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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

Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff

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For questions about this document, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov.



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

Preface

Public Comment

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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

Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff

This guidance represents 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 Coronavirus Disease 2019 (COVID-19). FDA is committed to providing timely guidance to support response efforts to the COVID-19 pandemic. FDA

recognizes that it will take time for device[1] manufacturers,[2] device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the 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 certain 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 transition guidance to describe FDA's recommendations for devices issued emergency use authorizations (EUAs) related to COVID-19.[4] The companion 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(s) of termination process required under section 564 of the Federal Food, Drug, and Cosmetic Act (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 its implementing regulations.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of

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[1] Section 201(h)(1) of the Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic Act.

[2] Throughout this guidance, when describing policies for devices that fall within enforcement policies issued during the COVID-19 public health emergency declared under section 319 of the Public Health Service Act, 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 declaration of the PHE related to COVID-19 under section 319 of the Public Health Service Act has expired and/or the relevant device emergency use declarations related to COVID-19 under section 564 of the Federal Food, Drug, and Cosmetic Act are terminated.

[4] The guidance "Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease, will be referred to as the "companion transition guidance" in the remainder of this guidance.

the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

In 2019, an outbreak of respiratory disease caused by a novel coronavirus began. 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 Secretary 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 (PHS Act) (hereinafter referred to as "section 319 PHE declaration") 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] On February 9, 2023, the HHS Secretary renewed the section 319 PHE declaration related to COVID-19, effective February 11, 2023. The section 319 PHE declaration related to COVID-19 is anticipated to expire at the end of the day on May 11, 2023.[7]

In response to the COVID-19 pandemic, the device supply chain has been stressed because the demand for certain devices has exceeded available supply. FDA recognized early in the COVID-19 pandemic 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 manufacturing limitations or supply chain issues due to disruptions caused by the COVID-19 pandemic.

FDA issued various guidance documents that describe enforcement policies for certain devices that are intended to support the emergency response to the COVID-19 pandemic.[8] These policies have helped to facilitate the availability of devices such as in vitro diagnostics, personal protective equipment intended for medical purposes, and ventilators. Additionally, FDA issued guidance to help expand the availability and remote monitoring capabilities of

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[5] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued on January 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 (March 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 (86 FR 11599), 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] See the HHS "Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap," (February 9, 2023), available at https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

[8] For links to the COVID-19-related FDA guidances, 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.

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.

Generally, the guidances that set forth COVID-19-related enforcement policies for certain devices initially stated that they were intended to remain in effect only for the duration of the section 319 PHE declaration. As FDA announced in the Federal Register on March 13, 2023, many of these guidance documents – the guidances in List 1 (see below) – have been revised to state that they are intended to continue in effect for 180 days after the section 319 PHE declaration expires unless a different intended duration is set forth in the finalized version of this guidance.[9,10] A different intended duration is ***not*** being set forth in this guidance – as described in Section V., the implementation date is the date the section 319 PHE declaration expires and the guidances are intended to continue in effect for 180 days after that date. FDA recommends reviewing the cover page for the relevant List 1 guidance to help determine the transition period for your device.

Given the magnitude of the response to the COVID-19 pandemic, FDA recognizes that a phased approach may help to ensure an orderly and transparent transition from the policies and recommendations in the List 1 guidances to normal operations. Further, FDA is taking into account that the manufacture, distribution, and use of devices in the context of the COVID-19 pandemic 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 help facilitate compliance with applicable legal 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, provide support to manufacturers, and assist the Agency in resource planning for marketing submission review.

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[9] See Guidance Documents Related to Coronavirus Disease 2019 (COVID-19) (88 FR 15417), available at https://www.federalregister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirus-disease-2019-covid-19. As discussed in that notice, FDA intends to further revise 4 of these COVID-19-related device guidances during the 180-day transition period after the section 319 PHE declaration expires (see Section IV., Table 3 of that notice). Also, as noted in that document, 2 COVID-19-related device guidances will no longer be in effect when the section 319 PHE declaration expires (see Section II., Table 1 of that notice).

[10] Although the duration of these guidances has been extended, we note that FDA could withdraw any of these guidances before that 180-day transition period ends if, for example, our approach for a particular guidance is no longer needed. FDA would do so consistent with our good guidance practices regulation (21 CFR 10.115).

III. Scope

This guidance applies to devices that fall within the enforcement policies described in the guidances identified in List 1 below.[11]

List 1

- Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 Public Health Emergency[12]
- Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency[13]
- Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency[14]
- Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency[15]
- Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the COVID-19 Public Health Emergency[16]
- Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the COVID-19 Public Health Emergency[17]

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[11] This guidance does not apply to devices that fall within the enforcement policies described in the following guidances: "Policy for Coronavirus Disease-2019 Tests (Revised)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised; "Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Revised)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests-revised; "Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-quality-standards-mammography-quality-standards-act-during-covid-19-public-health; "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency (Revised)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during; "Enforcement Policy for Clinical Electronic Thermometers During the COVID-19 Public Health Emergency," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public; and "Enforcement Policy for Face Masks and Barrier Face Coverings During the COVID-19 Public Health Emergency," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public.

