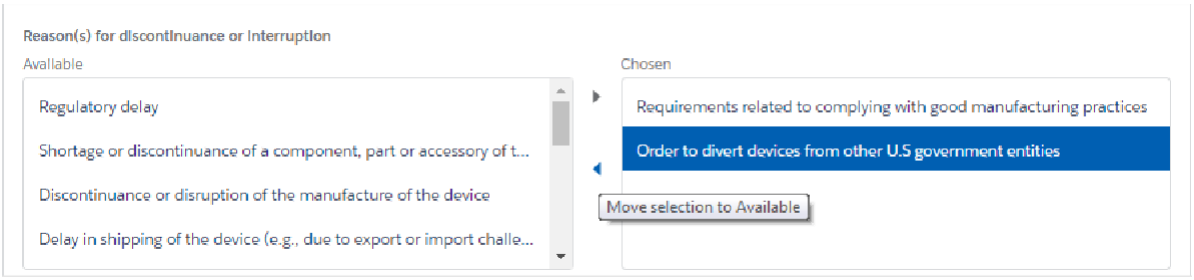
Reason(s) for discontinuance or interruption



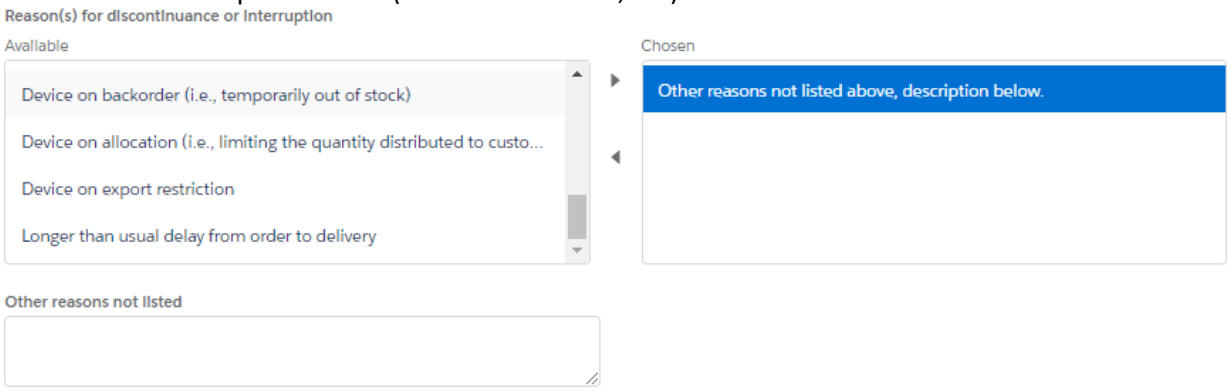
- Reason(s) for discontinuance or interruption – Select the reason(s) for the discontinuance or interruption by selecting the reason from the list available and selecting the right arrow between the “Available” and “Chosen” boxes. Multiple reasons can be moved at once by holding the control (Ctrl) key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



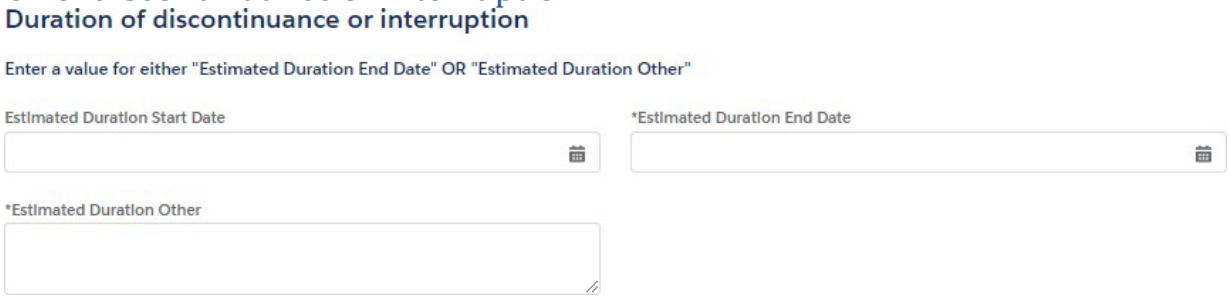
- If a reason is incorrectly selected, it can be removed by selecting the reason and then selecting the left arrow between the “Available” and “Chosen” boxes.



