Final Guidance: Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act

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Opening Remarks

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Final Guidance

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

Learning Objectives

- Background
- “Additional Notifications” (Section 506J(h))
- 506J Device List
- 506J Notifications and How Information is Used
- How to Notify the FDA of a Supply Disruption

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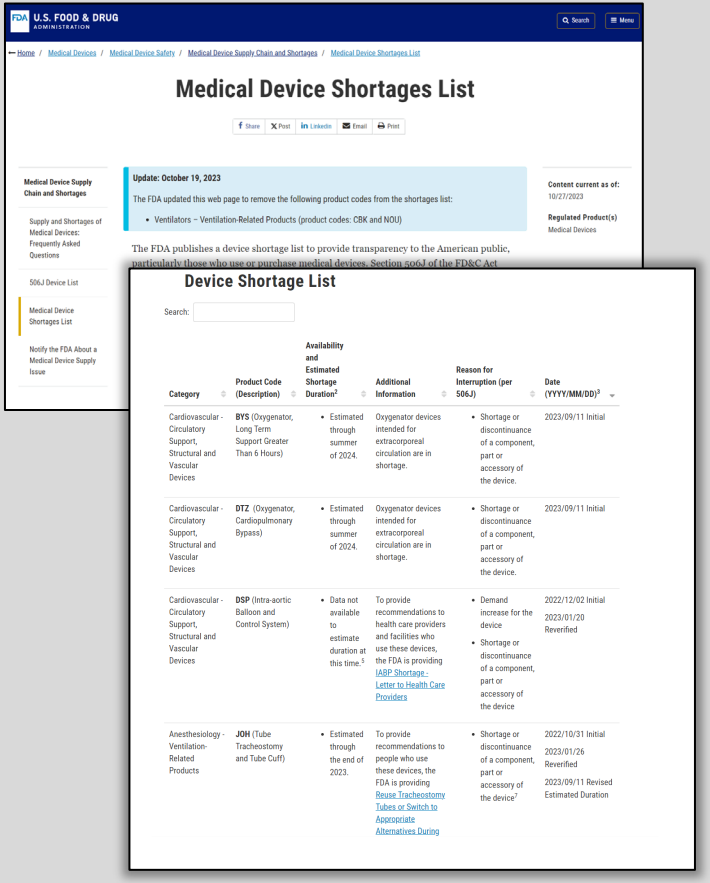
Background

The CARES Act and Section 506J: Manufacturer Obligations

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law on March 27, 2020

- **The CARES Act and Section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act):**
  - Gave FDA authorities to help prevent or mitigate medical device shortages
- **Requires manufacturers to notify FDA <u>during, or in advance of, a public health emergency</u> about:**
  - a permanent discontinuance or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in the supply of that device in the United States; and
  - the reasons for such discontinuance or interruption
- **Devices for which such notifications are required include those:**
  - that are critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery (section 506J(a)(1)); or
  - for which FDA determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency (section 506J(a)(2))

The CARES Act Added Section 506J



- **In general, under this authority, FDA must:**
  - establish and maintain a publicly available up-to-date list of devices that FDA determines to be in shortage in the U.S. (section 506J(g))
  - distribute information, "to the maximum extent practicable," on device discontinuances or interruptions to appropriate organizations, including physician, health provider, patient organizations, and supply chain partners, as appropriate (section 506J(c))
  - issue letters to those who fail to timely submit required 506J notifications to FDA and post these "failure to notify" letters on the FDA website *unless* we determine it was issued in error or the person had a reasonable basis for not notifying (section 506J(e))
  - prioritize and expedite the review of a premarket submission or facility inspection, as appropriate, that could help mitigate or prevent a shortage (section 506J(f))

Additional Notifications

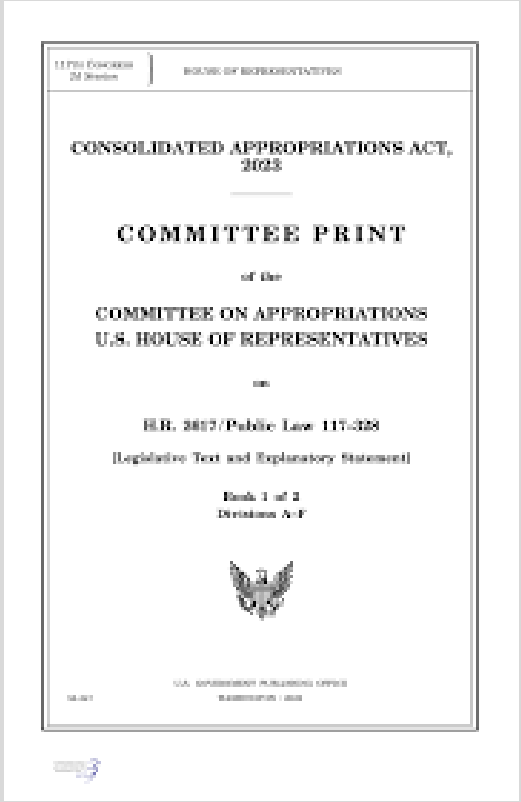
- Fiscal Year (FY) 2023 Omnibus* amended section 506J to add subsection (h), “Additional Notifications”:
  - Clarifies that FDA may receive voluntary notifications pertaining to the permanent discontinuance or interruption in the manufacture of a device at any time, unrelated to the declaration or potential declaration of a public health emergency
  - FDA has always accepted voluntary submissions of information across many topics, including device supply chain matters
  - 506J notifications are intended to supplement existing collaboration and communication between industry, FDA, and other interested parties

*Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) – Consolidated Appropriations Act (FY 2023 Omnibus)

FY 2023 Omnibus and Section 506J Guidance

Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) – Consolidated Appropriations Act (FY 2023 Omnibus):

- ***Additional Notifications:*** Section 2514(b) of the FY 2023 Omnibus directed FDA to issue draft guidance on voluntary notifications within one year of enactment of the Act and finalize within one year of the close of the comment period.
- ***506J Device List:*** Section 2514(c) of the FY 2023 Omnibus directed FDA to issue or revise draft guidance regarding requirements under section 506J and include a list of each device by FDA product code for which a manufacturer of such device is required to notify FDA in accordance with section 506J ("506J Device List")


CONSOLIDATED APPROPRIATIONS ACT, 2023

COMMITTEE PRINT

of the

COMMITTEE ON APPROPRIATIONS
U.S. HOUSE OF REPRESENTATIVES

on

H.R. 2617/Public Law 117-328

[Legislative Text and Explanatory Statement]

Book 1 of 2
Divisions A-F

November 2023: FDA Issued Two Guidance Documents

2023 Final Guidance: Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act

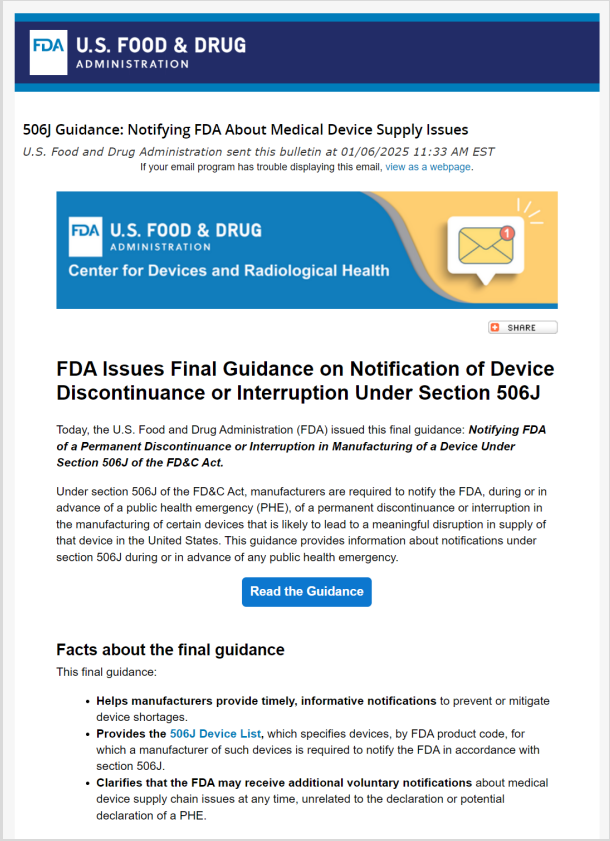
- Served as the baseline for information about notifications under section 506J during or in advance of a public health emergency

Draft Select Update Guidance: Select Updates for the 506J Guidance: 506J Device List and Additional Notifications

- Proposed select updates to the 506J Guidance issued November 2023
- Addressed the FY 2023 Omnibus requirements:
    - Clarified that FDA may receive additional voluntary notifications about medical devices at any time, unrelated to the declaration or potential declaration of a public health emergency (section 2514(b) of the FY 2023 Omnibus).
    - Issued Draft 506J Device List (section 2514(c) of the FY 2023 Omnibus).

506J Final Guidance

- Published January 7, 2025
- Supersedes the previous 506J Guidance published in November 2023
- The 506J Final Guidance:
  - Clarifies that FDA may receive voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a public health emergency (Omnibus § 2514(b)).
  - Includes the 506J Device List for which manufacturers of devices that FDA has identified by product code on this list are required to submit 506J notifications when statutory conditions are met (Omnibus § 2514(c)).



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506J Guidance: Notifying FDA About Medical Device Supply Issues

U.S. Food and Drug Administration sent this bulletin at 01/06/2025 11:33 AM EST

If your email program has trouble displaying this email, view as a webpage.