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

[13] 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.

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

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

[16] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease.

[17] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during.

- Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the COVID-19 Public Health Emergency[18]
- Enforcement Policy for Infusion Pumps and Accessories During the COVID-19 Public Health Emergency[19]
- Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the COVID-19 Public Health Emergency [20]
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency[21]
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the COVID-19 Public Health Emergency[22]
- Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency[23]
- Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the COVID-19 Public Health Emergency[24]
- Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the COVID-19 Public Health Emergency (Revised)[25]
- Enforcement Policy for Viral Transport Media During the COVID-19 Public Health Emergency (Revised)[26]

IV. Guiding Principles

In developing this guidance, and its companion transition guidance regarding devices issued EUAs related to COVID-19, several guiding principles were followed. Some derive from existing policies and are widely known, and others are key to understanding the approach set

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[18]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease.
[19]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public.
[20]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-shields-surgical-masks-and-respirators-during-coronavirus-disease-covid-19. Bifucaration of the "Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the COVID-19 Public Health Emergency (Revised)" guidance was announced in the Federal Register notice on March 13, 2023 (88 FR 15417). The guidance relating to face shields, surgical masks, and respirators is in List 1, and the guidance related to face masks and barrier face coverings, as noted in footnote 11, is outside the scope of this guidance.
[21]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.
[22]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease.
[23]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.
[24]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-modifications-fda-cleared-molecular-influenza-and-rsv-tests-during-coronavirus.
[25]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/coagulation-systems-measurement-viscoelastic-properties-enforcement-policy-during-coronavirus.
[26]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health.

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 the policies and recommendations in this guidance will help to ensure an orderly and transparent transition 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 another version of the device is FDA-cleared or -approved.
- As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type. This may include requesting a firm initiate a recall (see 21 CFR 7.45),[31] or taking other actions, including an enforcement action. Moreover, FDA may revise the enforcement policies and recommendations in the guidance, as appropriate.

V. Phased Transition Plan for Devices That Fall Within COVID-19 Enforcement Policies Described in Guidances in List 1

As previously stated, FDA recognizes that it will take time for device manufacturers, device distributors, healthcare facilities, healthcare providers, patients, consumers, and the Agency to adjust from policies adopted and operations implemented during the COVID-19 PHE to normal

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

[28] Life-supporting or life-sustaining devices are defined in 21 CFR 860.3. 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."

[31] 21 CFR 7.45(a) states that FDA "may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception. (2) That the firm has not initiated a recall of the product. (3) That an agency action is necessary to protect the public health and welfare."

operations. FDA seeks to encourage and facilitate an appropriate transition period to help, among other things, avoid exacerbating product shortages and supply chain disruptions. This transition plan takes into account that the guidances in List 1 will no longer be in effect after the 180-day transition period discussed in this guidance ends. The discussion below contains recommendations regarding the preparation and submission of marketing submissions (including the timing of such submissions),[32] manufacturers' actions if they do not wish to continue distributing their product after the end of Phase 2, and the distribution of devices that fall within the scope of this guidance.

For purposes of this guidance, devices are considered to be "already distributed" if they are finished devices[33] that are labeled and are in distribution[34] in the U.S. supply chain or are in the possession of the end user. For purposes of this guidance, FDA would generally consider devices to be "in distribution" to mean those finished, labeled devices that are no longer in the manufacturer's possession that are in transit to or held in a third party's device inventory not on behalf of the manufacturer, in a federal, state, or other government stockpile, or at a location where devices are then offered for direct sale to the end user.

Given the duration of the COVID-19 pandemic and the need to safeguard the public health in a post-pandemic environment, FDA is implementing a 180-day transition period that will begin on the "implementation date" (see discussion below regarding this date). The guidances in List 1 will no longer be in effect after the 180-day transition period ends. FDA believes a phased transition over the 180 days following the implementation date as set forth in this guidance will help foster compliance with applicable legal requirements. This approach consists of three phases as described later in this section and outlined in **Table 2**.

The implementation date is the date the COVID-19 section 319 PHE declaration expires or 45 days after the finalization of this guidance, whichever comes later. Because the COVID-19 section 319 PHE declaration is anticipated to expire at least 45 days after the finalization of this guidance, or May 11, 2023, the implementation date is that date. The guidance documents identified in List 1 will no longer be in effect after the 180-day transition period ends, or after November 7, 2023.

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[32] For purposes of this guidance, "marketing submission" means a premarket approval application (PMA), PMA supplement, premarket notification (510(k)) submission, humanitarian device exemption (HDE) application, or De Novo classification request (De Novo). 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 exemption are exceeded (see, e.g., 21 CFR 878.9).