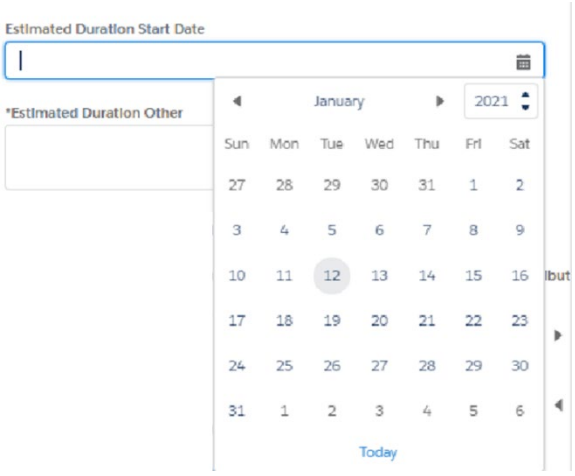
- If none of the reasons listed under the “Available” box describe the reason for your discontinuance or interruption, a text box is available for you to type a different reason that fits your situation. Select “Other reasons not listed above, description below” and then enter information into the provided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



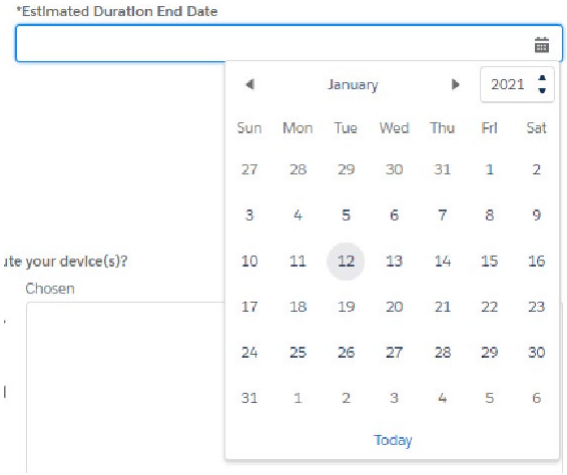
Duration of discontinuance or interruption



- 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.



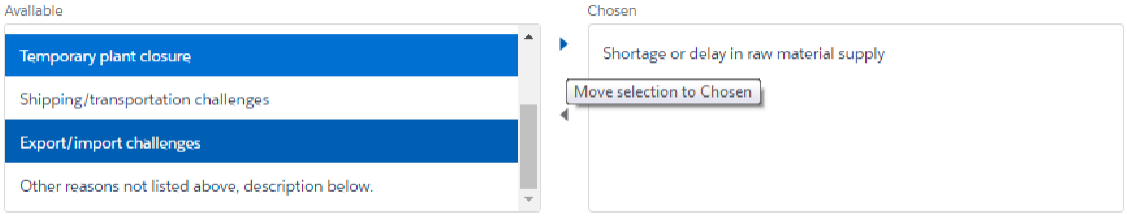
- Estimated Duration End Date –Select this field and use the calendar that appears and select the approximate end date of your discontinuance or interruption. The month can be changed by selecting the left and right arrows at the top; the year can be changed by selecting the field and selecting the correct 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.



