

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

# **Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency**

---

## **Draft Guidance for Industry and Food and Drug Administration Staff**

***DRAFT GUIDANCE***

**This draft guidance document is being distributed for comment purposes only.**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 December 2021.**

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draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Regulation, Policy, and Guidance Staff at [RPG@fda.hhs.gov](mailto:RPG@fda.hhs.gov).



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

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

## **Preface**

### **Additional Copies**

Additional copies are available from the FDA webpage titled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” *available at* <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, and the FDA webpage titled “Search for FDA Guidance Documents,” *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive a copy of the guidance. Please include the document number 21011 and complete title of the guidance in the request.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Table of Contents**

I.	Introduction.....	1
II.	Background.....	3
III.	Scope.....	4
IV.	Guiding Principles .....	6
V.	Phased Transition Plan for Devices That Fall Within COVID-19 Enforcement Policies .....	7
	A. If a manufacturer does not intend to distribute its device after the withdrawal of the guidances.....	10
	B. Phase 1 .....	11
	C. Phase 2 .....	12
	(1) “Notifications of Intent” for Certain Reusable Life-Supporting or Life-Sustaining Devices.....	12
	D. Phase 3 .....	14
	(1) Recommendations for Transition Implementation Plan.....	14
	(2) Discontinuing distribution of a device.....	15
	(3) Additional considerations.....	16
	E. Enforcement policy for devices with a marketing submission under review by FDA .....	17
VI.	Examples.....	17

1     **Transition Plan for Medical Devices**  
2     **That Fall Within Enforcement Policies**  
3     **Issued During the Coronavirus Disease**  
4     **2019 (COVID-19) Public Health**  
5     **Emergency**

---

7     **Draft Guidance for Industry and**  
8     **Food and Drug Administration Staff**

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

16    **I. Introduction**

17    FDA plays a critical role in protecting the United States (U.S.) from threats such as emerging  
18    infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is  
19    committed to providing timely guidance to support response efforts to this pandemic.  
20

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

21 FDA recognizes that it will take time for device<sup>1</sup> manufacturers,<sup>2</sup> healthcare facilities, healthcare  
22 providers, patients, consumers, and FDA to adjust from policies adopted and operations  
23 implemented during the declared COVID-19 public health emergency (PHE) to normal  
24 operations.<sup>3</sup> To provide a clear policy for all stakeholders and FDA staff, the Agency is issuing  
25 this guidance to describe FDA’s general recommendations for a phased transition process with  
26 respect to devices that fall within enforcement policies issued during the COVID-19 PHE,  
27 including recommendations regarding submitting a marketing submission, as applicable, and  
28 taking other actions with respect to these devices.  
29

30 FDA is concurrently issuing a companion guidance to describe FDA’s recommendations for this  
31 transition process with respect to devices issued Emergency Use Authorizations (EUAs) during  
32 the COVID-19 PHE.<sup>4</sup> The EUA transition guidance does not include phases as described in this  
33 transition plan for devices that fall within enforcement policies and instead relies on the advance  
34 notice of termination process set forth in section 564 of the FD&C Act. FDA believes that these  
35 transition guidances will help prepare manufacturers and other stakeholders for the transition to  
36 normal operations and foster compliance with applicable requirements under the FD&C Act and  
37 implementing regulations when the relevant EUAs and COVID-19-related enforcement policies  
38 cease to be in effect. This guidance is based on our current understanding of the COVID-19  
39 PHE, and may be updated as the PHE evolves.  
40

41 The contents of this document do not have the force and effect of law and are not meant to bind  
42 the public in any way, unless specifically incorporated into a contract. This document is intended  
43 only to provide clarity to the public regarding existing requirements under the law. FDA  
44 guidance documents, including this guidance, should be viewed only as recommendations, unless

---

<sup>1</sup> Section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that the term “device” means:

“an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term ‘device’ does not include software functions excluded pursuant to section 520(o) of the FD&C Act.”

<sup>2</sup> Throughout this guidance, FDA uses the term “manufacturer” to refer to any person who designs, manufactures, fabricates, assembles, or processes a finished device. See 21 CFR 820.3(o). Other entities, including those that introduce such devices into commercial distribution, such as initial importers and certain distributors, should ensure they understand, and where applicable, they should follow, the recommendations that pertain to such devices.

<sup>3</sup> Throughout this guidance, FDA refers to “normal operations” as a shorthand for the circumstances when the COVID-19 PHE under section 319 of the Public Health Service Act has expired and/or the relevant device COVID-19 emergency use declarations under section 564 of the FD&C Act are terminated.

<sup>4</sup> The FDA draft guidance document “Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency” will be referred to as the “companion guidance on devices issued EUAs” in the remainder of this guidance document.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

45 specific regulatory or statutory requirements are cited. The use of the word *should* in FDA  
46 guidance means that something is suggested or recommended, but not required.  
47

## 48 **II. Background**

49 There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus  
50 has been named “SARS-CoV-2,” and the disease it causes has been named “Coronavirus Disease  
51 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS)  
52 issued a declaration of a PHE related to COVID-19 in accordance with section 319 of the Public  
53 Health Service Act (PHSA) and mobilized the Operating Divisions of HHS.<sup>5</sup> In addition, on  
54 March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>6</sup>  
55

56 In response to the COVID-19 PHE, the device supply chain has been stressed because the  
57 demand for certain devices has exceeded available supply. FDA recognized early in the COVID-  
58 19 PHE the importance of maintaining the availability of certain devices. FDA’s policies have  
59 helped facilitate the availability of devices intended to diagnose, treat, and prevent COVID-19  
60 and associated conditions – including mitigating exposure to the SARS-CoV-2 virus – and to  
61 help address current manufacturing limitations or supply chain issues due to disruptions caused  
62 by the COVID-19 PHE.  
63

64 FDA issued various guidance documents that describe enforcement policies for certain  
65 devices that are intended to support the emergency response to the COVID-19 PHE.<sup>7</sup> These  
66 policies have helped to facilitate the availability of devices such as in vitro diagnostic tests,  
67 personal protective equipment intended for medical purposes, and ventilators. Additionally,  
68 FDA issued guidance to help expand the availability and remote monitoring capabilities of  
69 certain devices, including infusion pumps and non-invasive remote patient monitoring  
70 devices, to reduce the risk of exposure for patients, healthcare providers, and other healthcare  
71 professionals to individuals diagnosed with COVID-19. These guidances setting forth  
72 COVID-19-related enforcement policies currently state that they are intended to remain in  
73 effect only for the duration of the COVID-19 PHE.  
74

---

<sup>5</sup> Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (hereinafter referred to as “section 319 PHE declaration”) (originally issued on Jan. 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>6</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (February 24, 2021), available at <https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic>.