[33] See 21 CFR 820.3(*l*).

[34] See 21 CFR 807.3(b) (defining "commercial distribution").

A timeline for this process is provided in Figure 1.

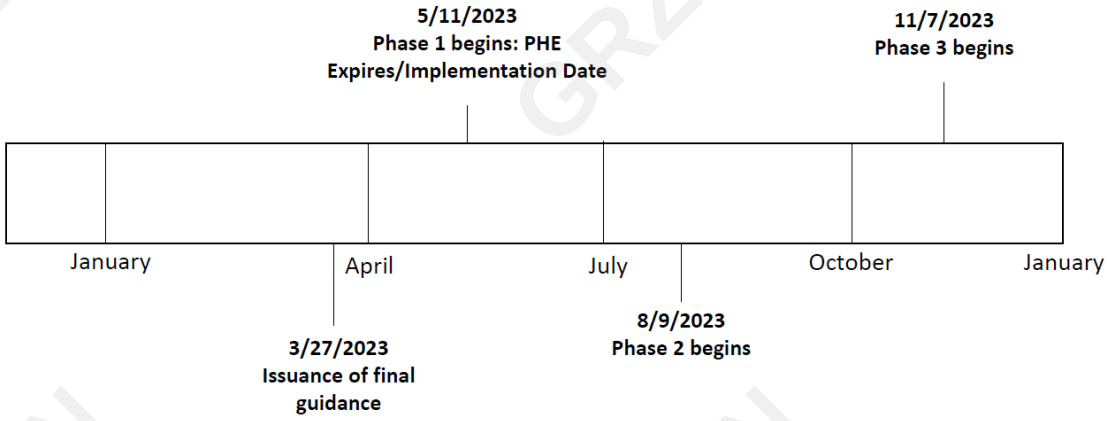


Figure 1. Transition Timeline. Implementation date occurring on the date the COVID-19 section 319 PHE declaration expires.

In the bullets below, FDA describes our transition period expectations and recommendations for all manufacturers that distributed devices as described in an enforcement policy in a guidance in List 1, both for those who do and do not pursue marketing authorization for their devices. FDA believes these expectations and recommendations will help facilitate a smooth and consistent transition to normal operations.

A summary of the three phases are as follows:

- **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.

- **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: (1) follow 21 CFR Part 806 (i.e., reports of corrections and removals requirements), and (2) if planning to continue to distribute their devices after Phase 2, 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. After the 180-day transition period ends, the guidances in List 1 will no longer be in effect. At this time, FDA does not intend to object to continued distribution of devices within the scope of this guidance

where a required marketing submission has been submitted and accepted[35] by FDA before the start of Phase 3 and FDA has not taken a final action[36] on the marketing submission. In addition, for these same devices, while the device is under FDA review, FDA does not intend to object to the devices not complying with certain Unique Device Identification (UDI) requirements (see 21 CFR Part 801 Subpart B) and other applicable labeling requirements (see 21 CFR Part 801) (see Section V.D.(1) of this guidance). This enforcement policy does not apply to other legal requirements (such as registration and listing, Quality System (QS), and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806, respectively).

The three phases of the transition plan, including additional considerations and recommendations related to each phase, are described in more detail below.

FDA recommends manufacturers submit a "Transition Implementation Plan" with their marketing submission that addresses the manufacturers' plans for dealing with devices already distributed in the case of a positive decision as well as in the case of a negative decision on the marketing submission (see Section V.D.(2) of this guidance). The marketing submission should be administratively complete in that it includes all of the information necessary for FDA to conduct a substantive review.[37] FDA understands there may be extenuating circumstances that make doing so difficult (e.g., ongoing clinical trial or longer term non-clinical studies). Manufacturers in such circumstances should engage with the Agency early in the transition period.[38]

FDA understands that there may be scenarios that are not specifically addressed in this guidance, but generally believes that the policies and recommendations described in **Table 2**, regardless of the specific scenario for a manufacturer, will help avoid disruptions in critical devices and allow

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[35] For more information regarding FDA's acceptance policies for marketing submissions, see the guidances "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.

[36] For purposes of this guidance, 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.

[37] See footnote 35.

[38] FDA recommends that manufacturers engage with the Agency through the Q-Submission Program, including requesting Pre-Submissions, to discuss extenuating circumstances. For details on the Q-Submission Program, refer to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

FDA to best manage its resources for review of marketing submissions. To address any unique considerations or other issues not otherwise discussed in this guidance, manufacturers may wish to initiate discussions with the Agency through the Q-Submission Program, including requesting feedback in Pre-Submissions. If the manufacturer's intent is to continue to distribute its device after Phase 2, the manufacturer should promptly start preparing, and FDA intends to help facilitate acceptance 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. Devices not distributed after Phase 2

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 Phase 2, at this time, FDA does not intend to object to the disposition and use[40] of already distributed devices (i.e., FDA does not intend to request market removal[41]) as follows:

1) Single-use, non-life-supporting/non-life-sustaining devices (e.g., face masks) that were distributed before the end of Phase 2 are used by the end user prior to the product expiration date, as applicable.
2) Reusable, non-life-supporting/non-life-sustaining devices (e.g., infusion pumps) that were distributed before the end of Phase 2 are used by their end user and either:
    a. Are restored[42] by the manufacturer to an FDA-cleared or -approved version of the device,[43] or
    b. Have[44] a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status (e.g., that the product lacks FDA clearance, approval, or authorization).
3) Reusable life-supporting/life-sustaining devices (e.g., ventilators, extracorporeal membrane oxygenation systems) that were distributed before the end of Phase 2 are restored[45] by the manufacturer to an FDA-cleared or -approved version of the device[46] so that they may be used by their end user. If not restored, a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status

[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 recognizes that not all uses would necessarily be violative. To the extent such use is violative, FDA generally does not intend to object as described herein.
[41] FDA uses the term "removal" consistent with the definition in 21 CFR 806.2(j).
[42] 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 on the appropriate disposition of a product if it is not otherwise discussed in this guidance.
[43] For example, an FDA-cleared or -approved version may include an earlier software version, component replacement, or different labeling that removes information related to the use of the device as described in an enforcement policy.
[44] The manufacturer should provide labeling to the original purchaser, and collaborate with the original purchaser to ensure that labeling is distributed to relevant stakeholders, including device distributors, healthcare facilities, healthcare providers, patients, consumers, etc.
[45] See footnote 42.
[46] See footnote 43.

(e.g., that the product lacks FDA clearance, approval, or authorization) should be provided,[47] and such devices are not to be used.[48,49] To help ensure accessibility to updated labeling, FDA recommends that stakeholders be provided an opportunity to request a physical copy of updated labeling, and after such request, be provided the requested labeling without additional cost.

Manufacturers that do not intend to distribute their devices after Phase 2 should also refer to relevant information included in other sections of this guidance (though note that recommendations in Section V.D.(1) are intended only for manufacturers that intend to distribute their device after the end of Phase 2). In addition, manufacturers should be aware of any applicable legal 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.

Manufacturers may also voluntarily withdraw their devices from the market. For manufacturers that do not intend to continue distributing their devices and that intend to voluntarily withdraw their devices from the market, FDA recommends completing withdrawal of the devices from the market prior to the withdrawal of the guidances in List 1; otherwise, if withdrawal of the devices from the market is not completed prior to the withdrawal of the guidances in List 1, FDA recommends restoring and/or updating labeling for reusable non-life-supporting/non-life-sustaining devices and for reusable life-supporting/life-sustaining devices as outlined in the policy above prior to the withdrawal of the guidances in List 1. Manufacturers should be aware of any applicable legal requirements for their device, such as adverse event reporting under 21 CFR Part 803, and continue to comply with such requirements for the duration in which they are applicable, which may extend beyond the cessation of distribution or withdrawal. Generally, it is anticipated that, over time, legal requirements will no longer apply when the manufacturer's device withdrawal activities are completed.

FDA encourages manufacturers that do not intend to continue to distribute their devices after Phase 2 to communicate with device distributors, healthcare facilities, healthcare providers, patients, and consumers, as appropriate, regarding their product disposition to assist all stakeholders with transition planning. In addition, thinking through elements of the "Transition Implementation Plan" outlined in Section V.D.(2) of this guidance may help manufacturers and stakeholders with this process.

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[47] See footnote 44.

[48] FDA recognizes that not all use would necessarily be violative.

[49] Should healthcare facilities wish to retain a device that lacks FDA clearance, approval, or authorization 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 EUA, as applicable. For governmental stockpilers that wish to retain a device that lacks requisite FDA clearance, approval, or authorization for use in the future, FDA recommends engaging with the Agency to discuss the public health need for future deployment and/or use of the device in specific circumstances (e.g., regional natural disaster, localized disease outbreaks).

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[50] under 21 CFR Part 803. Manufacturers should submit any adverse event reports that were stored (e.g., because of pandemic-related high employee absenteeism) and should refer to applicable FDA guidance regarding adverse event reporting during a pandemic.

During (and preferably before the start of) this phase, manufacturers that intend to continue distribution of their devices after Phase 2 should begin preparation of any required marketing submission to help avoid disruptions in critical devices and allow FDA to best manage its resources for review of marketing submissions. While preparing a marketing submission, manufacturers can use the FDA Guidance Search Tool[51] to identify relevant guidance documents that may be helpful in preparing the submission.