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

SHARE

FDA Issues Final Guidance on Notification of Device Discontinuance or Interruption Under Section 506J

Today, the U.S. Food and Drug Administration (FDA) issued this final guidance: ***Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.***

Under section 506J of the FD&C Act, manufacturers are required to notify the FDA, during or in advance of a public health emergency (PHE), of a permanent discontinuance or interruption in the manufacturing of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States. This guidance provides information about notifications under section 506J during or in advance of any public health emergency.

Read the Guidance

Facts about the final guidance

This final guidance:

- **Helps manufacturers provide timely, informative notifications** to prevent or mitigate device shortages.
- **Provides the 506J Device List,** which specifies devices, by FDA product code, for which a manufacturer of such devices is required to notify the FDA in accordance with section 506J.
- **Clarifies that the FDA may receive additional voluntary notifications** about medical device supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE.

Additional Notifications

Examples of When FDA Recommends Submission of Additional Voluntary 506J Notifications

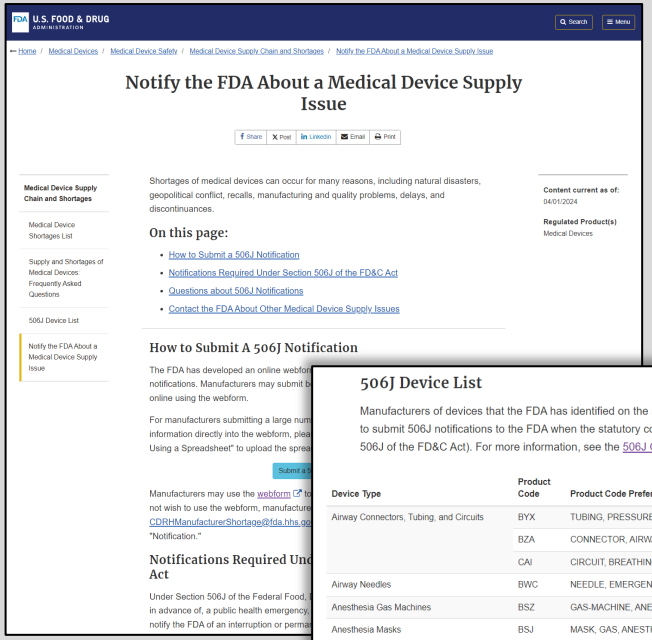
(Outlined in the 506J Guidance)

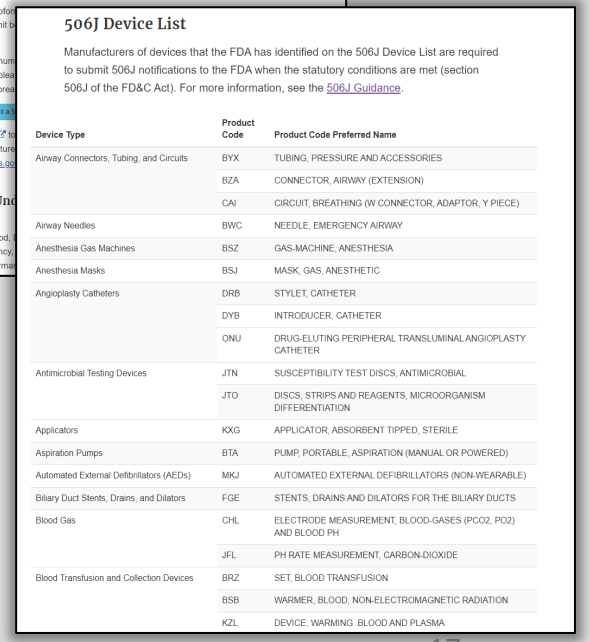
- Unplanned manufacturing challenges (such as labor shortages, delays in raw material supply, temporary plant closures, packaging or sterilization concerns, or other unforeseen circumstances that prevent the manufacturer from meeting demand);
- Unplanned distribution challenges (such as shipping/transportation delays, export/import challenges, procurement issues);
- Increased or projected increased demand unable to be met by the manufacturer (such as backorder, allocation, low fulfillment rates);
- Potential broader/connected interruptions (such as reliance on critical suppliers who are experiencing supply chain interruptions); and
- Circumstances affecting software-enabled device availability that may lead to a shortage (such as cybersecurity events).

