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Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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

For questions about this document, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov. For general questions about emergency use authorizations, contact the Office of the Commissioner/Office of the Chief Scientist/Office of Counterterrorism and Emerging Threats at AskMCMi@fda.hhs.gov.

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

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 20042 and complete title of the guidance in the request.

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Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) 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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 this transition process with respect to devices issued Emergency Use Authorizations (EUAs) 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 transitioning devices that fall within enforcement policies issued during the COVID-19 PHE.[4] FDA believes 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 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.

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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,
>
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (C) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 520(o) of the FD&C Act."

[2] Throughout this guidance, when describing policies for devices that have been issued an Emergency Use Authorization (EUA), 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 That Fall Within Enforcement Policies During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" will be referred to as the "companion guidance" in the remainder of this guidance document.

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 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 to 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 authorized, and continues to authorize, the emergency use of devices under section 564 of the FD&C Act.[7] Section 564 of the FD&C Act authorizes FDA, after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use (an "EUA declaration"), to authorize the emergency use of an unapproved product[8] or an unapproved use of an approved product for certain emergency circumstances.[9] FDA may issue an EUA to allow a

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[5] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (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] A list of all authorized COVID-19 device EUAs is available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[8] Under sections 564(a)(2)(A) and 564(a)(4)(D) of the FD&C Act, an unapproved product is one that "is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), 512, or 515 of [the FD&C] Act or section 351 of the Public Health Service Act or conditionally approved under section 571 of [the FD&C] Act."

[9] Pursuant to section 564 of the FD&C Act, and on February 4, 2020, the HHS Secretary determined that there is a public health emergency that has significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the SARS-CoV-2 virus that causes COVID-19. On the basis of such determination, the HHS Secretary declared on that same day, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the SARS-CoV-2 virus that causes COVID-19 (85 FR 7316), available at https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency. Based on the February 4, 2020 determination, the Secretary issued two (2) more declarations justifying emergency uses related to devices: on March 2, 2020, for certain personal respiratory

product to be used to diagnose, treat, or prevent a serious or life-threatening disease or condition referenced in the EUA declaration, when the statutory criteria are met, including FDA's determination that, based on the totality of scientific evidence, the product may be effective for such use, the known and potential benefits outweigh the known and potential risks for such use, and that there are no adequate, approved, and available alternatives.[10]

An EUA issued under section 564 of the FD&C Act will remain in effect for the duration of the relevant EUA declaration, unless FDA chooses to revoke the EUA because the criteria for issuance are no longer met or revocation is appropriate to protect public health or safety.[11] An EUA declaration under section 564 of the FD&C Act is distinct from, and is not dependent on, the declaration by the HHS Secretary of a PHE under section 319 of the Public Health Service Act. Therefore, an EUA may remain in effect beyond the duration of the declared PHE.

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) under an EUA.

FDA developed this guidance to describe a transition plan, among other things, to help avoid disruption in device supply and ensure that devices authorized under an EUA meet applicable FD&C Act requirements after the termination of the relevant COVID-19 EUA declaration under section 564(b) of the FD&C Act, if their manufacturers wish to continue distributing them.

Section 564 of the FD&C Act provides a statutory framework describing the circumstances in which an EUA declaration may terminate and the process for such termination.[12] Under section 564(b) of the FD&C Act, the Secretary of HHS is required to provide advance notice that an EUA declaration will be terminated and to publish such notice in the Federal Register.[13] When an EUA declaration is terminated, all EUAs issued under that declaration also terminate. After an

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protective devices (85 FR 13907), available at https://www.federalregister.gov/documents/2020/03/10/2020-04823/emergency-use-declaration, and on March 24, 2020 for devices, including alternative products used as devices (85 FR 17335), pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section, available at https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration.

[10] For more information on FDA's emergency use authorities under section 564 of the FD&C Act, see FDA's guidance for Industry and Other Stakeholders "Emergency Use Authorization of Medical Products and Related Authorities," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

[11] See section 564(f)-(g) of the FD&C Act.

[12] Section 564(b)(2) of the FD&C Act.

[13] Section 564(b)(3) and (4) of the FD&C Act.

EUA terminates, it ceases to be in effect and the emergency use of the product(s) are no longer authorized.

Pursuant to section 564(b)(2)(B) of the FD&C Act, when an EUA for an unapproved product ceases to be effective as a result of the termination of an EUA declaration, FDA must consult with the manufacturer of such product with respect to the appropriate disposition of the product. FDA believes that issuing this guidance in draft with a proposed transition policy and requesting public comment (including from manufacturers of authorized devices) may help the Agency to satisfy, or otherwise determine how to best satisfy, this requirement while also effectively managing Agency resources.