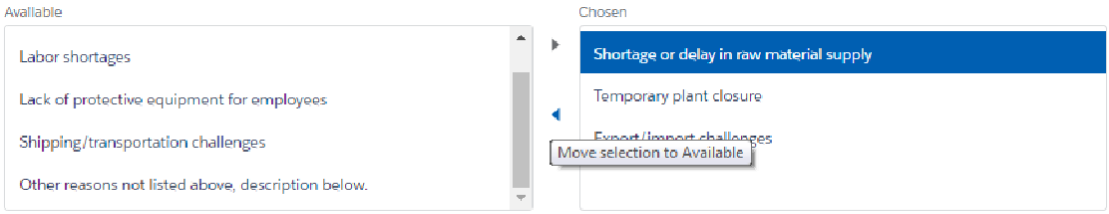
- Estimated Duration Other – If the duration of your discontinuance or interruption cannot be estimated to a date, this field can be utilized to type a response to describe the estimated duration. This field can be expanded by dragging the bottom right corner of the field up and down. (character limit: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

Manufacturing-specific inquiries

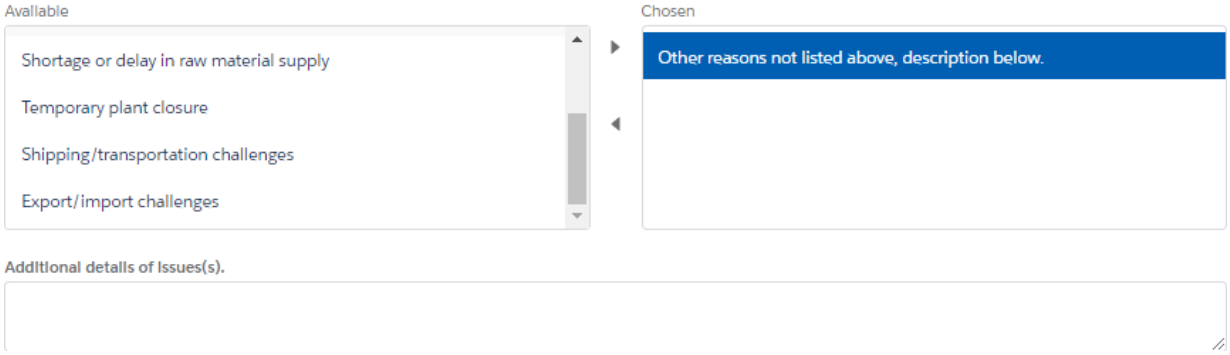
- Has your ability to manufacture or distribute your device(s) been affected? – Select the reason(s) that have impacted your ability to manufacture or distribute your device(s) by selecting the reason from the list available and selecting the right arrow between the "Available" and "Chosen" boxes. Multiple 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.



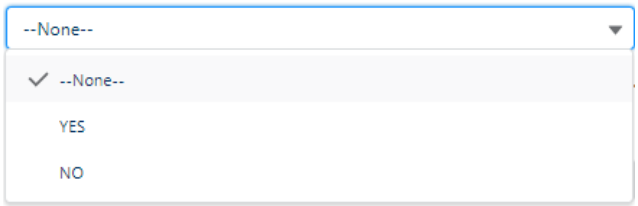
- If a reason is chosen accidentally, use the left arrow between the "Available" and "Chosen" boxes to remove a chosen reason.



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)



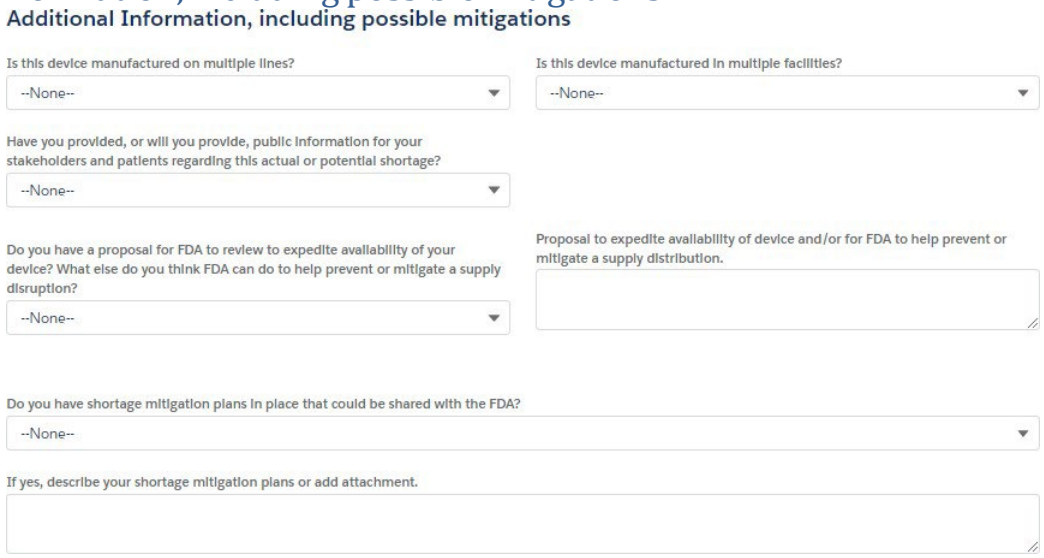
- Do you rely on any critical suppliers that might be affected by the interruption? – The default answer for this question is "None"; to select "Yes" or "No," use the drop-down menu.