The 506J Device List

The 506J Device List

- Manufacturers of devices that FDA has identified by product code on the 506J Device List are required to submit 506J notifications to the FDA when statutory conditions are met
  - 506J Device List resides on the FDA webpage: www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list
  - The list will evolve over time and FDA intends to periodically re-evaluate the list
  - Any revisions to the 506J Device List will follow the FDA's Good Guidance Practices
  - The list also includes CBER-regulated medical devices in accordance with the criteria set forth in section 506J(a)





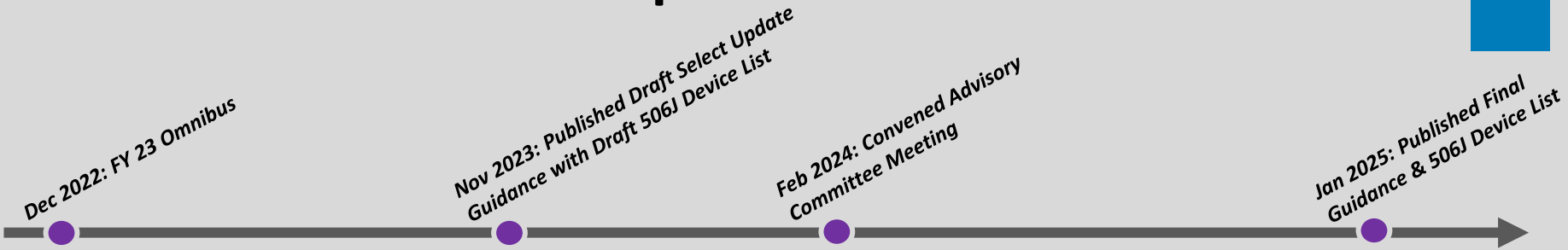
506J Device List

Manufacturers of devices that the FDA has identified on the 506J Device List are required to submit 506J notifications to the FDA when the statutory conditions are met (section 506J of the FD&C Act). For more information, see the 506J Guidance.

Device Type	Product Code	Product Code Preferred Name
Airway Connectors, Tubing, and Circuits	BYX	TUBING, PRESSURE AND ACCESSORIES
	BZA	CONNECTOR, AIRWAY (EXTENSION)
	CAI	CIRCUIT, BREATHING (W CONNECTOR, ADAPTOR, Y PIECE)
Airway Needles	BWC	NEEDLE, EMERGENCY AIRWAY
Anesthesia Gas Machines	BSZ	GAS-MACHINE, ANESTHESIA
Anesthesia Masks	BSJ	MASK, GAS, ANESTHETIC
Angioplasty Catheters	DRB	STYLET, CATHETER
	DYB	INTRODUCER, CATHETER
	ONU	DRUG-ELUTING PERIPHERAL TRANSLUMINAL ANGIOPLASTY CATHETER
Antimicrobial Testing Devices	JTN	SUSCEPTIBILITY TEST DISCS, ANTIMICROBIAL
	JTO	DISCS, STRIPS AND REAGENTS, MICROORGANISM DIFFERENTIATION
Applicators	KXG	APPLICATOR, ABSORBENT TIPPED, STERILE
Aspiration Pumps	BTA	PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)
Automated External Defibrillators (AEDs)	MKJ	AUTOMATED EXTERNAL DEFIBRILLATORS (NON-WEARABLE)
Biliary Duct Stents, Drains, and Dilators	FGE	STENTS, DRAINS AND DILATORS FOR THE BILIARY DUCTS
Blood Gas	CHL	ELECTRODE MEASUREMENT, BLOOD-GASES (PCO2, PO2) AND BLOOD PH
	JFL	PH RATE MEASUREMENT, CARBON-DIOXIDE
Blood Transfusion and Collection Devices	BRZ	SET, BLOOD TRANSFUSION
	BSB	WARMER, BLOOD, NON-ELECTROMAGNETIC RADIATION
	KZL	DEVICE, WARMING, BLOOD AND PLASMA

CBER: Center for Biologics Evaluation and Research

506J Device List Development



1 Developed the Draft 506J Device List

- Compiled an initial list of devices (by product code)
- Evaluated each product code against the statutory criteria outlined in section 506J
- Considered device characteristics and availability of suitable alternatives

2 Solicited and Considered Feedback

- Convened Advisory Committee Meeting
- Reviewed feedback from Advisory Committee and Docket, and Guidance Docket

3 Refined and Published 506J Device List

- Used public input and internal subject matter experts to refine 506J Device List consistent with section 506J
- Published 506J Device List

Development of Draft 506J Device List

Developed the Draft 506J Device List

- **Working sessions with clinical advisors and CDRH subject matter experts to identify devices that met the statutory criteria**

