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

Moderator: CAPT Kim Piermatteo
Presenters: Dr. Suzanne Schwartz, Dr. Tammy Beckham and Erin Quencer

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CAPT Kim Piermatteo: Hello this is CAPT Kim Piermatteo of the United States Public Health Service and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within FDA's Center for Devices and Radiological Health.

I'll be the moderator for this presentation on the final guidance titled, Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Food, Drug, and Cosmetic Act, or FD&C Act, which was issued on January 7, 2025.

This guidance is intended to assist interested parties in the implementation of Section 506J of the FD&C Act. It serves as the baseline for information about notifications under Section 506J during or in advance of any public health emergency. This guidance includes a list of devices, by FDA product code, for which a manufacturer of such devices is required to notify FDA in accordance with Section 506J of the FD&C Act.

During this presentation you will hear from: Dr. Suzanne Schwartz, Director of CDRH's Office of Strategic Partnerships and Technology Innovation or OST; Dr. Tammy Beckham, Director of OST's Office of Supply Chain Resilience; and Erin Quencer, Senior Regulatory Policy Analyst in CDRH's Office of Policy.

I'll now turn it over to Dr. Suzanne Schwartz to start the presentation.

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Dr. Suzanne Schwartz: Good afternoon. Thank you, Kim and Tammy for the opportunity to speak. I'd like to thank all of today's participants for joining to learn more about the 506J guidance and 506J device list. I'd like to open today's webinar by providing some background on CDRH's work to mitigate medical device shortages and share some context around the 506J guidance documents.

At the FDA, our mission is to protect and promote the public health. For CDRH, that includes assuring safe and effective medical devices are available for our nation's patients and healthcare providers. As the COVID-19 Public Health Emergency and other more recent natural disasters have shown, the medical device supply chain is fragile and complex. Underlying vulnerabilities in the supply chain mean that when a disruption occurs, whether from geopolitical events, economic forces, regulatory changes, natural disasters or other emergencies, shortages of medical devices are likely to result. And when there are shortages of medical devices, these tend to disproportionately put vulnerable patient populations at risk.

As we've seen, disruptions are uniquely challenging for pediatric patients from premature infants in neonatal intensive care units to children with chronic illnesses requiring long term medical interventions. The need for appropriately sized high-quality devices is paramount. With that visibility into the supply chain, hospitals and health systems are ill prepared to address shortages, forcing them to rely on unpredictable or ad hoc solutions which often increase the risk of serious complications.

Over the past several years, the Office of Supply Chain Resilience, or OSCR for short, has analyzed hundreds of potential shortages and collaborated with stakeholders to mitigate shortages of essential

devices, including blood collection tubes, saline flush syringes, tracheostomy tubes and more. As part of its role, OSCR identifies and communicates shortages as outlined under Section 506J of the FD&C Act, which was enacted by Congress in March 2020, as a result of the widespread disruptions early on in the COVID-19 Public Health Emergency. Under Section 506J manufacturers of certain devices are required to notify the FDA of an interruption in the manufacturing or discontinuance of those devices during or in advance of a public health emergency.

In December 2022, Congress enacted the Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act, otherwise known as PREVENT Pandemics Act. As part of the Consolidated Appropriations Act of 2023, also referred to as the 2023 Omnibus. This Act directed the FDA to publish guidance to facilitate voluntary notifications outside of a public health emergency, and also directed the FDA to issue new guidance on requirements under Section 506J that includes a list of each device by product code for which a manufacturer of such devices is required to notify the FDA during or in advance of a public health emergency.

In November 2023, we published draft guidance to facilitate voluntary notifications and published the proposed 506J device list. We then convened the General Hospital and Personal Use Devices panel of the Medical Devices Advisory Committee to provide feedback on the 506J device list specifically and advise on pandemic preparedness and response more generally.

In January of this year, we published the final guidance and 506J device list, based on the feedback from panelists and comments received by the public dockets for both the guidance and the Advisory Committee meeting.