<sup>7</sup> For links to the COVID-19-related FDA guidance documents, see the webpage “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” available at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

75 Given the magnitude of the COVID-19 PHE, FDA recognizes that continued flexibility, while  
76 still providing necessary oversight, will be appropriate to facilitate an orderly and transparent  
77 transition back to normal operations. Further, FDA is taking into account that the  
78 manufacture, distribution, and use of devices in the context of the COVID-19 PHE raises  
79 unique considerations. These unique considerations include, for example, the manufacturing  
80 of devices by non-traditional manufacturers to address supply issues and the distribution and  
81 use of capital or reusable equipment (e.g., ventilators, extracorporeal membrane oxygenation  
82 systems) that fall within enforcement policies.  
83

84 FDA developed this guidance to describe a phased approach, as set forth in Section V, among  
85 other things, to help avoid disruption in device supply and foster compliance with applicable  
86 statutory and regulatory requirements after the enforcement policies are no longer in effect.  
87 This phased approach will allow FDA to better understand the landscape of devices that fall  
88 within the relevant enforcement policies and provide increased support to manufacturers, and  
89 assist the Agency in resource planning for marketing submission review.  
90

### 91 **III. Scope**

92 This guidance applies to devices that fall within the enforcement policies described in the  
93 guidances identified in List 1 below.<sup>8, 9</sup>  
94  
95

#### **List 1**

- 96 • [Enforcement Policy for Remote Digital Pathology Devices During the COVID-19](#)  
97 [Public Health Emergency](#)<sup>10</sup>
- 98 • [Enforcement Policy for Imaging Systems During the COVID-19 Public Health](#)  
99 [Emergency](#)<sup>11</sup>
- 100 • [Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to](#)  
101 [Support Patient Monitoring During the COVID-19 Public Health Emergency](#)<sup>12</sup>
- 102 • [Enforcement Policy for Telethermographic Systems During the COVID-19 Public](#)  
103 [Health Emergency](#)<sup>13</sup>

---

<sup>8</sup> FDA intends to add or remove guidance documents to or from this list as appropriate (including when finalizing this guidance), and intends to remove guidances from the list if they are withdrawn.

<sup>9</sup> The FDA guidance document “Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>, is outside the scope of this guidance.

<sup>10</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-digital-pathology-devices-during-coronavirus-disease-2019-covid-19-public>.

<sup>11</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-imaging-systems-during-coronavirus-disease-2019-covid-19-public-health-emergency>.

<sup>12</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient>.

<sup>13</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health>.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

- 104 • [Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders](#)  
105 [During the COVID-19 Public Health Emergency](#)<sup>14</sup>
- 106 • [Enforcement Policy for Extracorporeal Membrane Oxygenation and](#)  
107 [Cardiopulmonary Bypass Devices During the COVID-19 Public Health Emergency](#)<sup>15</sup>
- 108 • [Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices](#)  
109 [During the COVID-19 Public Health Emergency](#)<sup>16</sup>
- 110 • [Enforcement Policy for Infusion Pumps and Accessories During the COVID-19](#)  
111 [Public Health Emergency](#)<sup>17</sup>
- 112 • [Enforcement Policy for Clinical Electronic Thermometers During the COVID-19](#)  
113 [Public Health Emergency](#)<sup>18</sup>
- 114 • [Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical](#)  
115 [Masks, and Respirators During the COVID-19 Public Health Emergency \(Revised\)](#)<sup>19</sup>
- 116 • [Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19](#)  
117 [Public Health Emergency](#)<sup>20</sup>
- 118 • [Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the](#)  
119 [COVID-19 Public Health Emergency](#)<sup>21</sup>
- 120 • [Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices](#)  
121 [During the COVID-19 Public Health Emergency](#)<sup>22</sup>
- 122 • [Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support](#)  
123 [Patient Monitoring During the COVID-19 Public Health Emergency \(Revised\)](#)<sup>23</sup>
- 124 • [Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV](#)  
125 [Tests During the COVID-19 Public Health Emergency](#)<sup>24</sup>

---

<sup>14</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease>.

<sup>15</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during>.

<sup>16</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease>.

<sup>17</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public>.

<sup>18</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public>.

<sup>19</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-barrier-face-coverings-face-shields-surgical-masks-and-respirators>.

<sup>20</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health>.

<sup>21</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease>.

<sup>22</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus>.

<sup>23</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>.

<sup>24</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-modifications-fda-cleared-molecular-influenza-and-rsv-tests-during-coronavirus>.

## Contains Nonbinding Recommendations

### Draft – Not for Implementation

- 126 • [Enforcement Policy for the Quality Standards of the Mammography Quality](#)  
127 [Standards Act During the COVID-19 Public Health Emergency](#)<sup>25</sup>
- 128 • [Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement](#)  
129 [Policy During the COVID-19 Public Health Emergency \(Revised\)](#)<sup>26</sup>

130

## 131 IV. Guiding Principles

132 In developing this guidance, and its companion guidance on devices issued EUAs during the  
133 COVID-19 PHE, several guiding principles were followed. Some derive from existing policies  
134 and are widely known, and others are key to understanding the specific approach set forth in this  
135 guidance. Thus, anyone using this guidance should bear in mind the following guiding  
136 principles:

137

- 138 • This guidance is intended to help facilitate continued patient, consumer, and healthcare  
139 provider access to devices needed in the prevention, treatment, and diagnosis of COVID-  
140 19.
- 141 • FDA believes an orderly and transparent transition is appropriate for devices that fall  
142 within the scope of this guidance. FDA’s policies and recommendations in this guidance  
143 are consistent with the Agency’s statutory mission to both protect and promote the public  
144 health.<sup>27</sup>
- 145 • FDA’s policies and recommendations follow, among other things, a risk-based approach  
146 with consideration of differences in the intended use and regulatory history of devices,  
147 including whether the device is life-supporting or life-sustaining,<sup>28</sup> capital or reusable<sup>29</sup>  
148 equipment, a single-use device,<sup>30</sup> and whether the device was previously FDA-cleared or  
149 -approved.
- 150 • As in other situations, if the Agency deems appropriate, FDA may, at any time, take  
151 action regarding a specific device or device type, including revocation or revision of an  
152 EUA, withdrawal or revision of an enforcement policy, or enforcement action.

---

<sup>25</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-quality-standards-mammography-quality-standards-act-during-covid-19-public-health>.

<sup>26</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/coagulation-systems-measurement-viscoelastic-properties-enforcement-policy-during-coronavirus>.

<sup>27</sup> See section 1003 of the FD&C Act.

<sup>28</sup> Life-supporting or life-sustaining devices are defined in 21 CFR 860.3(e). A list of life-supporting or life-sustaining devices can be found by searching FDA’s product classification database: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

<sup>29</sup> A reusable device is intended for repeated use either on the same or different patients, with appropriate cleaning and other reprocessing between uses. For additional information see the guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

<sup>30</sup> A single-use device is a device that is intended for one use or on a single patient during a single procedure. For additional information see the guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

153

154 **V. Phased Transition Plan for Devices That Fall Within**  
155 **COVID-19 Enforcement Policies**

156 As previously stated, FDA recognizes that it will take time for device manufacturers, healthcare  
157 facilities, healthcare providers, patients, consumers, and the Agency to adjust from policies  
158 adopted and operations implemented during the COVID-19 PHE to normal operations. FDA  
159 intends to encourage and facilitate an appropriate transition period to avoid exacerbating product  
160 shortages and supply chain disruptions, while outlining expectations and recommended steps for  
161 manufacturers to take during the transition period to help foster compliance with applicable  
162 statutory and regulatory requirements for devices within the scope of this guidance that  
163 manufacturers wish to continue distributing after the COVID-19 PHE.

164  
165 Given the duration of the COVID-19 pandemic and the need to safeguard the public health in a  
166 post-pandemic environment, FDA is proposing a 180-day transition period that will begin on the  
167 “implementation date” (see discussion below regarding this date) and end on the date that the  
168 guidances in List 1 are withdrawn.<sup>31</sup> FDA believes a phased approach over the course of 180  
169 days following the implementation date as set forth in this guidance can help foster compliance  
170 with applicable statutory and regulatory requirements once the relevant enforcement policies are  
171 no longer in effect. This approach consists of three phases as described later in this section and  
172 outlined in **Table 2**.

