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

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on November 17, 2023.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact CDRHManufacturerShortage@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

When final, this guidance will update “Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act,” issued November 17, 2023.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Preface

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

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Overview of Select Updates

The Food and Drug Administration (FDA or Agency) has developed this draft guidance to propose select updates to the FDA guidance “[Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act](#)” (hereafter referred to as the “506J Guidance”).¹ The 506J Guidance remains in effect, in its current form, until this draft guidance is finalized, at which time Section II. and Section III. of this draft guidance will supersede the recommendations in Section III.B. and Section IV., respectively, of the 506J Guidance. FDA intends to incorporate the updates proposed in this draft guidance into the 506J Guidance as one final guidance document after obtaining and considering public comment on these proposed select updates. The sections of the existing 506J Guidance that are unaffected by these proposed updates are not intended to be substantively changed, with the exception of technical edits for consistency.

On December 29, 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (“PREVENT Pandemics Act”) was signed into law as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (hereafter referred to as the “FY 2023 Omnibus”). Section 2514(c) of the FY 2023 Omnibus directed FDA to issue or revise guidance regarding requirements under section 506J of the Federal Food, Drug, and Cosmetic

¹ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc#:~:text=Section%20506J%20of%20the%20FD%26C%20Act%20requires%20manufacturers%20to%20notify,supply%20of%20that%20device%20in>

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33 Act (“FD&C Act”) and include a list of each device product code for which a manufacturer of
34 such device is required to notify FDA in accordance with section 506J. This draft guidance
35 proposes revisions to the 506J Guidance to meet the requirements under section 2514(c) of the
36 FY 2023 Omnibus. Additionally, section 2514 of the FY 2023 Omnibus amended section 506J to
37 add subsection (h), “Additional Notifications” and directed FDA to issue guidance “to facilitate
38 voluntary notifications.” Consistent with section 506J(h), FDA is proposing to update the 506J
39 Guidance to clarify for stakeholders that FDA may receive voluntary notifications regarding
40 supply chain issues at any time, unrelated to the declaration or potential declaration of a public
41 health emergency (PHE).
42

43 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
44 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
45 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
46 the word *should* in Agency guidances means that something is suggested or recommended, but
47 not required.
48

49 **II. Updates to Section III.B. 506J Device List**

50 FDA is proposing to replace Section III.B. of the 506J Guidance with the following language in
51 this Section II.
52

53 Section 2514(c) of the FY 2023 Omnibus directs FDA to issue guidance on the requirements
54 under section 506J of the FD&C Act and to include “a list of each device product code for which
55 a manufacturer of such device is required to notify the Secretary in accordance with section
56 506J”² (hereafter referred to as the “506J Device List”). Thus, manufacturers of a device on the
57 506J Device List must notify FDA in accordance with section 506J for each such device.
58

59 In response to Executive Order 14001, A Sustainable Public Health Supply Chain, signed on
60 January 21, 2021, FDA has led an interagency effort (including FDA, Centers for Medicare and
61 Medicaid Services, Centers for Disease Control and Prevention, Administration for Strategic
62 Preparedness and Response, United States Department of Veterans Affairs) in collaboration with
63 healthcare providers and industry representatives within the device ecosystem, to develop a
64 critical medical device list (CMDL). This list, when completed, will include devices critical for
65 supporting and sustaining life.
66

67 Leveraging the information and perspectives shared during the collaborative efforts to develop
68 the CMDL, as well as other sources of information and lessons learned during previous PHEs
69 and other events that have led to shortages of critical medical devices, FDA has developed a list
70 of devices, by FDA product code, according to the criteria set forth in section 506J(a). When
71 finalized, this will serve as the list for which a manufacturer of such devices is required to notify
72 FDA in accordance with section 506J. The 506J Device List is based on the requirements under
73 section 506J(a), as discussed in Section III.A. of the 506J Guidance.
74

² See section 2514(c) of the FY 2023 Omnibus.

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75 FDA’s website³ hosts the proposed 506J Device List. FDA expects that the list will evolve over
76 time and FDA intends to periodically reevaluate the list. Any revisions to the 506J Device List
77 will follow FDA’s good guidance practices.⁴
78

79 Manufacturers of devices that FDA has identified on this 506J Device List are required to submit
80 506J notifications to FDA when the statutory conditions are met (see Section III.C. of the 506J
81 Guidance for more information on when to notify FDA).⁵
82

(1) Devices FDA has determined are “critical to public health during a public health emergency” under Section 506J(a)(1)

85 The 506J Device List contains those devices FDA has determined are “critical to public health
86 during a public health emergency” within the meaning of section 506J(a)(1). In determining
87 whether a device is critical to public health during a PHE, FDA considers a number of factors.
88 For various reasons,⁶ and consistent with the language of section 506J, FDA considers whether a
89 device is critical to public health during *any* PHE.⁷ However, FDA also considers whether there
90 are certain devices that may be critical to *specific* PHEs.⁸ For example, FDA’s consideration of
91 whether a device is critical to a PHE includes, but is not limited to, the following:
92

- 93 • Whether the device is used to diagnose, treat, monitor, or prevent a serious disease or
94 medical condition; and if the device is “life-supporting, life-sustaining or intended for use
95 in emergency medical care or during surgery” (section 506J(a)(1)).
96
- 97 • Whether the lack of availability of the device is reasonably likely to cause serious injury
98 or death to patients, healthcare workers, or others if it is not available and there are no
99 suitable alternatives.