In today's webinar, we'll provide more information on the guidance titled, Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act. And we'll share more about the statutory authorities, prior guidance and details regarding both the guidance and the 506J device list.

As you listen to today's call, I encourage you to consider the ways in which manufacturers, by proactively and voluntarily notifying the FDA of interruptions and discontinuances can help to reduce impacts to vulnerable patient populations. OSCR and the FDA stand ready to work with industry and use our authorities to help industry mitigate shortages of essential medical devices.

Thank you all for your time and attention to this important topic for our nation's public health.

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Dr. Tammy Beckham: Thank you, Suzanne. My name is Tammy Beckham and I'm the director of the Office of Supply Chain Resilience. I will now give an overview of today's presentation.

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Dr. Tammy Beckham: For ease of reference, the link to this guidance is included on this slide. At the end of this presentation, we will be providing answers to several questions that have been submitted to CDRH about this guidance and the 506J device list.

In addition, if after this presentation, you still have questions about the final guidance you may submit your questions to CDRHManufacturerShortage@fda.hhs.gov if you are a manufacturer or to deviceshortages@fda.hhs.gov if you are a healthcare provider or other interested party.

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Dr. Tammy Beckham: The objectives of this presentation are to provide a background on Section 506J of the Federal Food, Drug, and Cosmetic Act, also known as the FD&C Act, and discuss CDRH's role in medical device supply chain and shortages.

We will also review FDA's ability to receive additional notifications outside of a public health emergency and discuss the 506J Device List and the process that was utilized to develop and gather input on development of the list.

We will also describe how CDRH uses information submitted in 506J notifications to determine if a shortage exist and determine potential mitigation actions; and we will spend just a few moments recapping the process for notifying FDA of supply disruptions through the 506J process.

To get us started, I will turn it over Erin Quencer to provide background on Section 506J.

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Erin Quencer: Thank you, Tammy.

Slide 7

Erin Quencer: Now I will provide background on Section 506J of the FD&C Act and the recent publication of 506J related guidances.

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Erin Quencer: In March 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was signed into law. The CARES Act amended the FD&C Act by adding Section 506J to the statute. Section 506J of the FD&C Act provides FDA with authorities intended to help prevent or mitigate medical device shortages. On this slide we outline the obligations of manufacturers.

Under Section 506J, during or in advance of a public health emergency, or a PHE, manufacturers are required to notify FDA of a permanent discontinuance or interruption in the manufacturing of certain devices that is likely to lead to a meaningful disruption in the supply of that device in the United States. Manufacturers must also provide the reasons for the discontinuance or interruption.

Under Section 506J, devices for which notifications are required include those devices 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; or devices 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.

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Erin Quencer: In addition to the manufacturer obligations, FDA also has certain obligations under Section 506J. For example, in general, FDA must establish and maintain a publicly available, up-to-date list of devices that FDA determines to be in shortage. This is referred to as the Medical Device Shortages List as shown on the left side of this slide. This is further explained in Section 506J(g) of the FD&C Act.

In general, to the maximum extent practicable and subject to the public health exception identified in Section 506J, FDA must also distribute information on device discontinuances or interruptions of the manufacture of devices under Section 506J(a) to appropriate organizations, including physicians, health providers, patient organizations, and supply chain partners, as appropriate and applicable. This is further explained in Section 506J(c) of the FD&C Act.

In general, FDA must also 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 a failure to notify letter was issued in error or the person had a reasonable basis for not notifying FDA. This is further explained in Section 506J(e) of the FD&C Act.

And, in general, FDA must also prioritize and expedite the review of a premarket submission or facility inspection, as appropriate, for a device or establishment that could help mitigate or prevent a shortage. This is further explained in Section 506J(f) of the FD&C Act.

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Erin Quencer: In December 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, was signed into law as part of the Consolidated Appropriations Act of 2023, hereafter referred to as the Fiscal Year 2023 Omnibus.

The Fiscal Year 2023 Omnibus amended the FD&C Act to add subsection h, titled Additional Notifications. Section 506J(h) clarifies that FDA may receive voluntary notifications pertaining to a 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.