173  
174 FDA intends to finalize this guidance promptly, after considering public comment on the draft,  
175 which may occur before the expiration of the COVID-19 section 319 PHE declaration (see  
176 Figure 1(a) below). In such a scenario, the implementation date would be the date the COVID-19  
177 section 319 PHE declaration expires. To help facilitate the transition to normal operations, FDA  
178 does not intend to withdraw the guidance documents in List 1 until 180 days after the  
179 implementation date.<sup>32</sup>

180  
181 FDA recognizes that circumstances could arise which require designation of an alternative  
182 implementation date, such as this guidance not being finalized in advance of the expiration of the  
183 COVID-19 section 319 PHE declaration, among other scenarios. In the event that the COVID-19  
184 section 319 PHE declaration expires before this guidance is finalized (see Figure 1(b) below),  
185 FDA does not intend to immediately withdraw the guidances identified in List 1, but rather  
186 intends to:

---

<sup>31</sup> FDA may consider future adoption of enforcement policies for certain devices that currently fall within an enforcement policy adopted during the COVID-19 PHE.

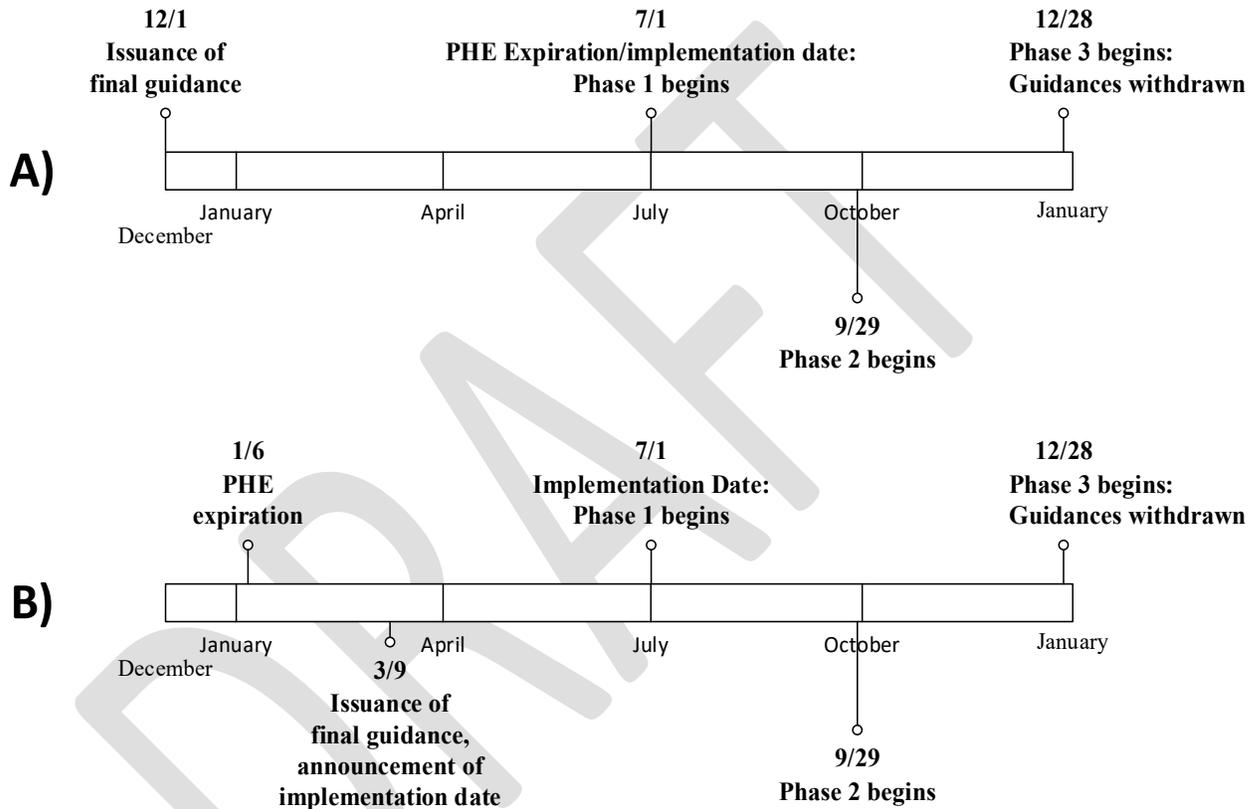
<sup>32</sup> Each of the guidances included in List 1 states that the enforcement policies set forth therein are “intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the PHSA.” As noted above, to encourage and facilitate an appropriate transition period, FDA is proposing to extend the duration of these guidances in List 1 to be aligned with the transition plan outlined in this guidance document.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

- 187 • Announce in this guidance: (1) the implementation date, which would be at least 45 days  
188 after the finalization of this guidance; and (2) the withdrawal date of the guidances in List  
189 1, which would be at least, 180 days after the implementation date; and
- 190 • Update the specified duration of the guidances in List 1 to align with this withdrawal  
191 date.

192  
193 Two hypothetical timelines for this process are provided in Figure 1.



194  
195 **Figure 1. Hypothetical Transition Timelines. A) Implementation date occurring on the**  
196 **expiration date of the COVID-19 section 319 PHE declaration. B) Implementation date**  
197 **occurring after the expiration of the COVID-19 section 319 PHE declaration.**

198  
199 In the bullets below, FDA describes its transition period expectations and recommendations for  
200 all manufacturers that distributed devices as described in an enforcement policy in a guidance in  
201 List 1, regardless of whether or not they are pursuing marketing authorization for their devices.  
202 We believe these expectations and recommendations will help facilitate a smooth and consistent  
203 transition back to normal operations.

204  
205 The three phases are as follows:  
206

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

- 207
- 208
- 209
- 210
- 211
- 212
- 213
- 214
- 215
- 216
- 217
- 218
- 219
- 220
- 221
- 222
- 223
- 224
- 225
- 226
- **Phase 1:** Begins on the implementation date. If not already doing so, manufacturers should follow 21 CFR Part 803 (i.e., adverse event reporting requirements) in order to prepare for Phase 3.<sup>33</sup>
  - **Phase 2:** Begins 90 days after the implementation date. Before the start of Phase 2 and in order to prepare for Phase 3, if not already doing so, manufacturers should follow 21 CFR Part 806 (i.e., reports of corrections and removals requirements), and if planning to continue to distribute their devices after the transition period should also follow 21 CFR Part 807 Subparts B-D (i.e., registration and listing requirements).
  - **Phase 3:** Begins 180 days after the implementation date. At the start of Phase 3, FDA intends to withdraw the guidances in List 1 and manufacturers will be expected to comply with all statutory and regulatory requirements applicable to their devices (e.g., 21 CFR Part 820, 21 CFR Part 801 Subpart B, and 21 CFR Part 830), except as discussed below regarding premarket authorization.<sup>34</sup> Prior to the start of Phase 3, FDA expects any marketing submission<sup>35</sup> for a device within the scope of this guidance to be submitted and accepted<sup>36</sup> if the manufacturer intends to continue distribution of the device after the guidances in List 1 are withdrawn. Where possible, FDA strongly encourages manufacturers to work to complete such submissions well in advance of the start of Phase 3 to avoid potential delays created by a large influx of new submissions and to best serve the public health. FDA does not intend to object to continued distribution<sup>37</sup> of devices within the scope of this guidance where a marketing submission has been submitted and

---

<sup>33</sup> FDA has issued guidance addressing the Agency’s enforcement approach to adverse event reporting during a pandemic with high employee absenteeism. See “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic>.