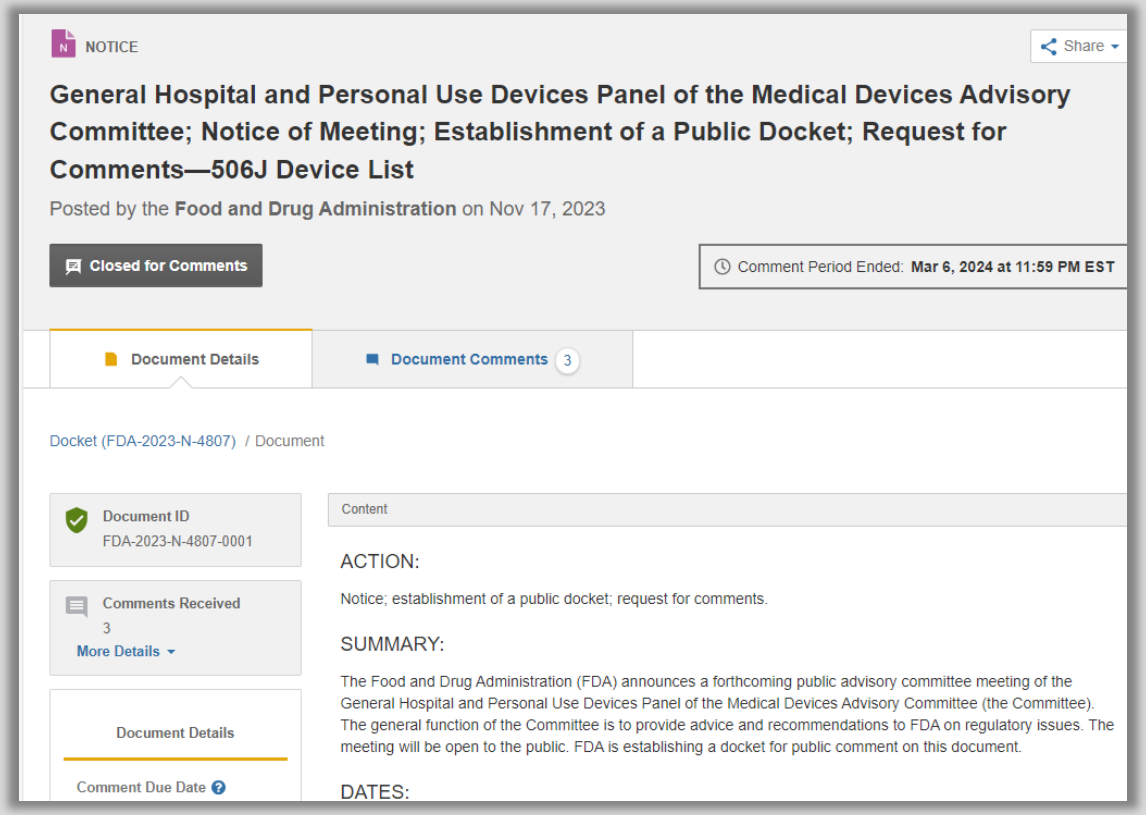
Devices that were considered for inclusion on the 506J Device List included those:

- **"that are critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery"** (section 506J(a)(1))
- In its deliberations, the FDA also considered:
  - Whether the device is used to diagnose, treat, monitor, or prevent a serious disease or medical condition;
  - Whether the lack of availability of the device is reasonably likely to cause serious injury or death to patients, healthcare workers, or others if it is not available and there are no suitable alternatives
- FDA focused on those devices that are critical to public health during a public health emergency

Solicited Feedback on the Draft 506J Device List

Feedback from Advisory Committee and Public Dockets

- **Feb 6, 2024 - Convened the General Hospital and Personal Use Devices Panel members to discuss and make recommendations (Advisory Committee)**
- **Solicited feedback via public dockets**
  - **FDA-2022-D-0053 (Draft Guidance)**
  - **FDA-2023-N-4807 (Advisory Committee)**



NOTICE

Share

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—506J Device List

Posted by the **Food and Drug Administration** on Nov 17, 2023

Closed for Comments

Comment Period Ended: **Mar 6, 2024 at 11:59 PM EST**

Document Details | Document Comments 3

Docket (FDA-2023-N-4807) / Document

Document ID
FDA-2023-N-4807-0001

Comments Received
3
More Details

Document Details

Comment Due Date

Content

ACTION:

Notice; establishment of a public docket; request for comments.

SUMMARY:

The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES:

Objectives of Advisory Committee Meeting

- **Obtain feedback on the draft 506J Device List**
  - Whether the proposed devices (by product code) meet the requirements outlined in section 506J of the FD&C Act
  - How supply chain resilience and vulnerabilities should be considered when determining device types (by product code) for inclusion or exclusion on the 506J Device List
  - How specific characteristics of a device type should be considered, such as:
    - Single-use disposable vs. multi-patient reusable devices
    - Convenience kits
    - Capital equipment (for example, imaging devices)
  - Additional considerations with respect to pandemic preparedness and response (per section 3302 of the “FY 2023 Omnibus”)