As we describe in the guidance, 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, which has proved to be essential to help prevent or mitigate supply chain disruptions and shortages.

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Erin Quencer: In addition to adding Section 506J(h) to the FD&C Act, the Fiscal Year 2023 Omnibus, also directed FDA to issue guidance as described on this slide.

Section 2514(b) of the Fiscal Year 2023 Omnibus directed FDA to issue a draft guidance on voluntary notifications within one year of enactment of the Act and also directed FDA to finalize the guidance within one year of the close of the comment period for that draft guidance.

Section 2514(c) of the Fiscal Year 2023 Omnibus directed FDA to issue or revise guidance regarding the 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. This list is referred to as the 506J Device List.

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Erin Quencer: Now that you have some background on our statutory authorities and the obligations of both manufacturers and FDA, I will now discuss the recent guidances we have published to assist interested parties in the implementation of Section 506J.

In November 2023, FDA issued the two guidances displayed on this slide. The final guidance on the left, referred to as the 506J guidance, was the finalization of the draft guidance that had published before the Fiscal Year 2023 Omnibus introduced new statutory requirements. This guidance served as the baseline for information about notifications under Section 506J during or in advance of a public health emergency.

In November 2023, we also published a draft select update guidance, as listed here on the right-hand side of the slide. This draft guidance was titled, Select Updates for the 506J Guidance: 506J Device List and Additional Notifications, and proposed select updates to the 506J guidance to address the Fiscal Year 2023 Omnibus requirements.

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Erin Quencer: On January 7, 2025, FDA finalized the draft select update guidance, discussed on the previous slide, by publishing the final guidance titled, Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act. This final guidance supersedes the previous final guidance published in November 2023 of the same title. At this time, there is only one 506J guidance.

This 506J final guidance adds to the November 2023 final guidance by clarifying 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. And this aligns with the requirement under Section 2514(b) of the Fiscal Year 2023 Omnibus. Additionally, this guidance includes the 506J Device List in accordance with the requirement in Section 2514(c) of the Fiscal Year 2023 Omnibus to publish 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.

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Erin Quencer: Now, I'd like to provide some additional information regarding voluntary notifications, also known as additional notifications.

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Erin Quencer: The final guidance provides some examples of when FDA recommends submission of voluntary 506J notifications. These examples include unplanned manufacturing challenges; unplanned distribution challenges; increased or projected increased demand unable to be met by the manufacturer; potential broader or connected interruptions; and circumstances affecting software-enabled device availability that may lead to a shortage.

As described in the guidance, submitting voluntary 506J notifications is an important step to alert FDA of a disruption and take advantage of opportunities for regulatory and non-regulatory mitigation strategies to potentially prevent and mitigate shortages, reducing the impact on patients and healthcare providers. The guidance also includes FDA's recommendations regarding timeframes for notifications, processes for receiving notifications, and actions FDA may take to mitigate or prevent a shortage.

We'll talk more about how FDA uses 506J notifications later in this presentation. Now I'll hand it over to Tammy to talk about the 506J Device List.

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Dr. Tammy Beckham: Thank you, Erin. I will now spend a few moments on the 506J Device List and the process that was used in developing the list.

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Dr. Tammy Beckham: As Erin stated earlier in the presentation, Section 506J of the FD&C Act requires manufacturers of devices that FDA has identified by product code on the 506J Device List to submit notifications to FDA when statutory conditions are met.

The 506J Device List is published on FDA's webpage, the link of which is included on this slide, and includes a list of devices by product code, for which 506J notifications are required during or in advance of a public health emergency.

In order to facilitate navigation and viewing of the 506J Device List, product codes have been grouped into device types, which, for the purpose of the 506J Device List, are defined as a group of devices with similar clinical use.

FDA expects the 506J Device List to evolve over time and intends to periodically re-evaluate the list. Any revisions to the 506J Device List will follow FDA's Good Guidance Practices.

As you will note, the list also includes a handful of CBER regulated medical devices in accordance with the criteria set forth in Section 506J(a). These CBER regulated medical devices are also included in the scope of the 506J guidance and in the 506J notification process described in the guidance.