<sup>34</sup> For more information regarding FDA regulatory requirements for a specific device and FDA policies related to those requirements, manufacturers can use the [FDA Guidance Search Tool](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/) to identify relevant guidance documents. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/>. Following the implementation date, FDA will look to any other applicable compliance policies and otherwise apply our general risk-based approach in making compliance and enforcement decisions. For more information, see the FDA guidance “Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-regarding-benefit-risk-medical-device-product-availability-compliance-and>.

<sup>35</sup> For the purposes of this guidance, “marketing submission” includes a premarket approval application (PMA), PMA supplement, premarket notification (510(k)) submission, humanitarian device exemption (HDE) application, or De Novo classification request. For devices that are class I or II and exempt from premarket notification (e.g., shoe covers, face shields), no 510(k) submission is required unless the limitations of exemptions are exceeded (see, e.g., 21 CFR 878.9). See Section V.C for more details.

<sup>36</sup> For more information regarding FDA’s acceptance policies for marketing submissions, see the FDA guidance documents “Refuse to Accept Policy for 510(k)s,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>, “Acceptance and Filing Reviews for Premarket Approval Applications (PMAs),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-and-filing-reviews-premarket-approval-applications-pmas>, and “Acceptance Review for De Novo Classification Requests,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests>.

<sup>37</sup> Throughout this guidance, FDA uses the term “distribution” to broadly refer to any distribution of a device within the scope of this guidance and, where applicable, actions taken in furtherance of distribution such as marketing.

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

227 accepted by FDA before the start of Phase 3 and FDA has not taken a final action<sup>38</sup> on  
228 the marketing submission, as described in Section V.E below.

229  
230 The three phases of the transition plan, including additional considerations and recommendations  
231 related to each phase, are described in more detail below. Upon receiving FDA marketing  
232 authorization or any final action on a marketing submission, the Agency expects manufacturers  
233 to comply with all applicable statutory and regulatory requirements for their devices, including to  
234 cease marketing if required. For FDA’s proposal regarding the disposition of already-distributed  
235 devices following a final Agency decision on a marketing submission, see Section V.D(1) below.

236  
237 FDA understands that there may be scenarios that are not specifically addressed in this guidance,  
238 but generally believes that the timeframes and actions described in **Table 2**, regardless of the  
239 specific scenario for a manufacturer, will help avoid disruptions in critical devices and allow  
240 FDA to best manage its resources for review of marketing submissions. In certain circumstances,  
241 manufacturers may wish to initiate discussions with the Agency through the Q-Submission  
242 Program, including Pre-Submissions, to develop a plan to address their specific scenario if it is  
243 not discussed in this guidance. Manufacturers are expected to work toward, and FDA intends to  
244 help facilitate, submission of a marketing submission before Phase 3 begins. For details on the  
245 Q-Submission Program, refer to the guidance “[Requests for Feedback and Meetings for Medical  
246 Device Submissions: The Q-Submission Program](#).”<sup>39</sup>

247

### **A. If a manufacturer does not intend to distribute its device 248 after the withdrawal of the guidances**

249  
250 When a manufacturer that has been distributing its device as described in an enforcement policy  
251 in a guidance in List 1 does not intend to continue to distribute its device after the relevant  
252 guidance has been withdrawn, FDA generally does not intend to object to the disposition of  
253 already distributed devices (i.e., FDA does not intend to request market removal)<sup>40</sup> as follows:

254

- 255 1) Single use, non-life-supporting/non-life-sustaining devices (e.g., face masks) that were  
256 distributed before the withdrawal of the relevant guidances remain distributed and are  
257 consumed by the end user.

---

<sup>38</sup> FDA uses the term “final action” to mean a Medical Device User Fee Amendments (MDUFA) decision, which can include positive decisions, negative decisions, and notices of withdrawals, consistent with the: 510(k) Actions/Clock guidance, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals>; De Novo Actions/Clock guidance, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals>; PMA Actions/Clock guidance, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals>.

<sup>39</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>.

<sup>40</sup> FDA uses the term “removal” consistent with the definition in 21 CFR 806.2(j).

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

- 258 2) Reusable, non-life-supporting/non-life-sustaining devices (e.g., non-invasive remote  
259 patient monitoring devices, infusion pumps) that were distributed before the withdrawal  
260 of the relevant guidance remain distributed and are used by their end user. Such devices  
261 should either:
- 262 a. Be restored by the manufacturer to the previously FDA-cleared or approved  
263 version of the device (e.g., earlier software version, component replacement),<sup>41</sup> or
  - 264 b. Have publicly available labeling that accurately describes the product features and  
265 regulatory status (i.e., that the product lacks FDA clearance or approval).
- 266 3) Reusable life-supporting/life-sustaining devices (e.g., ventilators, extracorporeal  
267 membrane oxygenation systems) that were distributed before the withdrawal of the  
268 relevant guidance remain distributed. Such devices should either:
- 269 a. Be restored by the manufacturer to the previously FDA-cleared or approved  
270 version of the device, or
  - 271 b. Have both publicly available and a physical copy of labeling that accurately  
272 describes the product features and regulatory status (i.e., that the product lacks  
273 FDA clearance or approval).<sup>42</sup>
- 274

275 Manufacturers that do not intend to market their devices after the withdrawal of the guidances in  
276 List 1 should also refer to the information included in the phased approach outlined below unless  
277 otherwise noted (e.g., certain information included below is intended only for manufacturers that  
278 intend to market their device after the transition period ends as outlined in Section V.E below).  
279 In addition, manufacturers should be aware of any applicable statutory and regulatory  
280 requirements for their device, such as adverse event reporting under 21 CFR Part 803, and are  
281 expected to comply with such requirements for the duration in which they are applicable, which  
282 may extend beyond the cessation of distribution.

283

## **B. Phase 1**

284  
285 Phase 1 starts on the implementation date, as described above. In order to prepare for Phase 3, if  
286 not already doing so, manufacturers should follow adverse event reporting requirements<sup>43</sup> under  
287 21 CFR Part 803. Manufacturers should submit any adverse event reports that were stored (e.g.,  
288 because of pandemic-related high employee absenteeism) consistent with FDA guidance.<sup>44</sup>

---

<sup>41</sup> In situations where manufacturers do not believe restoration is possible or in the best interest of public health, FDA recommends additional engagement with the Agency to develop a plan to address their specific scenario if it is not otherwise discussed in this guidance.

<sup>42</sup> FDA recognizes that facilities may wish to retain the device should it be authorized by FDA for use in the future; the future use of the device would be subject to the regulatory requirements of any future authorization, including marketing authorization or emergency use authorization.

<sup>43</sup> For more information on adverse event reporting requirements under 21 CFR Part 803, see the guidance “Medical Device Reporting for Manufacturers” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-reporting-manufacturers>.