Key Themes from the Advisory Committee

- Prioritize or tier the list to reflect variation, severity, and size of different types of public health emergencies
- Include additional device types used in surgery, respiratory care, and diagnostic testing, including kits, such as those used to gain vascular access
- List should contain accessories that are necessary to support, supplement, and/or augment parent devices included on the list
- Consider true “single-use” vs. those that could be safely reprocessed and reused during an emergency event
- Consider how listed devices are used in pediatric or other special populations and specifically indicate if there are certain “sizes” of devices included on the list for use in pediatric populations.
- Panelists recommended supply chain resilience and vulnerabilities should not be considered when determining a medical device's criticality and inclusion or exclusion from the list

Key Themes from the Comments

- Consider pediatric or other special populations
- Product code complexity
  - Product codes can contain a range of devices and accessories
- Include devices needed to ensure resiliency in blood supply chain
- Consider other lists which may have additional priority devices

506J Device List

506J Device List

- **Reviewed comments and feedback provided from the Advisory Committee and Public Dockets**
- **Where appropriate, incorporated feedback and refined the draft list consistent with Section 506J**

- The FDA working group considered comments and recommendations submitted to the dockets
- Key focus areas for the review included:
  - Reviewing devices specifically mentioned during the Advisory Committee and in the docket comments against the statutory criteria
  - A clinical evaluation to confirm devices would be required for responding to public health emergency
  - Natural disaster, pandemic, CBRNE event
  - FDA current information and previous experiences with shortages

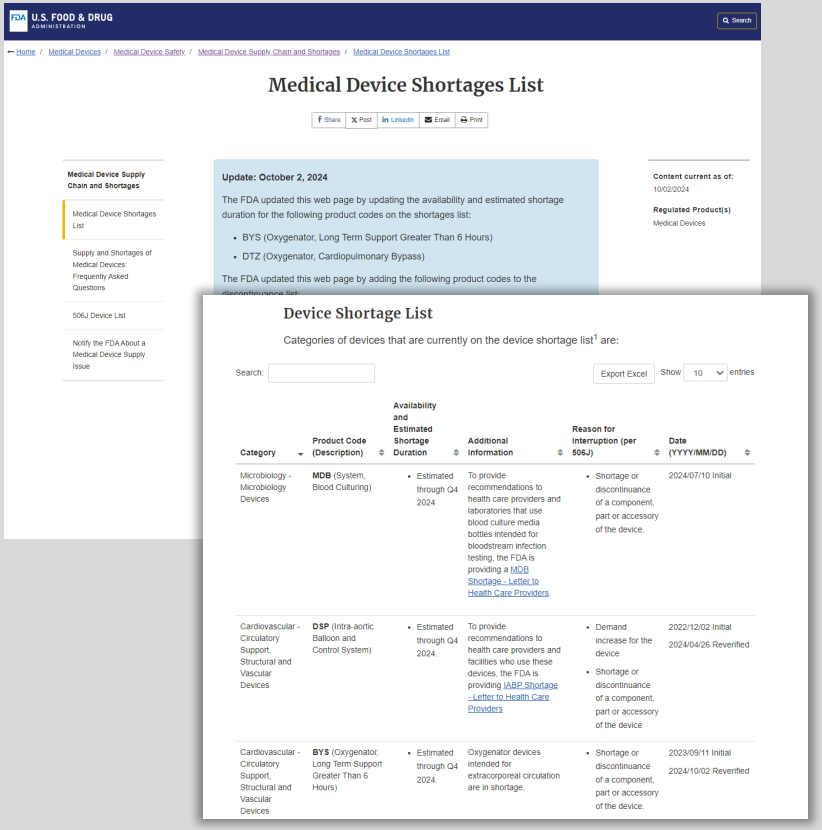
CBRNE: Chemical, Biological, Radiological, Nuclear, and Explosives

How the FDA Uses 506J Notifications

Medical Device Shortage List

- After conducting a shortage assessment, the FDA will determine if the medical device is in shortage or if a shortage is imminent.

- If the FDA concludes there is a shortage, the FDA will add the device product code to the Medical Device Shortage List and issue communications to impacted parties.



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Home / Medical Devices / Medical Device Safety / Medical Device Supply Chain and Shortages / Medical Device Shortages List

Medical Device Shortages List

Medical Device Supply Chain and Shortages

- Medical Device Shortages List
- Supply and Shortages of Medical Devices: Frequently Asked Questions
- 506J Device List
- Notify the FDA About a Medical Device Supply Issue

Update: October 2, 2024

The FDA updated this web page by updating the availability and estimated shortage duration for the following product codes on the shortages list:

- BYS (Oxygenator, Long Term Support Greater Than 6 Hours)
- DTZ (Oxygenator, Cardiopulmonary Bypass)

The FDA updated this web page by adding the following product codes to the

Content current as of: 10/02/2024

Regulated Product(s) Medical Devices

Device Shortage List

Categories of devices that are currently on the device shortage list[1] are:

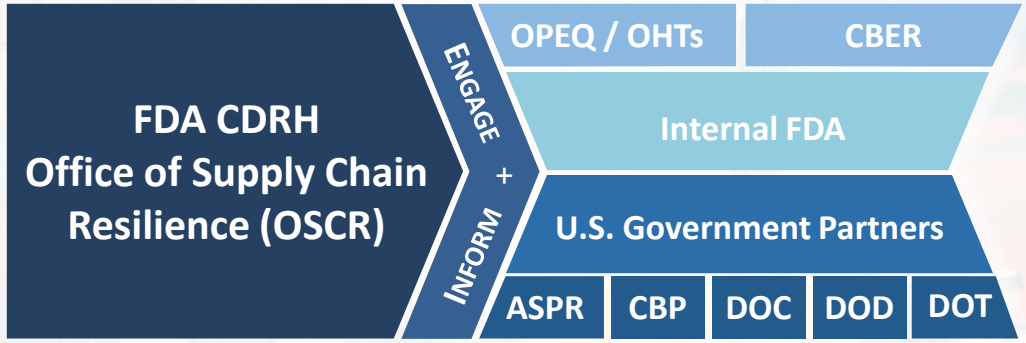
Search: Export Excel Show 10 entries

Category	Product Code (Description)	Availability and Estimated Shortage Duration	Additional Information	Reason for Interruption (per 506J)	Date (YYYY/MM/DD)
Microbiology - Microbiology Devices	**MDB** (System, Blood Culturing)	• Estimated through Q4 2024	To provide recommendations to health care providers and laboratories that use blood culture media bottles intended for bloodstream infection testing, the FDA is providing a MDB Shortage - Letter to Health Care Providers.	• Shortage or discontinuance of a component, part or accessory of the device.	2024/07/10 Initial
Cardiovascular - Circulatory Support, Structural and Vascular Devices	**DSP** (Intra-aortic Balloon and Control System)	• Estimated through Q4 2024.	To provide recommendations to health care providers and facilities who use these devices, the FDA is providing IABP Shortage - Letter to Health Care Providers	• Demand increase for the device • Shortage or discontinuance of a component, part or accessory of the device	2022/12/02 Initial 2024/04/26 Reverified
Cardiovascular - Circulatory Support, Structural and Vascular Devices	**BYS** (Oxygenator, Long Term Support Greater Than 6 Hours)	• Estimated through Q4 2024.	Oxygenator devices intended for extracorporeal circulation are in shortage.	• Shortage or discontinuance of a component, part or accessory of the device.	2023/09/11 Initial 2024/10/02 Reverified

506J Notifications: What We Do

CDRH uses 506J notifications to conduct Medical Device Shortage and Patient Impact Assessments which are then used to inform the use of potential prevention and mitigation strategies.

CDRH leads efforts to assess patient impact and mitigate medical device shortages



Example Prevention and Mitigation Strategies

Regulatory Mitigation Strategies:

- Expedited premarket submissions
- Emergency Use Authorizations (EUAs)
- Regulatory Discretion
- Letters to Healthcare Providers (LHCP)

Non-Regulatory Mitigation Strategies:

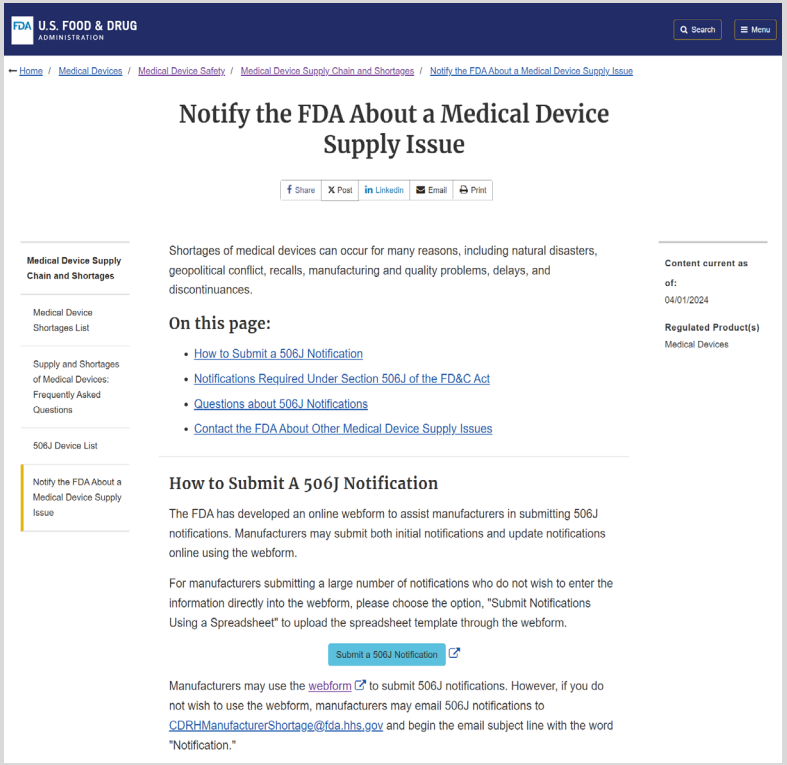
- Actions by other U.S. Government partners, including:
  - Transportation prioritization (CBP; DOT)
  - Defense Production Act (DPA) Priority Ratings and priority request letters
  - Clearance through CBP