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Dr. Tammy Beckham: Now I would like to spend a few minutes describing the process used to develop the 506J Device List.

After Congress passed the FY23 Omnibus in December 2022, FDA began its work to develop a draft 506J Device List. First, we assembled an internal FDA working group with representatives from the Office of Strategic Partnerships and Technology Innovation or OST, the Office of Product Evaluation and Quality or OPEQ, the CDRH Office of Policy and the Center for Biologics Evaluation & Research. The working group used a multi-step process to develop the draft list.

To start, an initial list of devices by product code was established and evaluated against the statutory criteria outlined in Section 506J(a). If the product codes met the statutory criteria, the working group also considered other device characteristics, and considered knowledge gained from previous public health emergencies. After deliberation and evaluation, in November of 2023, FDA published the draft 506J Device List and began the process to solicit and consider feedback on this list.

First, the draft 506J Device List was included in the Draft Select Update Guidance document which was published in November of 2023. As with any draft guidance, a public docket was opened to solicit public comment. Feedback, suggestions and comments on the draft guidance and the 506J Device List were collected as a part of this process.

Next, on February 6 of 2024, FDA convened a meeting of the General Hospital and Personal Use Devices Medical Device Advisory Committee to discuss and make recommendations on the draft 506J Device List. A public docket was also opened for the Advisory Committee panel meeting. Comments were accepted up to 30 days post meeting.

After considering the comments from both public dockets and the recommendations from the Advisory Committee Meeting, FDA published the 506J device list in January of 2025 as part of the 506J final guidance.

Next, I will provide more details on this process and how the 506J Device List was developed.

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Dr. Tammy Beckham: As described on the previous slide, the first step in the development of the draft 506J Device List was to develop an initial list that could be evaluated against the statutory criteria in Section 506J.

The initial list was developed using a broad and diverse set of inputs. As an example, the FDA working group utilized lessons learned during prior device shortage events and public health emergencies. The working group also considered other external sources to inform our deliberations.

We then evaluated the product codes against the statutory criteria. In Section 506J, Congress included criteria for which devices should be included on the 506J Device List. That criteria was, devices 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.

In addition, the FDA working group also considered other factors, for example, whether a device is critical to a public health emergency, to determine which devices should be included on the list. Such considerations included, for example whether the device is used to diagnose, treat, monitor, or prevent a serious disease or medical condition; or 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.

Ultimately, FDA focused on those devices that are critical to public health during a public health emergency, within the meaning of Section 506J.

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Dr. Tammy Beckham: After publishing the draft 506J Device List, on February 6 of 2024, FDA convened a meeting of the General Hospital and Personal Use Devices Medical Device Advisory Committee to discuss and make recommendations on medical device supply chain resiliency and shortage issues, including the draft 506J Device List.

Panelists provided detailed feedback and suggestions on the draft 506J Device List. And as previously mentioned, FDA also solicited feedback via two public dockets, including the docket for the draft guidance and the docket for the Advisory Committee meeting.

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Dr. Tammy Beckham: During the Advisory Committee meeting, the panelists were asked to provide feedback on a number of topics related to the 506J Device List, including: whether the proposed devices 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, and capital equipment. The panel was also asked to provide additional considerations with respect to pandemic preparedness and response.

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Dr. Tammy Beckham: The Advisory Committee meeting provided an opportunity for thoughtful dialogue and discussion of the draft 506J Device List. I want to highlight a few of the key themes and recommendations from the panel.

Recommendations included: the possibility of prioritizing or tiering the list to reflect the variation and severity of different types of public health emergencies; to consider for inclusion on the 506J Device List those kits that are used to gain vascular access, such as central venous line kits, paracentesis kits, dialysis line kits, and arterial line kits. To ensure the 506J Device List contained accessories necessary to support, supplement, and/or augment any parent devices that are included on the list. To consider the differences between true single-use medical devices and those single-use medical devices that could be safely reprocessed and reused during an emergency event. And to 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.