<sup>44</sup> For more information on adverse event reporting during the COVID-19 PHE, see the Guidance “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic>.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

289  
290 During (and preferably before) this phase, manufacturers that intend to continue distribution of  
291 their devices after the withdrawal of the guidances in List 1 should begin preparation of the  
292 applicable marketing submission to help avoid disruptions in critical devices and allow FDA to  
293 best manage its resources for review of marketing submissions.<sup>45</sup> While preparing a marketing  
294 submission, manufacturers can use the [FDA Guidance Search Tool](#)<sup>46</sup> to identify relevant  
295 guidance documents that may be helpful in preparing the submission.  
296

297 **C. Phase 2**

298 Phase 2 begins 90 days after the implementation date. Before the start of Phase 2 and in order to  
299 prepare for Phase 3, if not already doing so, manufacturers should submit reports of corrections  
300 and removals under 21 CFR Part 806. Manufacturers that intend to continue to distribute their  
301 devices after the transition period should also register their establishments and list<sup>47</sup> their  
302 device(s) or update existing registration and listing (R&L) if they have not already done so. If  
303 applicable, the manufacturer is expected to prepare to submit a marketing submission to FDA  
304 and have it accepted before the start of Phase 3 to help avoid disruptions in critical devices and  
305 allow FDA to best manage its resources for review of marketing submissions.  
306

307 In addition, FDA recommends that manufacturers of certain life-supporting or life-sustaining  
308 devices within the scope of this guidance submit a “Notification of Intent” to FDA as described  
309 in Section V.C(1) below.  
310

311 **(1) “Notifications of Intent” for Certain Reusable Life-**  
312 **Supporting or Life-Sustaining Devices**

313 Given the public health significance of certain reusable life-supporting or life-sustaining devices,  
314 FDA requests that manufacturers of such devices submit to FDA information about whether or  
315 not they intend to submit a marketing submission. This information will assist the Agency in  
316 resource planning for marketing submission review and providing increased support to  
317 manufacturers. This request applies to devices that fall within the scope of this guidance and that  
318 have a product code listed in Table 1:  
319  
320

**Table 1**

<b>Product Code</b>	<b>Device Type</b>	<b>Classification Regulation</b>
BSZ	Gas-machine, anesthesia	21 CFR 868.5160

---

<sup>45</sup> For the purposes of this guidance, “marketing submission” includes a premarket approval application (PMA), PMA supplement, premarket notification (510(k)) submission, humanitarian device exemption (HDE) application, or De Novo classification request.

<sup>46</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/>.

<sup>47</sup> 21 CFR Part 807, Subparts B-D.

***Contains Nonbinding Recommendations***

***Draft – Not for Implementation***

CAW	Generator, oxygen, portable	21 CFR 868.5440
BTT	Humidifier, Respiratory Gas, (Direct Patient Interface)	21 CFR 868.5450
QAV	High flow/high velocity humidified oxygen delivery device	21 CFR 868.5454
CBK	Ventilator, Continuous, Facility Use	21 CFR 868.5895
MNT	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	
NOU	Continuous, ventilator, home use	
MNS	Ventilator, continuous, non-life- supporting	
ONZ	Mechanical Ventilator	
BTL	Ventilator, Emergency, Powered (Resuscitator)	21 CFR 868.5925

321  
322 Manufacturers of the devices identified in Table 1 should submit the following information to the  
323 CDRH Document Control Center<sup>48</sup> before the start of Phase 2:  
324

- 325 • General information, including contact information, name and place of business, and  
326 email address;
- 327 • The title of the relevant enforcement policy guidance;
- 328 • Submission number(s) for related premarket submissions;
- 329 • A list of all model numbers or other device identifying information;
- 330 • Whether the manufacturer plans to submit a marketing submission; and
- 331 • If not planning to submit a marketing submission, the manufacturer should discuss, as  
332 applicable, its plans to discontinue distribution of the device, to restore the device to a  
333 previously FDA-cleared or -approved version, to provide a physical copy or electronic  
334 updated labeling, and any other efforts to address or mitigate potential risks of devices  
335 that remain distributed after the transition period has ended and the guidances in List 1  
336 have been withdrawn.

337  
338 If the device was previously FDA-cleared or approved and a modified version was distributed as  
339 described in a policy in a guidance in List 1, the manufacturer should submit this information as  
340 a premarket notification (i.e., 510(k)) or PMA “amendment” to the manufacturer’s existing

---

<sup>48</sup> The mailing address for the CDRH Document Control Center can be found in 21 CFR 807.90(a)(1). FDA encourages manufacturers to submit Notifications of Intent as eCopies. Information about the eCopy program can be found in the FDA guidance document “eCopy Program for Medical Device Submissions,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>.

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

341 device submission that was previously cleared or approved.<sup>49</sup> FDA recommends that  
342 manufacturers notate the following on the cover letter of the submission: “Attention: Notification  
343 of Intent.”  
344

### **D. Phase 3**

346 Phase 3 begins 180 days after the implementation date. At the start of Phase 3, FDA intends to  
347 withdraw the guidances in List 1.  
348

349 Before the start of Phase 3, any marketing submission<sup>50</sup> is expected to be submitted to and  
350 accepted by FDA if the manufacturer intends to continue distribution of the device after the  
351 withdrawal of the guidances in List 1.  
352

353 If a manufacturer submits a marketing submission, and that submission is accepted before the  
354 beginning of Phase 3, FDA does not intend to object to the continued distribution of the devices  
355 within the scope of this guidance as described in Section V.E below. FDA expects manufacturers  
356 of such devices to comply with all other statutory and regulatory requirements applicable to their  
357 devices. These requirements include but are not limited to the Quality System (QS) regulation  
358 under 21 CFR Part 820 and Unique Device Identification under 21 CFR Part 801 Subpart B and  
359 21 CFR Part 830, if applicable.  
360

#### **(1) Recommendations for Transition Implementation Plan**

362 We expect that some marketing submissions will include changes or updates to the device and/or  
363 its labeling compared to the product that was distributed during the COVID-19 PHE prior to  
364 Phase 3, and in some cases, a manufacturer may not receive a positive decision from FDA on its  
365 marketing submission. To help address such situations efficiently, we recommend that  
366 manufacturers include with their marketing submissions a proposed “transition implementation  
367 plan” that addresses the manufacturers’ plans for devices already distributed in the case of a  
368 positive decision or a negative decision on the marketing submission. We recommend that this  
369 include the following information, as applicable:<sup>51</sup>  
370

- 371 • Estimated number of devices that fall within the policies outlined in any of the guidances  
372 referenced in List 1 above that are currently in U.S. distribution;

---

<sup>49</sup> FDA recommends that the information be submitted as an “amendment” to the previous 510(k) or PMA file to facilitate efficient tracking of the “Notification of Intent” submissions.

<sup>50</sup> For devices that are class I or II and exempt from premarket notification (e.g., shoe covers, face shields), no 510(k) submission is required unless the limitations of exemptions are exceeded (see, e.g., 21 CFR 878.9).

<sup>51</sup> If the manufacturer has already submitted a “Notification of Intent” with some of this information (e.g., information on the number of devices currently in U.S. distribution that fall within the enforcement policies described in the guidance documents in List 1), FDA still recommends that manufacturers include a transition implementation plan with their marketing submission, noting any updates since the “Notification of Intent” was submitted to FDA.

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

- 373
- 374
- 375
- 376
- 377
- An explanation of the manufacturer’s benefit-risk based plan for disposition of already distributed product in the event of a negative decision on the marketing submission. If the manufacturer is proposing to leave already distributed product in place, the plan should address the rationale for doing so and considerations such as the following, where relevant:<sup>52</sup>
    - Process for notifying patients, consumers, healthcare facilities, healthcare providers, and distributors of the device’s regulatory status;
    - Process and timeline for restoring distributed devices to the previously FDA-cleared or approved version, providing publicly available labeling that accurately describes the product features and regulatory status, or providing both publicly available and a physical copy of updated labeling for reusable life-supporting/life-sustaining devices to describe their regulatory status; and
    - A description of the maintenance plan for distributed devices.
  - An explanation of the manufacturer’s plans for addressing already distributed product in the event of a positive decision on the marketing submission, including considerations such as the following, where relevant:
    - Process for notifying patients, consumers, healthcare facilities, healthcare providers, and distributors of the device’s regulatory status; and
    - Process and timeline for providing to users of previously distributed devices updated labeling or components that reflect any changes made to the cleared or approved device.
- 378
- 379
- 380
- 381
- 382
- 383
- 384
- 385
- 386
- 387
- 388
- 389
- 390
- 391
- 392
- 393

394

395 Depending on FDA’s evaluation of the marketing submission, FDA may engage with the manufacturer during the Agency’s review of the submission to discuss the appropriate disposition of already-distributed devices, including the transition implementation plan described above. If changes are made to the device (e.g., modifications to address a cybersecurity concern), the manufacturer should discuss possible correction or removal with FDA regarding devices already distributed to the end user. Moreover, FDA may request a firm initiate a recall of such devices in certain circumstances if a recall has not already been initiated (see 21 CFR 7.45).