FDA is taking into account that the use of devices during the COVID-19 pandemic may allow manufacturers to utilize a variety of data sources in their marketing submission. As such, FDA anticipates many manufacturers may wish to reference data from related marketing authorizations and submissions, and use real-world data obtained as a result of device use during the COVID-19 pandemic.[52] FDA recommends that marketing submissions include in the cover letter a statement that the device was distributed as described in an enforcement policy, as well as submission number(s) for related premarket submissions. This information will help FDA track devices that are transitioning to the required marketing authorization,[53] facilitate review of the submission, and help ensure that the transitioning devices can be appropriately considered in light of the policy described in Section V.D.(1) of this guidance.

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 follow correction and removal requirements under 21 CFR Part 806. Before the start of Phase 2, manufacturers that intend to continue to distribute their devices after Phase 2 should also register their establishments and list[54] their device(s) or update existing registration and listing (R&L) if they have not already done so. For manufacturers that register and list by the start of Phase 2, FDA recommends that manufacturers utilize the term "enforcement" (as a shorthand for "enforcement policy") in the premarket submission field if a submission number is not yet available. If the device

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[50] 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.

[51] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/.

[52] Data derived from real-world sources may be submitted in support of a marketing submission. See the guidance titled "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices.

[53] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.

[54] 21 CFR Part 807, Subparts B-D.

subsequently receives marketing authorization, FDA expects manufacturers to comply with all applicable registration and listing requirements, which may require updating the listing information.

As discussed above, manufacturers that intend to continue to distribute their devices after Phase 2 should continue preparation of any required marketing submission[55] as FDA expects such manufacturers 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 – regardless of whether they intend to continue distribution of their devices after Phase 2 – submit a "Notification of Intent" to FDA as described in Section V.C.(1) of this guidance.

(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 to FDA and continue distributing their product after Phase 2. This information will assist the Agency in resource planning for marketing submission review and providing 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
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	

[55] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.

Product Code	Device Type	Classification Regulation
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[56] before the start of Phase 2:[57]

- General information about the manufacturer, including contact information, name and place of business, and email address;
- 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 an FDA-cleared or -approved version, to provide a physical copy and/or electronic copy of updated labeling, and any other efforts to address or mitigate potential risks of devices that remain distributed after Phase 2.

If another version of the device is FDA-cleared or -approved and a modified version is/was distributed as described in a policy in a guidance in List 1, the manufacturer should submit this information in a premarket notification (i.e., 510(k)) or PMA "amendment" for the cleared or approved device.[58] FDA recommends that manufacturers notate the following on the cover letter of the submission: "Attention: Notification of Intent." To the extent the Notification of Intent contains trade secret information or confidential commercial or financial information, FDA will handle that information in accordance with applicable laws, including 21 CFR 20.61.

D. Phase 3

Phase 3 begins 180 days after the implementation date. After the 180-day transition period ends, the guidances in List 1 will no longer be in effect. Before the start of Phase 3, any required

[56] The mailing address for the CDRH Document Control Center can be found in 21 CFR 807.90(a)(1) and 814.104(d)(1). FDA encourages manufacturers to submit Notifications of Intent as eCopies. Information about the eCopy program can be found in the guidance "eCopy Program for Medical Device Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.

[57] Submitting this information as soon as possible after issuance of this guidance is encouraged because it will assist the Agency in resource planning, help to avoid any supply disruptions, and otherwise help to ensure a smooth transition for these devices after the guidances in List 1 are no longer in effect.

[58] FDA recommends that the information be submitted as an "amendment" to the 510(k) or PMA file to facilitate efficient tracking of the "Notification of Intent" submissions.

marketing submission[59] is expected to be submitted to and accepted by FDA if the manufacturer intends to continue distribution of the device after Phase 2. 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.

(1) Enforcement policy for devices with a marketing submission under review by FDA

As previously stated, FDA recognizes that it may take time for device manufacturers, including non-traditional device manufacturers, to adapt and adjust from their operations during the COVID-19 PHE to normal operations. As such, at this time, FDA does not intend to object to the continued distribution of devices within the scope of this guidance after the guidances in List 1 are no longer in effect where:

- The manufacturer has submitted a marketing submission[60] to FDA and it is accepted[61] by FDA before the start of Phase 3; and
- FDA has not taken a final action[62] on the marketing submission.

For these same devices, while the device is under FDA review, FDA does not intend to object to the devices not complying with certain UDI requirements (see 21 CFR Part 801 Subpart B) or other applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance.[63,64] As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type.

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[59] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act. 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 exemption are exceeded (see, e.g., 21 CFR 878.9).

[60] This includes a marketing submission for the device within the scope of the guidances in List 1, or a marketing submission for a device that is a derivative of, or the next generation of, the device within the scope of the guidances in List 1.

[61] Manufacturers that do not have an accepted marketing submission before the start of Phase 3 should refer to the policy described in Section V.A. of this guidance.

[62] See footnote 36.

[63] For example, if a manufacturer made modifications to the labeling of a cleared fetal doppler as described in the "Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency" guidance, FDA generally does not intend to object to the manufacturer not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in that guidance while the marketing submission for the modified device is under review.