Throughout the discussion, the Panel also described a host of additional device types that they believed would be critical to providing patient care in a public health emergency and should be considered for inclusion on the 506J Device List, including, but not limited to devices used in surgery, respiratory care, and diagnostic testing.

And finally, although different perspectives were considered, the Panel recommended that supply chain resilience and vulnerabilities should not be considered when determining a medical device's criticality for providing patient care, and therefore recommended that resilience should not be considered when determining device types for inclusion or exclusion from the 506J Device List. The Panel noted that rapid fluctuations in product resiliency could pose challenges to maintaining an updated list if such factors were considered.

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Dr. Tammy Beckham: The public dockets that were opened for both the guidance document and the Advisory Committee meeting also provided feedback and recommendations. FDA thanks everyone that submitted comments to the dockets. And at this time, I'll provide an overview of the feedback.

Like the Advisory Committee panelists, feedback to the comments encouraged FDA to consider pediatric or other special populations when determining which devices to include on the 506J Device List. It also highlighted the complexity of the product code structure, noting that product codes can sometimes be broadly defined and contain a range of devices and accessories, some of which may not meet the criteria for inclusion.

As mentioned previously, this topic also came up during the Advisory Committee meeting, in which we reminded panelists that the Fiscal Year 2023 Omnibus specifically directed FDA to create the 506J Device List by product code, which limits our ability to present the information in a different manner.

Other feedback highlighted the importance of specific devices for the resilience of the blood supply chain. And they also encouraged us to consider other lists which may have additional priority devices.

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Dr. Tammy Beckham: The FDA working group considered all of the comments and recommendations provided from the Advisory Committee and submitted via the public dockets. In an effort to refine and scope the 506J Device List, in a manner consistent with the statutory criteria set forth in Section 506J, FDA convened clinical experts to confirm product codes included on the list would be required for use in any one of three types of public health emergencies; a natural disaster, a pandemic or a Chemical, Biological, Radiological, Nuclear, and Explosives or CBRNE event.

After consideration of the feedback and further evaluation of the draft list, the 506J Device List was published in January of 2025 as part of the final guidance.

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Dr. Tammy Beckham: I would like to pivot now to describe how FDA uses information that is submitted in 506J notifications.

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Dr. Tammy Beckham: As discussed in a previous slide, under Section 506J, FDA is generally required to maintain a publicly available, up-to-date list of devices that FDA determines to be in shortage and communicate information, to the maximum extent practicable, on device continuance or interruption to appropriate organizations.

The medical device shortage list is maintained by the Office of Supply Chain Resilience, also referred to as OSCR, in the Office of Strategic Partnerships and Technology Innovation within the Center for Devices and Radiological Health.

When CDRH receives a notification through 506J, we utilize the information submitted with that notification to conduct an assessment to determine if the medical device is in shortage or if a shortage is imminent.

Section 506J(j)(2) of the FD&C Act defines shortage to mean a period of time when the demand or projected demand for the device within the United States exceeds the supply of the device. If CDRH determines that the device is in shortage, FDA will add the device's product code to the medical device shortage list and issue communications to impacted parties.

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Dr. Tammy Beckham: In addition to adding a device's product code to the shortage list, FDA also works with manufacturers and suppliers to determine if there is potential for preventing a shortage and/or mitigating impacts of an impending supply chain disruption.

CDRH's analysis is used to advise both internal FDA and intergovernmental partners of medical device supply chain issues and inform the use of both regulatory and non-regulatory mitigations to help prevent and/or mitigate shortages.

These mitigations can include but are not limited; to expedited premarket submissions, priority request letters, letters to healthcare providers containing recommendations for conservation strategies, as well as other mitigations in partnership with our U.S. Agency partners, including transportation prioritization, expedited clearance through customs and border patrol, and priority ratings through the Defense Production Act.

As you can see, notifications under Section 506J of the FD&C Act provide critical information that may allow us to proactively prevent and mitigate medical device shortages, thus minimizing the impact to patients and healthcare providers.