396

397

398

399

400

401

402

### **(2) Discontinuing distribution of a device**

403

404 FDA expects manufacturers to discontinue distribution of a device within the scope of this guidance:

405

406

- 407
- 408
- 409
- 410
- 1) Before the beginning of Phase 3, if the manufacturer has not submitted a marketing submission for its device and had it accepted by FDA; or
  - 2) On the date the manufacturer receives a negative decision on its marketing submission as FDA’s final action, or on the date the manufacturer withdraws its submission or

---

<sup>52</sup> While FDA recommends the inclusion of a benefit-risk based plan for disposition of distributed product be submitted with a marketing submission for devices within the scope of this guidance, FDA also believes such an approach is consistent with device end-of-life best practices and recommends that manufacturers consider and conduct such activities even if the manufacturer’s transition implementation plan is not prospectively shared with the Agency.

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

411 fails to provide a complete response to an FDA request for additional information<sup>53</sup>  
412 within the allotted time identified in FDA’s letter.

413  
414 In addition, manufacturers should be aware of any applicable statutory and regulatory  
415 requirements for their device, such as adverse event reporting under 21 CFR Part 803, and are  
416 expected to comply with such requirements for the duration in which they are applicable, which  
417 may extend beyond the cessation of distribution.

418

### 419 **(3) Additional considerations**

420 Before Phase 3, we expect manufacturers who intend to market their device after the withdrawal  
421 of the guidances in List 1 to have completed any steps necessary to transition into compliance  
422 with all statutory and regulatory requirements applicable to their devices.<sup>54</sup> However, FDA does  
423 not intend to object to continued distribution of devices that lack FDA marketing authorization in  
424 the circumstances outlined in Section V.E below. Under section 704(a)(1) of the FD&C Act,  
425 FDA may enter and inspect any factory, warehouse, or establishment in which devices are  
426 manufactured, processed, packed, or held for introduction into interstate commerce or after  
427 introduction into interstate commerce, at reasonable times and within reasonable limits and in a  
428 reasonable manner.<sup>55</sup>

429

430 FDA recognizes that there may be situations that raise unique compliance considerations. For  
431 example, non-traditional device manufacturers that previously operated under different quality  
432 standards or requirements may face challenges that take more time to address in transitioning to  
433 a system that fully complies with 21 CFR Part 820. FDA intends to take such considerations into  
434 account when making case-by-case compliance and enforcement decisions. In some cases,  
435 manufacturers who intend to continue distributing their devices beyond the start of Phase 3 may  
436 request an exemption or variance from a device QS requirement as outlined in 21 CFR 820.1(e)  
437 and section 520(f)(2) of the FD&C Act. FDA strongly encourages that any request for an  
438 exemption or variance be submitted within 90 days of the announcement of the implementation  
439 date for this guidance in order to provide the Agency adequate time to review and act upon the  
440 request.

---

<sup>53</sup> For more information on FDA requests for additional information (i.e., deficiency letters) and how to respond, see the FDA guidance “Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions>.

<sup>54</sup> For more information regarding FDA regulatory requirements for a specific device and FDA policies related to those requirements, manufacturers can use the [FDA Guidance Search Tool](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/) to identify relevant guidance documents. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/>. Following the transition period, FDA will look to any other applicable compliance policies and otherwise apply our general risk-based approach in making compliance and enforcement decisions. For more information, see the FDA guidance “Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-regarding-benefit-risk-medical-device-product-availability-compliance-and->

<sup>55</sup> Under section 301(e)-(f) of the FD&C Act, it is a prohibited act to refuse to permit access to certain records required under the FD&C Act or to refuse to permit entry or inspection as authorized by section 704 of the FD&C Act.

441

442

443

## **E. Enforcement policy for devices with a marketing submission under review by FDA**

444

445

446

447

448

As previously stated, FDA recognizes that it may take time for manufacturers, including non-traditional manufacturers of devices, to adapt and adjust their operations during the COVID-19 PHE back to normal operations. At this time, FDA does not intend to object to the continued distribution of devices within the scope of this guidance after the start of Phase 3 where:

449

450

451

- The manufacturer has submitted a marketing submission to FDA and had it accepted by FDA before the start of Phase 3; and
- FDA has not taken a final action on the marketing submission.

452

453

454

455

456

457

The enforcement policy described in this section (Section V.E) applies only to requirements to obtain FDA marketing authorization. It does not apply to other applicable statutory and regulatory requirements (such as registration and listing, QS requirements, and reports of corrections and removals required under 21 CFR Parts 807, 820, and 806).

458

## **VI. Examples**

459

460

461

462

463

464

465

466

467

468

469

The following hypothetical examples are intended to illustrate the phased transition plan outlined above. To exemplify the timeline of the phased transition plan outlined in Section V above, for purposes of the examples, we set the hypothetical implementation date for all devices that fall within this enforcement policy as July 1, consistent with the hypothetical timeline shown in Figure 1. The dates outlined in each example follow this example phased transition plan timeline. The dates described below are not intended to propose an actual implementation date to begin this transition plan; they are hypothetical and for illustrative purposes only. Note that these generalized examples do not account for every possible detail, risk, or consideration a manufacturer should evaluate or that may be relevant to FDA decisions regarding a particular device.

470

### **Example 1**

471

472

473

474

A 510(k)-cleared cardiac monitor was modified to add Bluetooth functionality<sup>56</sup> to remotely monitor COVID-19 patients as described in the policies in the FDA guidance, “[Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency \(Revised\)](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-for-non-invasive-remote-monitoring-devices-used-to-support-patient-monitoring-during-the-coronavirus-disease-2019-covid-19-public-health-emergency-revised).”<sup>57</sup>

---

<sup>56</sup> Manufacturers should also consult the FDA guidance document “Multiple Function Device Products: Policy and Considerations,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations>, for more information about how such a function can affect the regulation of a device.

<sup>57</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

475

476

**a) Manufacturer who intends to continue distributing  
beyond the start of Phase 3 and receives a positive  
decision on its marketing submission**

477

478

479 Phase 1 (July 1): In the above-referenced guidance document, FDA describes its intent not to  
480 object to modification of certain remote monitoring devices in certain circumstances without  
481 marketing authorization by FDA. The enforcement policy in the guidance does not address other  
482 requirements, including adverse event reporting, reports of corrections and removals, and QS  
483 requirements. The manufacturer continues to comply with requirements under 21 CFR Parts 803,  
484 806, and 820.

485

486 Phase 2 (September 29): As an indication of its intent to market its device beyond the start of  
487 Phase 3, the portable cardiac monitor manufacturer updates its existing listing under 21 CFR Part  
488 807 Subparts B-D. On October 1, the manufacturer submits a marketing submission to FDA,  
489 which is accepted by the Agency. Along with its marketing submission, the manufacturer  
490 includes a “transition implementation plan” for already-distributed portable cardiac monitors.