This guidance contemplates that the advance notice of termination of each EUA declaration pertaining to devices will be published in the Federal Register 180 days before the day on which the EUA declaration is terminated. For the purposes of this guidance, FDA refers to the date on which an EUA is terminated as the "EUA termination date." For the time between the advance notice of termination of an EUA declaration and the EUA termination date, manufacturers of devices with EUAs authorized pursuant to such an EUA declaration and others[14] must continue to comply with the terms of the devices' respective EUAs, including applicable Conditions of Authorization identified in the EUA letters of authorization for the devices.

In addition, FDA recommends that manufacturers of devices authorized under EUAs plan now, while the pandemic is ongoing, their post-EUA regulatory and disposition strategies. When an EUA declaration is terminated, the Agency intends to promptly publish notice of the termination in the Federal Register and an explanation of the reasons for the termination.[15] FDA requests public comment on the timeline proposed in this guidance from all interested stakeholders.

III. Scope

This guidance applies to devices that have been issued an EUA under section 564 of the FD&C Act on the basis of a device-related COVID-19 EUA declaration. Current good manufacturing practice deviations authorized under section 564A(c) of the FD&C Act are outside the scope of this guidance.

This guidance does not apply to devices for which FDA has revoked the EUA under section 564(g)(2)(B)-(C) of the FD&C Act because the criteria under section 564(c) of the FD&C Act were no longer met or because other circumstances made such revocation appropriate to protect the public health or safety.

[14] Certain EUAs include conditions of authorization for parties other than the manufacturer, such as healthcare facilities or distributors.

[15] Section 564(h)(1) of the FD&C Act.

IV. Guiding Principles

In developing this guidance and its companion guidance regarding devices that fall within enforcement policies issued 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.[16]
- 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,[17] capital or reusable[18] equipment, a single-use device,[19] 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.

V. Transition Plan for Devices Authorized Under an EUA

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. This transition plan takes into account the advance notice of termination of the EUA declarations pertaining to devices, and the discussion below contains

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

[17] 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.

[18] 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.

[19] 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.

recommendations regarding the preparation and submission of marketing submissions (including the timing of such submissions),[20] manufacturers' actions if they do not wish to continue distributing their product beyond the EUA termination date, and the distribution[21] of devices within the scope of this guidance.

FDA understands that there may be scenarios that are not specifically addressed in this guidance. 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 should submit any Pre-Submissions with the understanding that their device will no longer be authorized for emergency use beginning on the EUA termination date. Therefore, if the manufacturer's intent is to continue to distribute its device after the EUA for the device is no longer in effect, FDA encourages the manufacturer to work toward, and FDA intends to help facilitate, submission of a marketing submission before the EUA termination date. For details on the Q-Submission Program, refer to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."[22]

A. "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 that have been issued an EUA, FDA recommends that manufacturers of such devices submit to FDA information regarding whether or not they intend to submit a marketing submission to continue distributing their product after the EUA termination date. This information will assist the Agency in resource planning for marketing submission review and providing increased support to manufacturers. This request applies to EUA-authorized devices with 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

[20] 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).

[21] 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.

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

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
QOO	Tubing Connector for Co-venting	No corresponding CFR section

Manufacturers of the devices identified in Table 1 should submit the following information to the CDRH Document Control Center[23] as soon as possible after this guidance is finalized:[24]

- General information, including contact information, name and place of business, and email address;
- The EUA request number;
- 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 EUA termination date.

The manufacturer should submit this information designated with the EUA number as an "EUA

[23] 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 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.

[24] Earlier submission of this information is encouraged and 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 EUA termination date. If this information is submitted after publication of the advance notice of termination of the EUA declaration, FDA recommends submission within 90 days of that publication.

report." FDA recommends that manufacturers notate the following on the cover letter of the submission: "Attention: Notification of Intent."