[64] Based on comments received on this draft guidance, as well as the companion transition guidance, FDA understands that updating the labeling of these devices while they are under FDA review, and then again if they are subsequently cleared, approved, or authorized, would be challenging for manufacturers. This policy takes those comments into account and is least burdensome for manufacturers and FDA. As noted elsewhere, manufacturers should engage with the Agency if they have questions specific to their device (e.g., regarding updating the device labeling to acknowledge that the device is currently under FDA review when the FDA review is expected to take an extended period of time).

The enforcement policy in this section (Section V.D.(1)) relates to FDA marketing authorization (e.g., 510(k) clearance), and certain UDI and other applicable labeling requirements. It does not apply to other legal requirements (such as registration and listing,[65] QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806, respectively) that may apply.[66] Moreover, it does not apply after FDA has taken a final action on the marketing submission for a device. At that time, FDA expects manufacturers to comply with all applicable regulatory requirements for the device/manufacturer. Following the device's marketing authorization, this includes labeling updates (see 21 CFR Part 801), compliance with UDI requirements (see 21 CFR Part 801 Subpart B and Part 830), and any applicable updates to registration and listing information, including the submission number (see 21 CFR Part 807 Subparts B-D). After marketing authorization, manufacturers also should follow the steps outlined in their Transition Implementation Plan.

In addition, and as always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type. This may include FDA requesting a firm initiate a recall (see 21 CFR 7.45)[67] or taking other actions, including an enforcement action. Moreover, FDA may revise the enforcement policies and recommendations in the guidance, as appropriate.

As mentioned previously, FDA recommends that marketing submissions include in the cover letter a statement that the device is/was distributed as described in an enforcement policy, and submission number(s) for related premarket submissions. This information will help FDA track devices that are transitioning to the required marketing authorization,[68] facilitate review of the submission, and help ensure that transitioning devices can be appropriately considered in light of the policy described in this section (Section V.D.(1) of this guidance). The marketing submission should be administratively complete in that it includes all of the information necessary for FDA

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[65] For manufacturers that register and list by the start of Phase 2, FDA recommends that manufacturers utilize the term "enforcement" in the premarket submission field if a submission number is not yet available. If the device subsequently receives marketing authorization, FDA expects manufacturers to comply with all applicable registration and listing requirements, which may require updating the listing information.

[66] 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/. After the start of Phase 3, 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 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.

[67] 21 CFR 7.45(a) states that FDA "may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception. (2) That the firm has not initiated a recall of the product. (3) That an agency action is necessary to protect the public health and welfare."

[68] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.

to conduct a substantive review.[69] FDA understands there may be extenuating circumstances that may make doing so difficult (e.g., ongoing clinical trial or longer term non-clinical studies). Manufacturers in such circumstances should engage with the Agency early in the transition period.[70]

In addition, during this transition period and after the start of Phase 3, FDA may receive questions from stakeholders (e.g., other Agencies, governmental stockpilers, healthcare providers) about a device's regulatory status for devices distributed as described in this section (Section V.D.(1)) while the marketing submission is under review by FDA. Typically, if a device has an EUA or conventional marketing authorization (e.g., 510(k) clearance), this information would be publicly available. The existence of a marketing submission under review is not typically disclosed unless certain circumstances apply, such as when the device is on the market.[71] As such, for devices distributed as described in this section, FDA may share that a manufacturer is distributing such device as described in the policy in this guidance, which could indirectly reveal that the manufacturer has a marketing submission under review by FDA.[72]

(2) Recommendations for "Transition Implementation Plan"

FDA anticipates that some marketing submissions will include changes or updates to the device and/or its labeling compared to the product that was distributed as described in the relevant guidance in List 1. For example, a manufacturer may have distributed fetal dopplers as described in an enforcement policy, and the manufacturer intends to submit a marketing submission for such fetal dopplers with an additional, new indication. In addition, in some cases, a manufacturer may not receive a positive decision from FDA on its marketing submission.

To help address all of these situations efficiently, FDA recommends manufacturers include in the cover letter of their marketing submissions a "Transition Implementation Plan" that addresses the manufacturers' plans for dealing with devices already distributed in the case of a positive decision as well as in the case of a negative decision on the marketing submission. To the extent the Transition Implementation Plan contains trade secret information or confidential commercial or financial information, FDA will handle that information in accordance with applicable laws, including 21 CFR 20.61.

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[69] For more information regarding FDA's acceptance policies for marketing submissions, see the guidances "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.

[70] FDA recommends that manufacturers engage with the Agency through the Q-Submission Program, including requesting Pre-Submissions, to discuss extenuating circumstances. For details on the Q-Submission Program, refer to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

[71] See, e.g., 21 CFR 807.95(a)(1).

[72] To the extent the marketing submission contains trade secret information or confidential commercial or financial information, FDA will handle that information in accordance with applicable laws, including 21 CFR 20.61.