491

492 Phase 3 (December 28): The above-referenced guidance document is withdrawn at the start of  
493 Phase 3, and FDA has not yet taken a final action on the manufacturer’s marketing submission.  
494 Under these circumstances, FDA does not intend to object to the continued distribution of the  
495 portable cardiac monitor without FDA marketing authorization before FDA takes a final action  
496 on the marketing submission (see Section V.E above). The manufacturer continues to comply  
497 with all other statutory and regulatory requirements applicable to the device (such as registration  
498 and listing, QS requirements, and reports of corrections and removals required under 21 CFR  
499 Parts 807, 820, and 806).

500

501 The manufacturer receives a positive decision on its marketing submission on January 6 (90 days  
502 after submission), although outstanding software anomalies were identified and modifications to  
503 the device were made during FDA’s premarket review. Based on the transition implementation  
504 plan included with the marketing submission, FDA is aware of the number of distributed devices  
505 that may have these anomalies and engages with the manufacturer on how to address these issues  
506 with the already-distributed devices. The manufacturer initiates a correction to address the  
507 software anomalies in the portable cardiac monitors that were distributed prior to the positive  
508 marketing decision.

509

510

**b) Manufacturer who intends to continue distribution  
beyond the start of Phase 3 and receives a negative  
decision on its marketing submission**

511

512

513 Phase 1 (July 1): In the above-referenced guidance document, FDA describes its intent not to  
514 object to modification of certain remote monitoring devices in certain circumstances without  
515 marketing authorization by FDA. The enforcement policy in the guidance does not address other  
516 requirements, including adverse event reporting, reports of corrections and removals, and QS

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

517 requirements. The manufacturer continues to comply with requirements under 21 CFR Parts 803,  
518 806, and 820.

519  
520 Phase 2 (September 29): As an indication of its intent to market its device beyond the start of  
521 Phase 3, the portable cardiac monitor manufacturer updates its existing listing under 21 CFR Part  
522 807 Subparts B-D. On October 15, the manufacturer submits a marketing submission to FDA,  
523 which is accepted by the Agency. Along with its marketing submission, the manufacturer  
524 includes a “transition implementation plan” for already-distributed portable cardiac monitors.

525  
526 Phase 3 (December 28): The above-referenced guidance document is withdrawn at the start of  
527 Phase 3, and FDA has not yet taken final action on the manufacturer’s marketing submission.  
528 Under these circumstances, FDA does not intend to object to the continued distribution of the  
529 portable cardiac monitor without FDA marketing authorization before FDA takes a final action  
530 on the marketing submission (see Section V.E above). The manufacturer continues to comply  
531 with all other statutory and regulatory requirements applicable to the device (such as registration  
532 and listing, quality systems, and reports of corrections and removals required under 21 CFR Parts  
533 807, 820, and 806).

534  
535 The manufacturer receives a negative decision on its marketing submission on January 15 (90  
536 days after submission), due to outstanding software anomalies that were identified and could not  
537 be addressed by the manufacturer during FDA’s premarket review. As described in the transition  
538 implementation plan included with the marketing submission, the manufacturer initiates a  
539 correction to restore the remote patient monitor to the previously cleared version. In addition, the  
540 manufacturer ceases distributing the modified device.

541

## 542 **Example 2**

543 A previously cleared diagnostic x-ray system was modified to become portable and falls within  
544 the enforcement policy described in the FDA guidance “[Enforcement Policy for Imaging  
545 Systems During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#).”<sup>58</sup>

546

547 Phase 1 (July 1): In the above-referenced guidance document, FDA describes its intent not to  
548 object to modifications to certain imaging systems in certain circumstances without marketing  
549 authorization by FDA. The enforcement policy in the guidance does not address other  
550 requirements, including requirements in 21 CFR Parts 803, 807 Subparts B-D, 806, 820, and  
551 830. The manufacturer continues to comply with these requirements.

552

553 Phase 2 (September 29): As an indication of its intent to market its device beyond the start of  
554 Phase 3, the portable x-ray system manufacturer updates its existing listing, under 21 CFR Part  
555 807 Subparts B-D. On September 29, the manufacturer submits a marketing submission to FDA,

---

<sup>58</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-imaging-systems-during-coronavirus-disease-2019-covid-19-public-health-emergency>.

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

556 which is accepted by the Agency. In its marketing submission, the manufacturer includes a  
557 “transition implementation plan” for already-distributed portable x-ray systems.  
558

559 Phase 3 (December 28): The above-referenced guidance document is withdrawn at the start of  
560 Phase 3, and FDA has not yet taken final action on the manufacturer’s marketing submission.  
561 Under these circumstances, FDA does not intend to object to the continued distribution of the  
562 portable x-ray system without marketing authorization before FDA takes a final action on the  
563 marketing submission (see Section V.E above). The manufacturer continues to comply with all  
564 other statutory and regulatory requirements applicable to the device (such as registration and  
565 listing, quality systems, and reports of corrections and removals required under 21 CFR Parts  
566 807, 820, and 806).

567  
568 The manufacturer does not respond to a request from FDA for additional information within the  
569 specified timeframe identified in the Agency’s deficiency letter. FDA issues a notice of  
570 withdrawal as the Agency’s final action on the marketing submission on March 15. FDA and the  
571 manufacturer engage regarding the manufacturer’s benefit-risk plan to address already-  
572 distributed devices. FDA may request the firm initiate a recall of such devices in certain  
573 circumstances if a recall has not already been initiated (see 21 CFR 7.45). In addition, the  
574 manufacturer ceases distributing the modified device.  
575

### **Example 3**

576  
577 A previously cleared ventilator was modified to make material changes to components in the gas  
578 pathway to accommodate supplier shortages and falls within the enforcement policy described in  
579 the FDA guidance, “[Enforcement Policy for Ventilators and Accessories and Other Respiratory  
580 Devices During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency.](#)”<sup>59</sup>  
581

582 Phase 1 (July 1): In the above-referenced guidance document, FDA describes its intent not to  
583 object to modifications to ventilators in certain circumstances without marketing authorization  
584 by FDA. The enforcement policy in the guidance does not address other requirements, including  
585 requirements in 21 CFR Parts 803, 807 Subparts B-D, 806, 820, and 830. The manufacturer  
586 continues to comply with these requirements.  
587

588 Phase 2 (September 29): As an indication of its intent to market its device beyond the start of  
589 Phase 3, the ventilator manufacturer ensures that its existing listing, under 21 CFR Part 807  
590 Subparts B-D, is up to date. On October 1, the ventilator manufacturer also submits an  
591 amendment to the manufacturer’s previously cleared marketing submission to the CDRH  
592 Document Control Center with “Attention: Notification of Intent” on the cover letter of the  
593 submission to describe the manufacturer’s intent to submit a marketing submission. This  
594 submission amendment includes the information outlined in Section V.C(1) above. In its

---

<sup>59</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus>.

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

595 marketing submission that was accepted by the Agency on December 20, the manufacturer  
596 includes a “transition implementation plan” for already-distributed ventilators.

597  
598 Phase 3 (December 28): The above-referenced guidance document is withdrawn at the start of  
599 Phase 3, and FDA has not yet taken final action on the manufacturer’s marketing submission.  
600 Under these circumstances, FDA does not intend to object to the continued distribution of the  
601 ventilator without FDA marketing authorization before FDA takes final action on the marketing  
602 submission (see Section V.E above). The manufacturer continues to comply with all other  
603 statutory and regulatory requirements applicable to the device (such as registration and listing,  
604 QS requirements, and reports of corrections and removals required under 21 CFR Parts 807, 820,  
605 and 806).