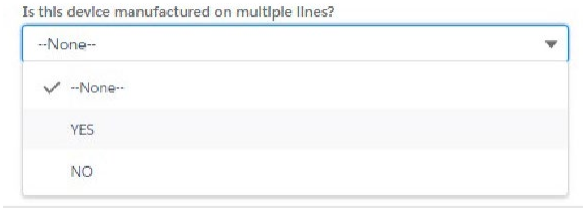
- If "Yes" is selected, provide a description in the text field to the right of this question. If your answer does not fit in the text field, provide information as an attachment. There is an "Add files" button at the bottom of this form to upload files as attachments. This field can be

expanded by dragging the bottom right corner of the field up and down. (character limit: 32,768)

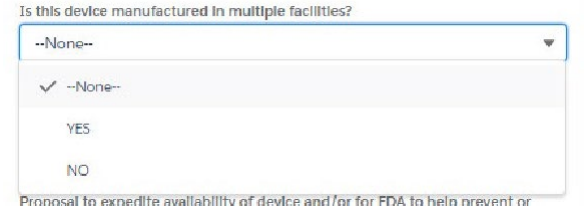
Additional Information, including possible mitigations



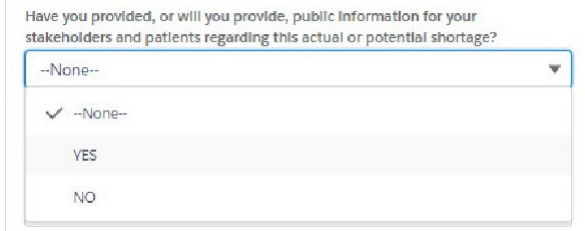
- Is this device manufactured on multiple lines – The default answer for this question is “None”; to select “Yes” or “No,” use the drop-down menu.



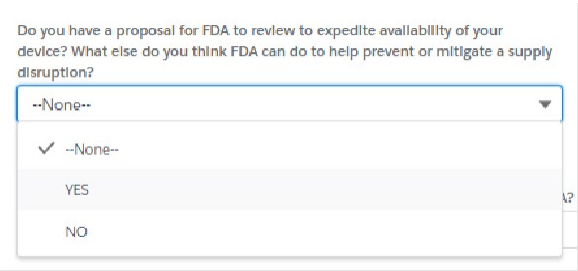
- Is this device manufactured in multiple facilities – The default answer for this question is “None;” to select “Yes” or “No,” use the drop-down menu.



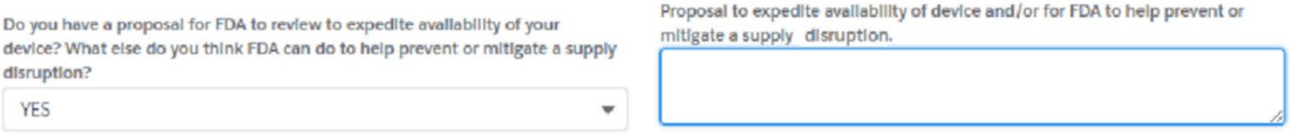
- Have you provided, or will you provide public information to your stakeholders and patients regarding this actual or potential shortage? – The default answer for this question is “None;” to select “Yes” or “No,” use the drop-down menu.