B. Marketing submissions for devices distributed after the EUA termination date

For manufacturers of authorized devices that intend to continue distributing their devices after the EUA termination date, please refer to the recommendations and policies in the subsections below. FDA recommends that manufacturers submit their marketing submissions to FDA with sufficient time for the submission to be accepted by FDA[25] before the EUA termination date. After the EUA termination date, while an accepted marketing submission is under consideration by FDA and after receiving marketing authorization from the Agency, FDA expects that manufacturers will comply with all applicable regulatory requirements for the device/manufacturer, including but not limited to the applicable marketing submission requirements, Quality System (QS) Regulation under 21 CFR Part 820, adverse event reporting requirements under 21 CFR Part 803, registration and listing under 21 CFR Part 807 Subparts B-D, and Unique Device Identification under 21 CFR Part 801 Subpart B and 21 CFR Part 830, except as discussed below regarding an enforcement policy for devices with a marketing submission under review by FDA (see Section V.B(2) below).[26]

(1) Recommendations for Transition Implementation Plan

FDA expects that some marketing submissions will include changes or updates to the device and/or its labeling compared to the product that has been distributed under the EUA prior to the EUA termination date, and in some cases, a manufacturer may not receive a positive decision from FDA on its marketing submission. 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 below. To help address all of these situations efficiently, we recommend that manufacturers include with their marketing submissions a

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[25] 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.

[26] 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 EUA termination 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.

"transition implementation plan" that addresses the manufacturers' plans both for dealing with devices already distributed in the case of a positive decision or in the case of a negative decision on the marketing submission. We recommend that this plan include the following information, as applicable:[27]

- Estimated number of devices under an EUA currently that are 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:[28]
    - 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).

[27] 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), 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.

[28] While FDA recommends that a benefit-risk based plan for disposition of distributed product be included 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.

(2) 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 adjust from their operations during the COVID-19 PHE back to normal operations. FDA does not intend to object to the continued distribution of devices within the scope of this guidance after the EUA termination date where:

- The manufacturer has submitted a marketing submission to FDA and had it accepted by FDA before the EUA termination date; and
- FDA has not taken a final action on the marketing submission.

The enforcement policy identified in this section (Section V.B(2)) applies only to requirements to obtain FDA marketing authorization (e.g., 510(k) clearance). It does not apply to other applicable requirements (such as registration and listing, QS requirements, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806) that would apply to previously authorized devices that the manufacturer continues to distribute after an EUA ceases to be in effect.

During the period after the EUA termination date, for devices for which a marketing submission has been accepted by FDA but before FDA has taken final action on the submission, labeling should be updated to accurately state that the product was authorized under an EUA issued during the COVID-19 PHE and remains under FDA review for clearance or approval.

C. If a manufacturer does not intend to continue to distribute its device after the EUA termination date

When a manufacturer does not intend to continue to distribute its device beyond the EUA termination date, FDA generally does not intend to object to the disposition of already distributed devices (i.e., FDA does not intend to request market removal)[29] as follows:

1) Single use, non-life-supporting/non-life-sustaining devices (e.g., face masks) that were distributed before the EUA termination date remain distributed and are consumed by the end user.
2) Reusable, non-life-supporting/non-life-sustaining devices (e.g., remote patient monitoring devices) that were distributed before the EUA termination date 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 (e.g., earlier software version, component replacement),[30] or

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

[30] 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.

   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, continuous renal replacement therapy systems) that were distributed before the EUA termination date 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).[31]
4) In vitro diagnostic devices that were distributed before the EUA termination date remain distributed and are used for no more than 2 years after the EUA termination date or until the expiration date, whichever is less.

D. Discontinuing distribution of a device

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

1) On the EUA termination date, if the manufacturer has not submitted a required marketing submission for its device and had it accepted by FDA before the EUA termination date; 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[32] within the time identified in FDA's letter.

In addition, manufacturers should be aware of any applicable FD&C Act 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.

E. Additional considerations

Before the EUA termination date, FDA expects manufacturers who intend to distribute their devices after the EUA termination date to have completed any steps necessary to transition into compliance with all FD&C Act requirements applicable to their devices once their EUAs are no

[31] Should facilities wish to retain the device 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.

[32] 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.

longer in effect. However, FDA does not intend to object to continued distribution of devices that lack the required FDA marketing authorization in the circumstances outlined in Section V.B(2). 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.[33]

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 after the EUA termination date 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. This exemption or variance should be requested within 90 days of publication of the advance notice of termination of the EUA declaration pertaining to the device at issue.

VI. Examples

The following hypotheticals are intended to illustrate the transition policy outlined above. To exemplify the timeline of the transition plan outlined in this section (Section VI), for purposes of the examples, we set the hypothetical advance notice of termination date for the EUA declaration pertaining to the device at issue as July 1 in Year 1, and the EUA termination date as January 1 in Year 2. This date is not intended to propose an actual advance notice of termination or EUA termination date; it is 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 single-use surgical mask that is intended for use in healthcare settings by health care personnel as personal protective equipment to provide a physical barrier to fluids and particulate materials, was authorized for emergency use under an umbrella EUA for surgical masks.[34] The manufacturer does not intend to continue distributing the surgical mask after the EUA is no longer in effect.