606  
607 The ventilator manufacturer receives a positive decision on its marketing submission on  
608 February 20. The manufacturer continues to distribute the modified ventilator with updated  
609 labeling. In addition, the manufacturer sends notice to users of the modified ventilator that were  
610 distributed during the COVID-19 PHE apprising them of the regulatory status of the device and  
611 providing the updated labeling.

612

#### 613 **Example 4**

614 A new telethermographic system that has not been FDA-cleared and is intended for adjunctive  
615 diagnostic screening by providing an initial body temperature assessment for triage use, falls  
616 within the enforcement policy described in the FDA guidance, “[Enforcement Policy for  
617 Telethermographic Systems During the Coronavirus Disease 2019 \(COVID-19\) Public Health  
618 Emergency](#).”<sup>60</sup>

#### 619 **a) Manufacturer who intends to continue distribution** 620 **beyond the start of Phase 3**

621 Phase 1 (July 1): In the guidance, FDA describes its intent not to object to the distribution and  
622 use of certain telethermographic system without submission of a 510(k), reports of corrections  
623 and removals, registration and listing, and compliance with the QS regulation and unique device  
624 identification requirements in certain circumstances. The enforcement policy in the guidance  
625 does not address other requirements, including requirements in 21 CFR Part 803. The  
626 manufacturer continues to comply with 21 CFR Part 803.

627  
628 Phase 2 (September 29): As an indication of its intent to market its device beyond the start of  
629 Phase 3 the telethermographic system manufacturer registers and lists, consistent with 21 CFR  
630 Part 807 Subparts B-D. On October 1, the manufacturer submits a marketing submission to FDA,  
631 which is accepted by the Agency. In its marketing submission, the manufacturer includes a  
632 “transition implementation plan” for already-distributed telethermographic systems.

633

---

<sup>60</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health>.

## *Contains Nonbinding Recommendations*

### *Draft – Not for Implementation*

634 Phase 3 (December 28): The above-referenced guidance document is withdrawn at the start of  
635 Phase 3, and FDA has not yet taken final action on the manufacturer’s marketing submission.  
636 Under these circumstances, FDA does not intend to object to the continued distribution of the  
637 telethermographic system without FDA marketing authorization before FDA takes a final action  
638 on the marketing submission (see Section V.E above). The manufacturer complies with all other  
639 statutory and regulatory requirements applicable to the device (such as registration and listing,  
640 QS requirements, and reports of corrections and removals required under 21 CFR Parts 807, 820,  
641 and 806).

642  
643 The manufacturer receives a “not substantially equivalent” decision on March 1 after FDA’s  
644 review of the manufacturer’s marketing submission. The manufacturer ceases distributing the  
645 telethermographic system. FDA and the manufacturer engage regarding the manufacturer’s  
646 benefit-risk based plan to address already-distributed devices. FDA may request the firm initiate  
647 a recall of such devices in certain circumstances if a recall has not already been initiated (see 21  
648 CFR 7.45).

649

#### **b) Manufacturer who does not intend to continue distribution beyond the start of Phase 3**

650  
651  
652 A new telethermographic system that has not been FDA-cleared and is intended for adjunctive  
653 diagnostic screening by providing an initial body temperature assessment for triage use was  
654 distributed under the enforcement policy described in the FDA guidance, “[Enforcement Policy  
655 for Telethermographic Systems During the Coronavirus Disease 2019 \(COVID-19\) Public  
656 Health Emergency](#).”<sup>61</sup>

657  
658 Phase 1 (July 1): In the above-referenced guidance document, FDA describes its intent not to  
659 object to the distribution and use of certain telethermographic system without submission of a  
660 510(k), reports of corrections and removals, registration and listing, and compliance with the QS  
661 regulation and unique device identification requirements in certain circumstances. The  
662 enforcement policy in the guidance does not address other requirements, including 21 CFR Part  
663 803. The manufacturer continues to comply with 21 CFR Part 803.

664  
665 Phase 2 (September 29): The manufacturer decides that it does not want to continue to market  
666 and distribute the device beyond the start of Phase 3. The manufacturer ceases distributing the  
667 device on November 1, and notifies end users of the regulatory status of the device. In addition,  
668 the manufacturer continues to report adverse events that it becomes aware of, even after the  
669 manufacturer has ceased distributing the telethermographic system.

670  
671 Phase 3 (December 28): The above-referenced guidance document is withdrawn at the start of  
672 Phase 3. The manufacturer leaves previously-distributed telethermographic systems in the field.  
673 The manufacturer makes revised labeling for the system publicly available, and such labeling

---

<sup>61</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health>.

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

674 accurately describes all product features and notes that the product is not FDA-cleared or  
675 approved for marketing. Further, the manufacturer sends notice to users concerning the  
676 regulatory status of the devices and continues to engage in adverse event reporting to FDA  
677 concerning the device.

DRAFT

Table 2

PHASE	1	2	3
TIME	0 days (implementation date)	90 days after the implementation date	180 days after the implementation date
<b>ACTIONS</b>	<p>In order to prepare for Phase 3, manufacturers should, if not already doing so, follow adverse event reporting requirements under 21 CFR Part 803. Manufacturers should submit any stored adverse event reports consistent with <a href="#">FDA guidance</a>.<sup>62</sup></p> <p>Manufacturers should begin to prepare their marketing submissions, if applicable.</p>	<p>In order to prepare for Phase 3, Manufacturers that intend to continue to continue to distribute their devices after the transition period should register their establishments and list their device(s), or update their existing registration and listing, under 21 CFR Part 807 Subparts B-D. Manufacturers should also submit reports of corrections and removals consistent with 21 CFR Part 806.</p> <p>Manufacturers of devices under the product codes listed in Section V.C(1) should send a Notification of Intent to FDA.</p> <p>Manufacturers should prepare to submit a marketing submission to FDA and have it accepted by FDA before the start of Phase 3.</p>	<p>FDA withdraws the guidances in List 1 containing COVID-19 related enforcement policies.</p> <p>Before the start of Phase 3, if manufacturers submit a marketing submission(s), and that submission is accepted by FDA, FDA does not intend to object to the continued distribution of the device after the withdrawal of the guidances in List 1 as described in Section V.E (see also below). With the marketing submission, the manufacturer should include a “transition implementation plan” that addresses the manufacturer’s plans for devices already in distribution in the case of a positive decision or a negative decision on the marketing submission. FDA recommends that the transition implementation plan include the information in Section V.D(1), as applicable.</p> <p>FDA does not intend to object to the continued distribution of devices under the circumstances outlined in Section V.E: the manufacturer has submitted a marketing submission to FDA and had it accepted by FDA before the start of Phase 3 and FDA has not taken a final action on the marketing submission. However, the manufacturer is expected to comply with all other applicable statutory and regulatory requirements (such as registration and listing, QS requirements, and reports of corrections and removals required under 21 CFR Parts 807, 820, and 806).</p> <p>FDA expects distribution to cease if the manufacturer does not submit a required marketing submission and had it accepted by FDA before the beginning of Phase 3, or on the date the manufacturer receives a negative decision on its marketing submission as FDA’s final action, or on the date the manufacturer withdraws its submission or fails to provide a complete response to an FDA request for additional information within the allotted time identified in FDA’s letter.</p>

<sup>62</sup> For more information on adverse event reporting during the COVID-19 PHE, see the FDA Guidance “Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic>.