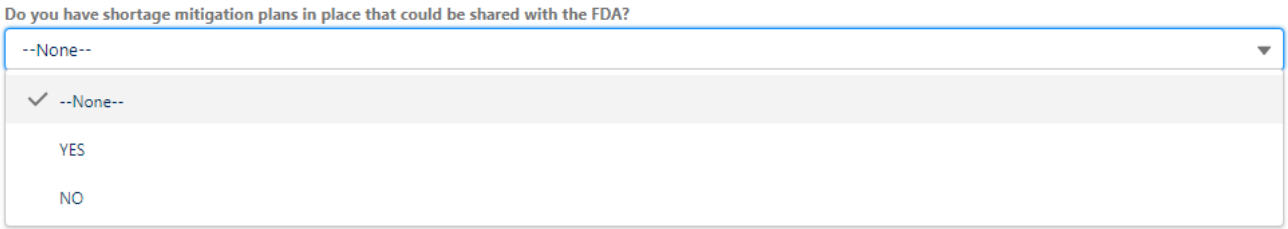
- Do you have a proposal for FDA to review to expedite availability of your device? – The default answer for this question is “None;” to select “Yes” or “No,” use the drop-down menu.



- 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)

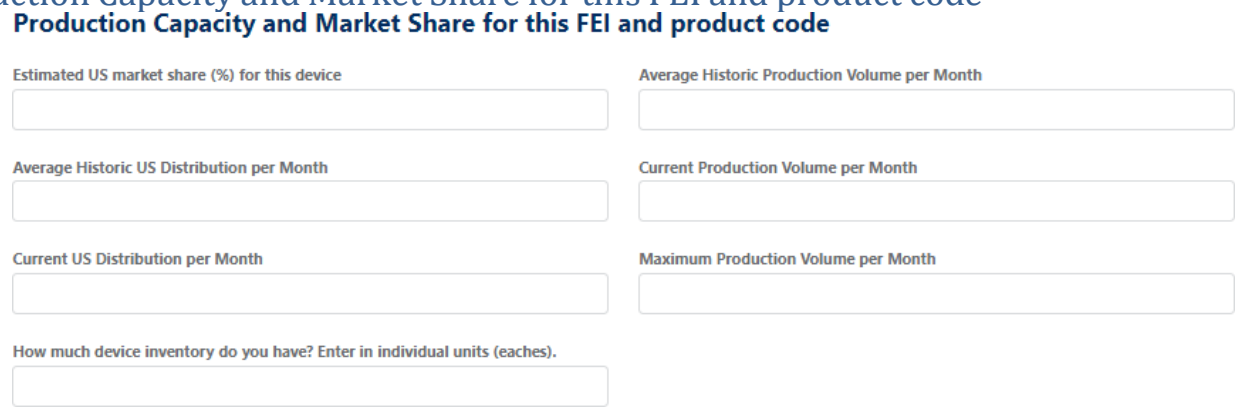


- Do you have shortage mitigation plans in place that could be shared with FDA? The default answer for this question is “None.” To select “Yes” or “No,” use the drop-down menu.