Again, we do this by working across a broad group of interested parties to include suppliers, manufacturers, group purchasing organizations, distributors, transportation companies, healthcare systems and our other federal partners in the United States government.

In situations where there may be an impending shortage, FDA's ability to prevent and mitigate shortages really depends on timely notifications. The earlier FDA receives a notification of a supply interruption, the greater our ability to mitigate or prevent a shortage.

And now I'm going to hand it back to Erin to walk through the rest of the presentation.

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Erin Quencer: Thank you, Tammy. Now I will provide a brief overview of the process for submitting a 506J Notification.

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Erin Quencer: FDA website, titled Notify the FDA About a Medical Device Supply Issue, contains the most current information about submitting a 506J Notification to FDA.

Manufacturers may use a web form to submit 506J Notifications. The webform includes the appropriate prompts and fields to submit the information. For manufacturers with a large number of impacted devices, there is also a spreadsheet template available on this site that can be used to submit the information needed by uploading through the webform.

For manufacturers that do not wish to utilize this method, notifications may be emailed to CDRHManufacturerShortage@fda.hhs.gov for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER, and include a subject line beginning with the word Notification.

If a manufacturer has questions regarding 506J Notifications, the manufacturer should contact the Agency at those same email addresses. Which for devices regulated by CDRH is CDRHManufacturerShortage@fda.hhs.gov or for devices regulated by CBER cbershortage@fda.hhs.gov and include Question in the subject line of the email.

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Erin Quencer: Section 506J(a) requires manufacturers of devices identified by product code on the 506J Device List to submit notifications of: a permanent discontinuance in the manufacture of the device, except for discontinuances as a result of an approved modification of the device; or an interruption of the manufacture of the device 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.

Additionally, in order for FDA to meet our requirements to establish and maintain a medical device shortages list, manufacturers must also include the following in their 506J Notifications: the category or name of the device, the manufacturer's name, the reason for the 506J Notification, selecting from the categories listed in the guidance and Section 506J(g)(2)(c), and the estimated duration of the discontinuance or interruption.

Additional information is helpful, but not required, such as the FDA product code; submitter name and contact information; marketing submission number, if applicable; the FDA Establishment Identifier number, or FEI number; and the notification type that is, is it a new 506J Notification or an update.

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.

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Erin Quencer: On this slide we have listed the resources we mentioned earlier during the presentation, along with the full URLs that you can access after the presentation.

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Erin Quencer: In 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 from November 2023 of the same title, and clarifies that FDA may receive additional, voluntary notifications at any time. This final guidance also includes the 506J Device List.

Manufacturers may refer to the FDA website titled, Notify the FDA about a Medical Device Supply Issue, to find more information and resources about the 506J notification process, including instructions on how to submit a 506J notification and a link to the webform.

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CAPT Kim Piermatteo: Thank you Suzanne, Tammy and Erin for your presentations.

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CAPT Kim Piermatteo: During the development of this presentation, we considered questions that were previously submitted to our 506J mailbox from the public. We incorporated responses to many of these questions within the presentation you just heard, as appropriate. The following questions, however, were not fully addressed in this presentation, and, therefore, Tammy and Erin will be taking this opportunity to provide some additional information in response to these specific previously submitted questions.

Erin, I'll turn it over to you.

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Erin Quencer: Thanks Kim. The first question we would like to discuss is, are 506J notifications required for devices not listed in the 506J Device List?

Our response to this question is, the 506J Device List is a list of product codes for which a manufacturer of such device is required to notify the Secretary in accordance with Section 506J of the FD&C Act. Thus, manufacturers of a device on the 506J Device List must notify FDA if they experience a permanent discontinuance in manufacturing of the device or an interruption in manufacturing of the device that is

likely to lead to a meaningful disruption in supply of that device in the United States during or in advance of a PHE.

While devices with a product code that does not appear on the 506J Device List are not required to submit notifications to FDA, the Agency welcomes information on such devices and encourages manufacturers to provide such information if they are experiencing an interruption in manufacturing or discontinuance of a device.