FDA recommends the Transition Implementation Plan include the following information, as applicable:[73]

- 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;
- 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:[74]
    - Process for notifying patients, consumers, healthcare facilities, healthcare providers, and device distributors of the device's regulatory status;
    - Process and timeline for restoring already distributed devices to an FDA-cleared or -approved version;
    - Process and timeline for providing[75] a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status (e.g., that the product lacks FDA clearance, approval, or authorization) for reusable devices. To help ensure accessibility to updated labeling for reusable life-supporting/life-sustaining devices, FDA recommends that stakeholders be provided an opportunity to request a physical copy of updated labeling, and after such request, be provided the requested labeling without additional cost; and
    - A description of the maintenance plan for already 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 device distributors of the device's regulatory status; and
    - Process and timeline for providing to users of already distributed devices updated labeling or components for the cleared or approved device, including updated labeling or components to reflect any cleared/approved changes to the already distributed device.

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[73] If the manufacturer has already submitted a Notification of Intent with some of this information, 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.

[74] While FDA recommends the inclusion of a benefit-risk based plan for disposition of already 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.

[75] The manufacturer should provide labeling to the original purchaser, and collaborate with the original purchaser to ensure that labeling is distributed to relevant stakeholders, including device distributors, healthcare facilities, healthcare providers, patients, consumers, etc.

FDA encourages manufacturers to collaborate with device distributors, healthcare facilities, healthcare providers, patients, and consumers, as appropriate, regarding their Transition Implementation Plan to assist all stakeholders with transition planning.

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 described in the Transition Implementation Plan. For marketing submissions that include changes to the device compared to the already distributed 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, as needed. As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type (e.g., requesting a firm initiate a recall (see 21 CFR 7.45),[76] or taking other actions, including an enforcement action).

E. Discontinuing distribution of a device

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

1) Before the start of Phase 3, if the manufacturer has not submitted a required marketing submission[77] for its device and had it accepted by FDA before the start of Phase 3; 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 fails to provide a complete response to an FDA request for additional information[78] within the allotted time identified in FDA's letter.

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

FDA encourages manufacturers to communicate with device distributors, healthcare facilities, healthcare providers, patients, and consumers, as appropriate, regarding their product disposition to assist all stakeholders with transition planning.

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[76] 21 CFR 7.45(a) states that FDA "may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception. (2) That the firm has not initiated a recall of the product. (3) That an agency action is necessary to protect the public health and welfare."

[77] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.

[78] For more information on FDA requests for additional information (i.e., deficiency letters) and how to respond, see the 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.

F. Quality System considerations

FDA recognizes that there may be situations that raise unique compliance considerations, particularly regarding QS requirements. 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. Some manufacturers who intend to continue distributing their devices beyond Phase 2 may choose to 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. Any such exemption or variance should be requested within 90 days of the announcement of the implementation date for this guidance to help ensure FDA considers your request in time.

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. of this guidance, for purposes of the examples, FDA set the implementation date for all devices that fall within this enforcement policy as the implementation date, May 11, 2023, consistent with the timeline shown in Figure 1. The dates outlined in each example follow this example phased transition plan timeline. 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 fetal doppler was modified to add Bluetooth functionality[79] as described in the policies in the guidance, "Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency."[80]

a) Manufacturer who intends to continue distributing beyond Phase 2 and receives a positive decision on its marketing submission

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to modification of certain fetal dopplers in certain circumstances without marketing authorization by FDA. The enforcement policy in the guidance does not address other

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[79] Manufacturers should also consult the guidance "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.

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

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 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the fetal doppler manufacturer updates its existing listing under 21 CFR Part 807 Subparts B-D, as applicable. On October 1, 2023, 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 fetal dopplers in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, 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 fetal doppler before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The manufacturer receives a positive decision on its marketing submission on December 29, 2023 (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 already distributed devices that may have these anomalies and engages with the manufacturer on how to address these issues with the already distributed devices and provide updated electronic labeling to the relevant stakeholders. The manufacturer initiates a correction to address the software anomalies in the fetal dopplers that were distributed prior to the positive marketing decision.

Additionally, as part of its Transition Implementation Plan, the manufacturer updates its website to add the updated device labeling. All devices distributed after receiving the positive decision will have the updated labeling.

b) Manufacturer who intends to continue distribution beyond Phase 2 and receives a negative decision on its marketing submission

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to modification of certain fetal dopplers 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 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the fetal doppler manufacturer updates its existing listing under 21 CFR Part 807 Subparts B-D, as applicable. On October 15, 2023, 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 fetal dopplers in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, 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 fetal doppler before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The manufacturer receives a negative decision on its marketing submission on January 15, 2024 (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 fetal doppler to the FDA-cleared version. In addition, the manufacturer ceases distributing the modified device.

Example 2

A FDA-cleared diagnostic x-ray system was modified to become portable and falls within the enforcement policy described in the guidance "Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency."[81]

Phase 1 (May 11, 2023): In the above-referenced guidance, 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.