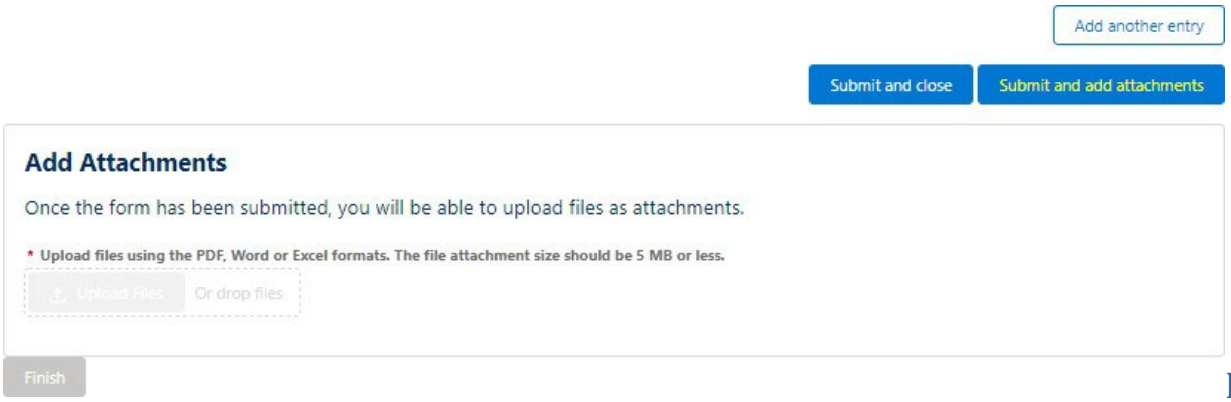


- If “Yes” is selected, provide a description in the text field below this question. If your answer does not fit in the text field, provide information as an attachment. There is an “Add files” button at the bottom of this form to upload files as attachments. This field can be expanded by dragging the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

Production Capacity and Market Share for this FEI and product code



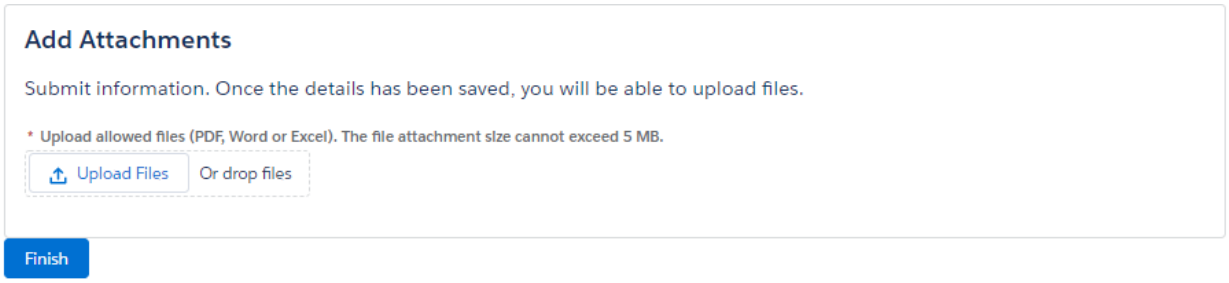
- Estimated US market share (%) for this device – Enter a number between 0 – 100 (character limit: unlimited but numerical values only)
- Average Historic Production Volume per Month – Enter a number (character limit: 14 numbers)
- Average Historic US Distribution per Month – Enter a number (character 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

- 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

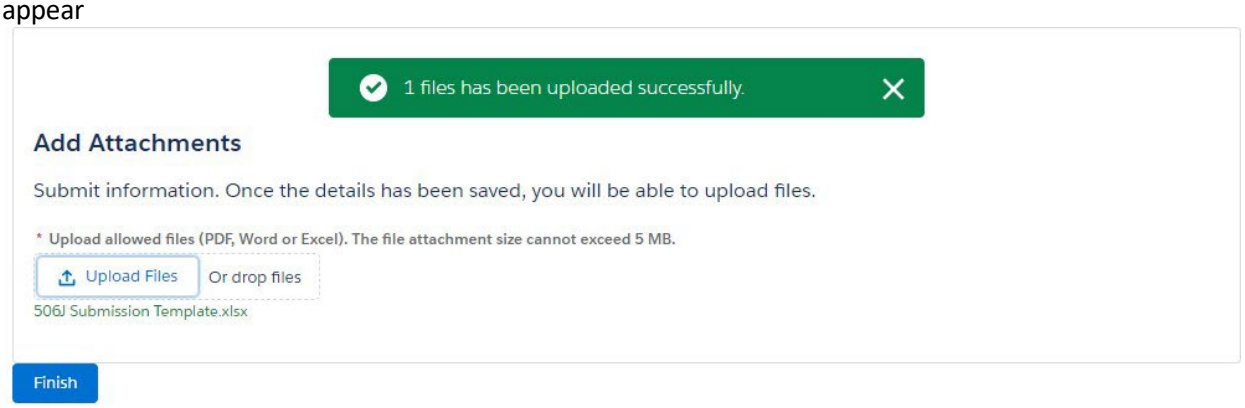


Submitting a Spreadsheet

- 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.