The second question we'd like to discuss is, what happens if a manufacturer fails to submit a 506J Notification?

Our response to this question is, if a manufacturer makes a device with a product code that appears on the 506J Device List, that device is subject to Section 506J and the manufacturer is required to submit a 506J Notification. In accordance with Section 506J(e)(1), if a manufacturer fails to provide a notification required by Section 506J(a) in accordance with the timelines set forth in Section 506J(b), FDA is directed to issue a letter informing the manufacturer of such failure. No later than 30 days after the issuance of such letter the manufacturer must submit to FDA a written response setting forth the basis for non-compliance and providing the information required by Section 506J(a). For more information see Section 506J(e)(2) of the FD&C Act.

Subject to those limitations outlined in Section 506J(e)(3), not later than 45 calendar days after the issuance of the letter to the manufacturer, FDA will make that letter and any response received available to the public on FDA's website with appropriate redactions to protect trade secrets or confidential commercial information. See Section 506J(e)(3) for more information.

For those medical devices not listed on the 506J Device List, manufacturers are encouraged, on a voluntary basis, to notify the FDA about medical device supply issues, including manufacturing interruptions and discontinuances. FDA welcomes information from manufacturers at any time that may help us better understand supply chain challenges, promote device availability, and help mitigate or prevent device shortages.

I'll now turn it back over to Tammy to discuss two more additional questions.

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Dr. Tammy Beckham: Thanks Erin. Another question we received is, if a manufacturer intends to discontinue a current version of a product due to the release of an updated version, does that constitute a discontinuance?

The answer to that is, manufacturers of devices that FDA has identified on the 506J Device List are required to submit 506J Notifications to the FDA when statutory conditions in Section 506J of the FD&C Act are met. As stated in the 506J guidance, for purposes of this guidance, FDA interprets a permanent discontinuance to mean when the manufacturer ceases manufacturing and distributing a product indefinitely for business or other reasons. Section 506J(a) makes it clear that manufacturers are not required to notify FDA of permanent discontinuances that occur as a result of an approved modification of the device.

Should the manufacturer have additional questions, manufacturer should contact the Agency at CDRHManufacturerShortage@fda.hhs.gov for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER, and include Question in the subject line of the email.

The last question that was previously submitted that we're going to discuss during this presentation is, my company is the registered importer for a foreign-manufactured device included on the 506J Device List and we do not have visibility into the supply chain. Who should be submitting the 506J Notification, us as the importer or the foreign manufacturer?

Our response is, for the purpose of the 506J Guidance, FDA interprets the term manufacturer to mean the entity that holds the device marketing authorization or the 510(k), or, if a marketing submission is not required, the entity responsible for listing the medical device under Section 510(j) of the FD&C Act. As described in the 506J Guidance, if a manufacturer relies on a contract manufacturer or others in the production process, the manufacturer is responsible for ensuring the contract manufacturers, supply chain partners, or other entities provide them with sufficient notice and information to fulfill their notification obligations under 506J of the FD&C Act.

Thank you to those who submitted these questions to the 506J mailbox. I'll turn it back over to you, Kim.

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CAPT Kim Piermatteo: Thanks Erin and Tammy for providing these responses. Tammy, I'd now like to turn it back to you for our viewers Call to Action.

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Dr. Tammy Beckham: Thanks Kim. After watching this presentation, we'd like to ask you to: review the 506J Guidance; review the 506J Device List; and 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 are 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 for devices regulated by CDRH or cbershortage@fda.hhs.gov for devices regulated by CBER, and include the word Question in quotation marks in the subject line of the email.

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CAPT Kim Piermatteo: Thank you, Tammy. This presentation and other learning modules can be found at CDRH Learn via the link provided on this slide.

Other resources available to you that are provided as this slide, are, Device Advice, for text-based information on premarket and postmarket topics. And the contact information for the Division of Industry and Consumer Education or DICE, whom you may contact for additional information on this or any other medical device regulatory topics.

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CAPT Kim Piermatteo: Thank you for watching. This concludes the presentation.