OPEQ: Office of Product Evaluation and Quality; OHT: Office of Health Technology; ASPR: Administration for Strategic Preparedness & Response; CBP: Customs & Border Protection; DOC: Department of Commerce; DOD: Department of Defense; DOT: Department of Transportation

How to Notify FDA of a Supply Disruption

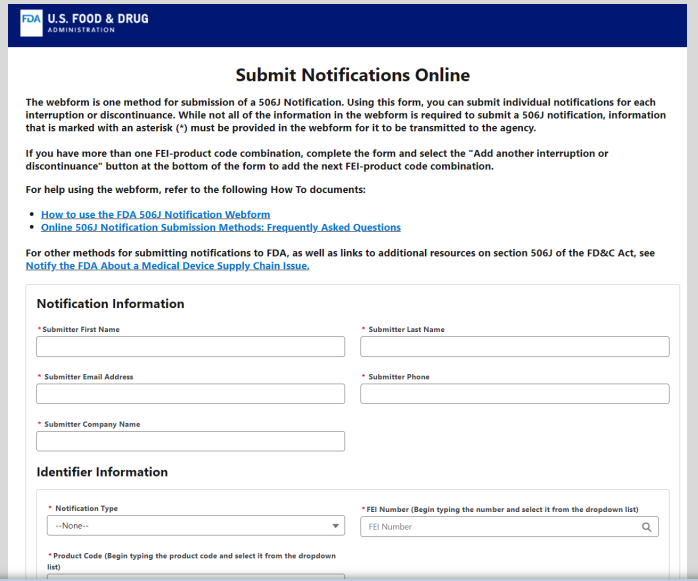
How to Submit a 506J Notification

- FDA's website, Notify the FDA About a Medical Device Supply Issue, contains the most current information about submitting 506J notifications to FDA
- Ways to submit a 506J Notification:
  - 506J Webform
  - 506J Spreadsheet Template (batch submissions)
  - Email



What Information to include in 506J Notifications

- The category or name of the device that is the subject of the 506J notification;
- The name of the manufacturer submitting the 506J notification;
- The reason for the 506J notification; and
- The estimated duration of the discontinuance or interruption of the device that is the subject of the notification.



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Submit Notifications Online

The webform is one method for submission of a 506J Notification. Using this form, you can submit individual notifications for each interruption or discontinuance. 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.

If you have 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.

For help using the webform, refer to the following How To documents:

- How to use the FDA 506J Notification Webform
- 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.

Notification Information

* Submitter First Name
* Submitter Last Name
* Submitter Email Address
* Submitter Phone
* Submitter Company Name

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)

Any information provided to FDA that is trade secret or confidential information will be treated as such, consistent with section 552(b)(4) of title 5, United States Code, section 1905 of title 18, United States Code, and other applicable laws.

Resources

Slide Number	Cited Resource	URL
4	506J Final Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc
13, 17	506J Device List	www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list
29	Notify the FDA About a Medical Device Supply Issue	www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/notify-fda-about-medical-device-supply-issue

Summary

- Section 506J requires manufacturers to notify FDA—during or in advance of a public health emergency—of a permanent discontinuance or interruption in the manufacturing of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States
- The final guidance issued in January 2025 supersedes the previous guidance issued in November 2023 and clarifies that FDA may receive voluntary notifications at any time
- The 506J Device List provides a list of devices, by product code, for which a manufacturer of such devices is required to notify the FDA in accordance with section 506J
- Manufacturers can follow the instructions on the “Notify the FDA About a Medical Device Supply Issue” website to submit 506J notifications


FDA
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ADMINISTRATION

Previously Submitted Questions

Previously Submitted Questions 1-2

Previously Submitted Questions 3-4

Your Call to Action

Your Call to Action

- Review 506J Guidance
- Review 506J Device List
- Notify the FDA during or in advance of a public health emergency—of a permanent discontinuance or interruption in the manufacturing of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States
- If you are unsure whether you need to submit a notification, contact us at CDRHManufacturerShortage@fda.hhs.gov or cbershortage@fda.hhs.gov, and include “Question” in the subject line of the email

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (9 am – 12:30 pm; 1 – 4:30 pm ET)


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