[33] 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.

[34] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#surgicalmasks.

On July 1, the advance notice of termination of the relevant EUA declaration is published. On the EUA termination date (January 1), the relevant EUA declaration is terminated and the EUA is no longer in effect. On January 1, the manufacturer ceases distribution of the surgical mask. The manufacturer submits any reports of corrections or removals consistent with 21 CFR Part 806. User exhaustion of already distributed surgical masks is described in Section V.C above.

Example 2

A continuous ventilator was authorized under the umbrella EUA for ventilators and ventilator accessories[35] to support patients who develop respiratory distress due to COVID-19.

On July 1, the advance notice of termination of the relevant EUA declaration is published. Before August 1, to help FDA plan for transition-related premarket review activities, the manufacturer informs FDA that it does not intend to pursue marketing authorization by submitting an "EUA report" to the CDRH Document Control Center with "Attention: Notification of Intent" on the cover letter of the submission. This EUA report includes the information outlined in Section V.A above.

On the EUA termination date (January 1), the relevant EUA declaration is terminated and the umbrella EUA is no longer in effect. The ventilator manufacturer ceases distribution of the ventilator. FDA does not intend to object if the manufacturer develops a plan for the already distributed product to remain distributed, including product in the possession of end users, and provides a physical copy of labeling as outlined in Section V.C for those hospitals that have expressed an interest in keeping the ventilators. As part of the plan, the manufacturer should interact with affected hospitals, document the hospitals' interest, and communicate to FDA its strategy for providing this labeling to the relevant healthcare facilities, and carry out implementation of the updated labeling. For healthcare facilities wishing to retain the ventilator 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.

Example 3

A non-traditional device manufacturer worked with a traditional device manufacturer (original equipment manufacturer (OEM)) to produce, as a contract manufacturer, ventilators that were designed by the traditional device manufacturer. Such devices were authorized under the umbrella EUA for ventilators and ventilator accessories and distributed by the OEM during the COVID-19 PHE.

On July 1, the advance notice of termination of the relevant EUA declaration is published. Before August 1, to help FDA plan for transition-related premarket review activities, the OEM informs FDA that it intends to pursue a marketing authorization through submission of an "EUA

[35] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas.

report" to the CDRH Document Control Center with "Attention: Notification of Intent" on the cover letter of the submission. This EUA report includes the information outlined in Section V.A above.

On October 1, the OEM submits a marketing submission to FDA. In its marketing submission, the OEM includes a "transition implementation plan" for already distributed ventilators.

On the EUA termination date (January 1), the relevant EUA declaration is terminated and the umbrella EUA is no longer in effect. The OEM and contract manufacturer must both comply with all applicable regulatory requirements for the devices. The OEM has submitted a marketing submission, had it accepted by FDA, and has provided updated device labeling to accurately reflect that the product was authorized under an EUA issued during the COVID-19 PHE and remains under FDA review for clearance or approval. Under these circumstances, FDA does not intend to object to the continued distribution of the ventilators before FDA takes a final action on the marketing submission (see Section V.B(2) above).

In this scenario, the OEM does not respond to an FDA request 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 28. FDA and the manufacturer engage on the manufacturer's benefit-risk plan to address already distributed devices. FDA may request that the firm initiate a recall of such devices in certain circumstances if a recall has not already been initiated (see 21 CFR 7.45).

Example 4

A molecular diagnostic test kit manufactured by a commercial manufacturer was issued an individual EUA for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens, nasal swab specimens, and pooled samples in authorized laboratories.[36]

On July 1, the advance notice of termination of the relevant EUA declaration is published. On October 1, the manufacturer submits a marketing submission to FDA. In its marketing submission, the manufacturer includes a "transition implementation plan" for already distributed molecular diagnostic test kits.

On the EUA termination date (January 1), the relevant EUA declaration is terminated and the EUA for the device is no longer in effect. The manufacturer must comply with all applicable regulatory requirements for the device. The manufacturer has submitted a marketing submission, had it accepted by FDA, and has provided updated device labeling to accurately reflect that the product was authorized under an EUA issued during the COVID-19 PHE and remains under FDA review for clearance and approval. Under these circumstances, FDA does not intend to

[36] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#individual-molecular.

object to the continued distribution of the device before FDA takes a final action on the marketing submission (see Section V.B(2) above).

In this scenario, the manufacturer receives a positive decision on February 20, as part of FDA's final action on the marketing submission. No outstanding issues were identified during FDA review that would result in a correction or removal of the test kits that were already distributed.