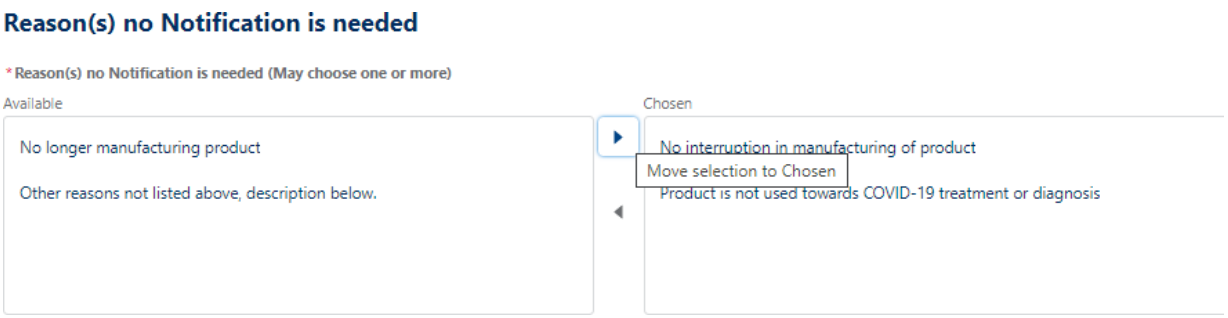
Select the template spreadsheet you filled with your information

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

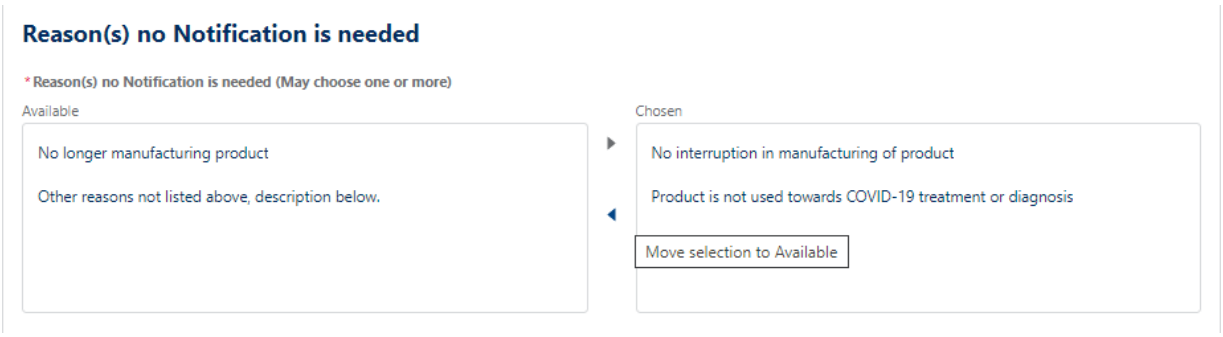


If indicating no interruption or permanent discontinuance

- 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.



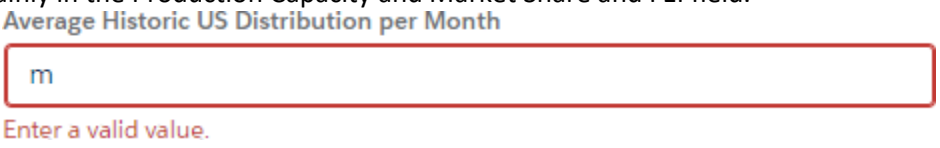
- If a reason is incorrectly selected, it can be removed by selecting the reason and then selecting the left arrow between the "Available" and "Chosen" boxes.