100
101 These considerations, coupled with FDA’s experience in responding to previous supply chain
102 disruptions and shortages and the subsequent continued implementation of section 506J has
103 informed the development of the 506J Device List. The categories set forth in this list reflect, at
104 this time, the device product codes that FDA has determined are critical to public health during a
105 PHE, and for which manufacturers should notify FDA, as appropriate. However, if FDA learns
106 new information, consistent with the factors summarized above, FDA intends to reevaluate the
107 device types that are critical to public health during a PHE and update the 506J Device List
108 accordingly.
109

³ See FDA’s website on “506J Device List,” available at <https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list>

⁴ See 21 CFR 10.115(g)(4).

⁵ See section 506J(a).

⁶ For example, multiple PHEs may exist at one time.

⁷ Some devices, such as personal protective equipment devices, may be critical to public health during any PHE.

⁸ Specific PHEs may have certain devices that are critical to that specific PHE. For example, diagnostic tests may be critical to a specific PHE.

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110 **(2) Devices FDA has determined additional information is**
111 **needed under Section 506J(a)(2)**

112 During or in advance of a PHE, FDA may also identify, under section 506J(a)(2), devices or
113 device types for which we have determined “that information on potential meaningful supply
114 disruptions” is needed. In making such determination, FDA’s considerations may include, but
115 not be limited to devices that are specific to a type of illness or event (e.g., respiratory illness;
116 traumatic burns and/or wounds resulting from a disaster).

117
118 If FDA determines there are devices or device types for which information on potential
119 meaningful supply disruptions is needed during a specific PHE, FDA intends to add such devices
120 or device types to the 506J Device List to assist manufacturers in determining whether they must
121 submit a 506J notification to FDA.
122

123 **III. Updates to Section IV. Additional Notifications**

124 FDA is proposing to replace Section IV. of the 506J Guidance with the following language in
125 this Section III.
126

127 Section 2514 of the FY 2023 Omnibus amended section 506J of the FD&C Act to add subsection
128 (h), “Additional Notifications.” Section 506J(h) clarifies for stakeholders that FDA may receive
129 voluntary notifications pertaining to the permanent discontinuance or interruption in the
130 manufacture of a device at any time, unrelated to the declaration or potential declaration of a
131 PHE.
132

133 Under section 506J(h), manufacturers of devices that are “life-supporting, life-sustaining, or
134 intended for use in emergency medical care or during surgery, or any other device the Secretary
135 determines to be critical to the public health” may submit voluntary, additional notifications to
136 FDA “pertaining to a permanent discontinuance in the manufacture of the device (except for any
137 discontinuance as a result of an approved modification of the device) or an interruption in the
138 manufacture of the device that is likely to lead to a meaningful disruption in the supply of that
139 device in the United States, and the reasons for such discontinuance or interruption.” FDA’s
140 interpretation of who should submit notifications using section 506J(h) is consistent with our
141 interpretation in Section III.A. of the 506J Guidance.
142

143 For purposes of this guidance, FDA interprets section 506J(h) to clarify that FDA may receive
144 additional notifications about medical devices at any time, unrelated to the declaration or
145 potential declaration of a PHE. FDA has always accepted voluntary submissions of information
146 across many topics, including device supply chain matters. Section 506J(h) does not alter FDA’s
147 ability or authority to receive voluntary information on supply chain or other matters. For
148 example, early in the COVID-19 pandemic, prior to the enactment of section 506J, FDA
149 solicited and received voluntarily information from manufacturers of critical devices regarding
150 supply chain disruptions and manufacturing capacity. During the COVID-19 pandemic, FDA
151 also received notifications regarding manufacturing interruptions and permanent discontinuances
152 of a wide range of devices, not all of which were critical to public health. FDA further solicited –

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153 and received – voluntary information from manufacturers that were not experiencing
154 interruptions in manufacturing. This information is imperative to FDA’s ability to help prevent
155 and mitigate shortages. As such, any time a manufacturer of any device is experiencing a
156 permanent discontinuance or interruption in the manufacture of a device, the manufacturer is
157 encouraged to submit a notification to FDA. For example, if manufacturers are experiencing any
158 of the following circumstances, we recommend they submit a 506J notification to the FDA:
159

- 160 • Unplanned manufacturing challenges (e.g., labor shortages, delays in raw material
161 supply, temporary plant closures, packaging or sterilization concerns, or other unforeseen
162 circumstances that prevent the manufacturer from meeting demand);
- 163 • Unplanned distribution challenges (e.g., shipping/transportation delays, export/import
164 challenges, procurement issues);
- 165 • Increased or projected increased demand unable to be met by the manufacturer (e.g.,
166 backorder, allocation, low fulfillment rates);
- 167 • Potential broader/connected interruptions (e.g., reliance on critical suppliers who are
168 experiencing supply chain interruptions); and
- 169 • Actions or circumstances affecting software-enabled devices that may disrupt healthcare
170 operations (e.g., device cybersecurity vulnerabilities or exploits).

171
172 FDA encourages submission of these additional voluntary notifications to FDA within 7 calendar
173 days after an interruption in manufacturing occurs, or no later than 7 calendar days after the
174 manufacturer decides to permanently discontinue the device, as applicable. Section III.C. of the
175 506J Guidance provides more information about when to submit notifications to FDA. For these
176 additional notifications, we recommend that manufacturers provide updates to the initial 506J
177 notification when there is a change in status to help ensure that FDA is acting on the most current
178 information.
179

180 Section III.D. of the 506J Guidance provides more information about what information to
181 include in 506J notifications. 506J notifications may include both information required by
182 section 506J (see Section III.D.1. of the 506J Guidance) and additional information to help
183 inform FDA’s supply chain analysis (see Section III.D.2. of the 506J Guidance). Section III.E. of
184 the 506J Guidance provides more information about how to submit notifications. Section III.D.
185 of the 506J Guidance provides more information about how the Agency uses information from
186 notifications, including actions FDA may take to help mitigate or prevent a shortage resulting
187 from a discontinuance or interruption in the manufacture of a device for which a notification is
188 received.