U.S. FOOD & DRUG ADMINISTRATION

How to Use the 506J Notification Spreadsheet Template

Center for Devices and Radiological Health

Updated May 2023

Contents

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 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

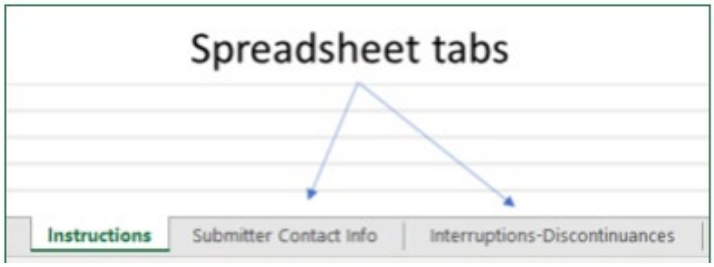
Instructions: Using This Template to Submit a Large Number of FEI-Product Code Combinations

This spreadsheet template provides a 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. This spreadsheet is updated to include new information from Establishment Registration and Device Listings.

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

Submitter Contact Info (* asterisk indicates information necessary for completeness)				
*Submitter First Name	*Submitter Last Name	*Submitter E-Mail	*Submitter Phone Number	*Submitter Company Name
Jane (Example)	Doe	Jane.Doe@medicaldevices.inc	+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 (* asterisk indicates information necessary for completeness)											
*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)

Medical Device Details

- 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

Manufacturing-specific inquiries

Manufacturing-specific inquiries							
Has your ability to manufacture or distribute your device(s) been affected? (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)	Additional Details of Issue(s)

- 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	
Do you rely on any critical suppliers that might be affected by the interruption? (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)	Do you have a proposal for the FDA to expedite availability of your device? (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 individual units (eaches)].

- 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 that 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)