Error Messages

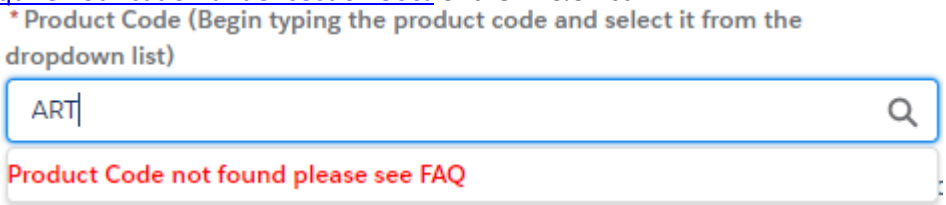
Enter a valid value

- 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.



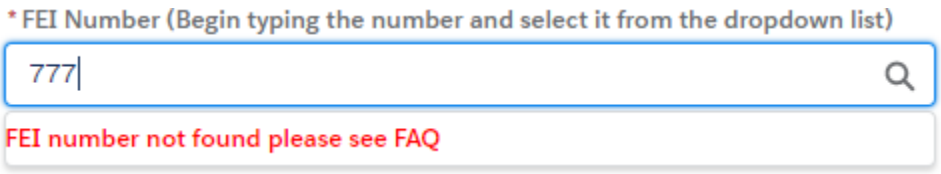
Product Code not found see FAQ

- 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.



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.



Enter a value

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

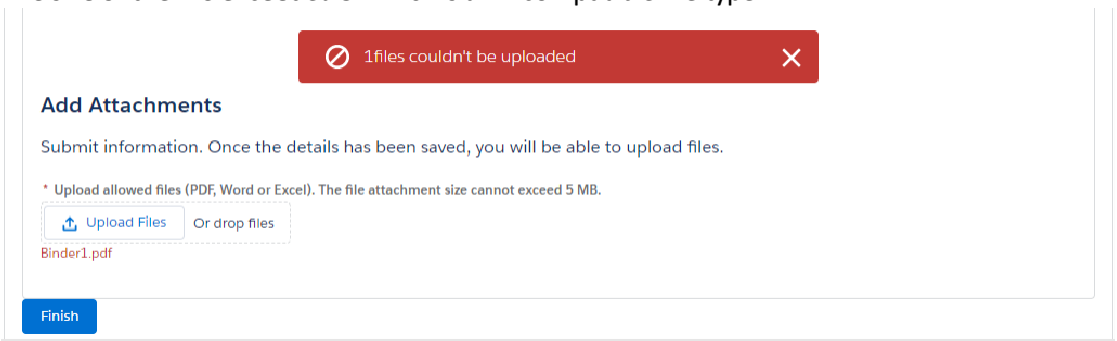
You have entered an invalid format

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

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

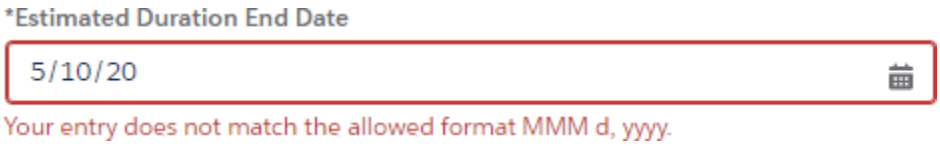
Upload errors

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



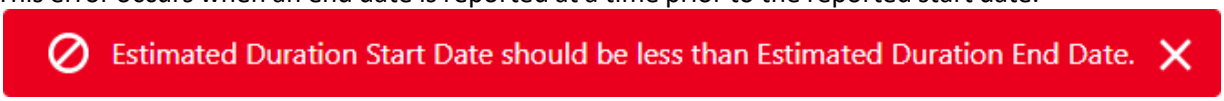
Your entry does not match the allowed format MMM d, yyyy

- 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 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.



Required field errors

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