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[81] 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.

Phase 2 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the portable x-ray system manufacturer updates its existing listing, under 21 CFR Part 807 Subparts B-D, as applicable. On September 29, 2023, 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 portable x-ray systems in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, 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 x-ray system before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

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, 2024. FDA and the manufacturer engage regarding the manufacturer's Transition Implementation Plan to address already distributed devices. The diagnostic x-ray is a reusable, non-life-supporting/non-life-sustaining device; as such, the manufacturer, following the Transition Implementation Plan, updates its website to accurately describe the product features and regulatory status of the already distributed, modified 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 FDA-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 guidance, "Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency."[82]

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to modifications to ventilators in certain circumstances without marketing authorization by FDA.

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

The enforcement policy in the guidance does not address other requirements, including requirements in 21 CFR Parts 803, 807 Subparts B-D, 806, and 820, and 830. The manufacturer continues to comply with these requirements.

Phase 2 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the ventilator manufacturer updates its existing listing, under 21 CFR Part 807 Subparts B-D, as applicable. On October 1, 2023, 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) of this guidance. In its marketing submission that was accepted by the Agency on December 20, the manufacturer includes a "Transition Implementation Plan" for already distributed ventilators in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, 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 ventilator before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The ventilator manufacturer receives a positive decision on its marketing submission on January 2, 2024. The manufacturer continues to distribute the modified ventilator with updated labeling. In addition, the manufacturer communicates with users of the modified ventilator, distributed as described in the above-referenced guidance, apprising them of the regulatory status of the device and providing updated electronic 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 guidance, "Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency."[83]

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

a) Manufacturer who intends to continue distribution beyond Phase 2

Phase 1 (May 11, 2023): 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 UDI, and other applicable labeling 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 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the telethermographic system manufacturer registers and lists, consistent with 21 CFR Part 807 Subparts B-D, as applicable. On October 5, 2023, 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 in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, 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 telethermographic system before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer complies with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The manufacturer receives a "not substantially equivalent" decision on January 3, 2024, 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 Transition Implementation 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 Phase 2

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 guidance, "Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency."[84]

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to the distribution and use of a certain telethermographic system without submission of a 510(k), reports of corrections and removals, registration and listing, and compliance with the QS regulation, UDI, and other applicable labeling 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 (August 9, 2023): The manufacturer decides that it does not want to continue to market and distribute the device beyond Phase 2. The manufacturer ceases distributing the device on November 1, 2023. The telethermographic system is a reusable, non-life-supporting/non-life-sustaining device. Devices that were distributed before the end of Phase 2 remain distributed. 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 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends. Prior to the start of Phase 3, the manufacturer provides updated electronic labeling for the telethermographic system, and such labeling accurately describes all product features and notes that the product is not FDA-cleared, -approved, or -authorized for marketing. The manufacturer leaves already distributed telethermographic systems in the field. The manufacturer continues to engage in adverse event reporting to FDA concerning the device.

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

Table 2 . Summary of Recommendations for a Phased Transition			
PHASE	**1**	**2**	**3**
STARTING TIME	**0 days** (implementation date – May 11, 2023)	**90 days** after the implementation date – August 9. 2023	**180 days** after the implementation date – November 7, 2023
ACTIONS	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 and should refer to applicable FDA guidance regarding adverse event reporting during a pandemic. Manufacturers that intend to continue distribution of their devices after Phase 2 should begin to prepare their required marketing submissions.	Before the start of Phase 2, manufacturers that intend to continue to continue to distribute their devices after Phase 2 should register their establishments and list their device(s), or update their existing registration and listing, under 21 CFR Part 807 Subparts B-D, as applicable. Before the start of Phase 2, if not already doing so, manufacturers should submit reports of corrections and removals consistent with 21 CFR Part 806 (regardless of whether they intend to continue distribution of their devices after Phase 2). Manufacturers of devices under the product codes listed in Table 1 of this guidance should send a Notification of Intent to FDA (regardless of whether they intend to continue distribution of their devices after Phase 2). Manufacturers that intend to distribute their devices after Phase 2 should continue to prepare to submit a marketing submission to FDA and have it accepted by FDA before the start of Phase 3.	After the 180-day transition period ends, the List 1 guidances containing COVID-19 related enforcement policies will no longer be in effect. Before the start of Phase 3, if manufacturers submit a marketing submission(s), and that submission is accepted by FDA, at this time, FDA does not intend to object to the continued distribution of the device after Phase 2 as described in Section V.D.(1) of this guidance. 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.(2) of this guidance, as applicable. Moreover, for devices for which FDA has accepted a marketing submission prior to the start of Phase 3, FDA does not intend at this time to object to the devices not complying with certain UDI and other applicable labeling requirements where they are labeled as described in the relevant List 1 guidance. This enforcement policy does not apply to other applicable legal requirements (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806, respectively).

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