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 to receive a copy of the guidance. Please include the document number 21011 and complete title of the guidance in the request.

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

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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. Introduction

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

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

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

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

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[1] 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,
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> (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
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> 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."

[2] 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.

[3] 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.

[4] 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.

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

II. Background

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

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

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

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[5] 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.

[6] 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-ofthe-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic.

[7] 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.

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

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

III. Scope

This guidance applies to devices that fall within the enforcement policies described in the guidances identified in List 1 below.[8, 9]

List 1

- Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 Public Health Emergency[10]
- Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency[11]
- Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency[12]
- Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency[13]

[8] 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.

[9] 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.

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

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

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

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

- Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the COVID-19 Public Health Emergency[14]
- Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the COVID-19 Public Health Emergency[15]
- Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the COVID-19 Public Health Emergency[16]
- Enforcement Policy for Infusion Pumps and Accessories During the COVID-19 Public Health Emergency[17]
- Enforcement Policy for Clinical Electronic Thermometers During the COVID-19 Public Health Emergency[18]
- Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the COVID-19 Public Health Emergency (Revised)[19]
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency[20]
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the COVID-19 Public Health Emergency[21]
- Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency[22]
- Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency (Revised)[23]
- Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the COVID-19 Public Health Emergency[24]

[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease.
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during.
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease.
[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public.
[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public.
[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-barrier-face-coverings-face-shields-surgical-masks-and-respirators.
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.
[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease.
[22] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.
[23] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during.
[24] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-modifications-fda-cleared-molecular-influenza-and-rsv-tests-during-coronavirus.

- Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency[25]
- Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the COVID-19 Public Health Emergency (Revised)[26]

IV. Guiding Principles

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

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

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

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

[27] See section 1003 of the FD&C Act.

[28] 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.

[29] 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.

[30] 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.

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

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

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

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

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

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

[32] 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.

- **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.[33]
- **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.[34] Prior to the start of Phase 3, FDA expects any marketing submission[35] for a device within the scope of this guidance to be submitted and accepted[36] 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[37] of devices within the scope of this guidance where a marketing submission has been submitted and

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[33] 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.

[34] 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 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.

[35] 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.

[36] 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.

[37] 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.

accepted by FDA before the start of Phase 3 and FDA has not taken a final action[38] on the marketing submission, as described in Section V.E below.

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

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

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

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

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

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[38] 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.

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

[40] FDA uses the term "removal" consistent with the definition in 21 CFR 806.2(j).

2) Reusable, non-life-supporting/non-life-sustaining devices (e.g., non-invasive remote patient monitoring devices, infusion pumps) that were distributed before the withdrawal of the relevant guidance remain distributed and are used by their end user. Such devices should either:
    a. Be restored by the manufacturer to the previously FDA-cleared or approved version of the device (e.g., earlier software version, component replacement),[41] or
    b. Have publicly available labeling that accurately describes the product features and regulatory status (i.e., that the product lacks FDA clearance or approval).
3) Reusable life-supporting/life-sustaining devices (e.g., ventilators, extracorporeal membrane oxygenation systems) that were distributed before the withdrawal of the relevant guidance remain distributed. Such devices should either:
    a. Be restored by the manufacturer to the previously FDA-cleared or approved version of the device, or
    b. Have both publicly available and a physical copy of labeling that accurately describes the product features and regulatory status (i.e., that the product lacks FDA clearance or approval).[42]

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

B. Phase 1

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

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[41] 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.

[42] 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.

[43] 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.

[44] 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.

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

C. Phase 2

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 submit reports of corrections and removals under 21 CFR Part 806. Manufacturers that intend to continue to distribute their devices after the transition period should also register their establishments and list[47] their device(s) or update existing registration and listing (R&L) if they have not already done so. If applicable, the manufacturer is expected to prepare to submit a marketing submission to FDA and have it accepted before the start of Phase 3 to help avoid disruptions in critical devices and allow FDA to best manage its resources for review of marketing submissions.

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

(1) "Notifications of Intent" for Certain Reusable Life-Supporting or Life-Sustaining Devices

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

Table 1

Product Code	Device Type	Classification Regulation
BSZ	Gas-machine, anesthesia	21 CFR 868.5160

[45] 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.
[46] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/.
[47] 21 CFR Part 807, Subparts B-D.

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

Manufacturers of the devices identified in Table 1 should submit the following information to the CDRH Document Control Center[48] before the start of Phase 2:

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

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

[48] 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.

device submission that was previously cleared or approved.[49] FDA recommends that manufacturers notate the following on the cover letter of the submission: "Attention: Notification of Intent."

D. Phase 3

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

Before the start of Phase 3, any marketing submission[50] is expected to be submitted to and accepted by FDA if the manufacturer intends to continue distribution of the device after the withdrawal of the guidances in List 1.

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

(1) Recommendations for Transition Implementation Plan

We expect that some marketing submissions will include changes or updates to the device and/or its labeling compared to the product that was distributed during the COVID-19 PHE prior to Phase 3, and in some cases, a manufacturer may not receive a positive decision from FDA on its marketing submission. To help address such situations efficiently, we recommend that manufacturers include with their marketing submissions a proposed "transition implementation plan" that addresses the manufacturers' plans for devices already distributed in the case of a positive decision or a negative decision on the marketing submission. We recommend that this include the following information, as applicable:[51]

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

[49] 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.

[50] 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).

[51] 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.

- 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:[52]
    - 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.

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).

(2) Discontinuing distribution of a device

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

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

[52] 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.

fails to provide a complete response to an FDA request for additional information[53] within the allotted time identified in FDA's letter.

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

(3) Additional considerations

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

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

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[53] 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.

[54] 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 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.

[55] 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.

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

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:

- 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.

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).

VI. Examples

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.

Example 1

A 510(k)-cleared cardiac monitor was modified to add Bluetooth functionality[56] 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)."[57]

[56] 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.

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

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

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

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

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

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

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

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

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

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

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

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

Example 2

A previously cleared diagnostic x-ray system was modified to become portable and falls within the enforcement policy described in the FDA guidance "Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."[58]

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

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

[58] 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.

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

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

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

Example 3

A previously cleared ventilator was modified to make material changes to components in the gas pathway to accommodate supplier shortages and falls within the enforcement policy described in the FDA guidance, "Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."[59]

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

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

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

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

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

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

Example 4

A new telethermographic system that has not been FDA-cleared and is intended for adjunctive diagnostic screening by providing an initial body temperature assessment for triage use, falls within the enforcement policy described in the FDA guidance, "Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."[60]

a) Manufacturer who intends to continue distribution beyond the start of Phase 3

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

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

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

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

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

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

A new telethermographic system that has not been FDA-cleared and is intended for adjunctive diagnostic screening by providing an initial body temperature assessment for triage use was distributed under the enforcement policy described in the FDA guidance, "Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."[61]

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

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

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

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

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

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Table 2			
PHASE	**1**	**2**	**3**
TIME	**0 days** (implementation date)	**90 days** after the implementation date	**180 days** after the implementation date
ACTIONS	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 FDA guidance.[62] Manufacturers should begin to prepare their marketing submissions, if applicable.	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. Manufacturers of devices under the product codes listed in Section V.C(1) should send a Notification of Intent to FDA. Manufacturers should prepare to submit a marketing submission to FDA and have it accepted by FDA before the start of Phase 3.	FDA withdraws the guidances in List 1 containing COVID-19 related enforcement policies. 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. 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). 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.

[62] 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.