with the applicable regulations, revoke the ACHC's deeming authority under CLIA.

Should circumstances result in our withdrawal of ACHC 's approval, we will publish a notice in the **Federal Register** explaining the justification for removing its approval.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, and the implementing regulations in 42 CFR part 493, subpart E, are currently approved under OMB control number 0938–0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–06280 Filed 3–24–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1149]

Transition Plan for Medical Devices Issued Emergency Use Authorizations Related to Coronavirus Disease 2019 (COVID–19); Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19).'' FDA recognizes that it will take time for device manufacturers, device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the COVID–19 pandemic to ''normal operations.'' 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 EUAs related to COVID–19, including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices.

DATES: The announcement of the guidance is published in the **Federal Register** on March 27, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–1149 for ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19)'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jacqueline Gertz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD 20993–0002, 240–402–9677.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, the Secretary of Health and Human Services (the Secretary) issued a declaration of a public health emergency (PHE) related to COVID–19 in accordance with section 319 of the Public Health Service Act (section 319 PHE) (42 U.S.C. 247d) and mobilized the Operating Divisions of the Department of Health and Human Services (HHS).[1] Pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3), on February 4, 2020, the Secretary determined that there is a PHE that has significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the SARS–CoV–2 virus that causes COVID–19. On the basis of such determination, the 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). Based on the February 4, 2020, determination, the Secretary issued two more declarations justifying emergency uses related to devices: on March 2, 2020, for certain personal respiratory protective devices (85 FR 13907), and on March 24, 2020, for devices, including alternative products used as devices (85 FR 17335). On March 15, 2023, the Secretary amended the February 4, 2020 determination to recognize the fact that there is ''a public health emergency, *or a significant potential for a public health emergency,* that affects, or has a 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 (emphasis added) (88 FR 16644).

Section 564 of the FD&C Act authorizes FDA, after the Secretary has made a declaration of emergency or threat justifying authorization of emergency use, to authorize the emergency use of an unapproved product or an unapproved use of an approved product for certain emergency circumstances. FDA may issue an EUA to allow a 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.

An EUA issued under section 564 of the FD&C Act remains in effect for the duration of the relevant EUA declaration, unless the EUA is revoked because the criteria for issuance are no longer met or revocation is appropriate to protect public health or safety (see section 564(f) through (g) of the FD&C Act).

Given the magnitude of the response to the COVID–19 pandemic, including the number of devices issued EUAs, FDA recognizes that stakeholders may need time to adjust after the termination of the device EUA declarations to help to ensure an orderly and transparent transition to ''normal operations.'' The Agency is issuing this guidance to describe FDA's general recommendations for this transition process with respect to devices issued EUAs related to COVID–19, 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 that fall within certain enforcement policies issued during the section 319 PHE related to COVID–19.

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 EUA declaration related to COVID–19. This guidance does not apply to devices for which FDA has revoked the EUA under section 564(g)(2)(B) through (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.

HHS intends to publish the advance notice of termination of each EUA declaration pertaining to devices in the **Federal Register** 180 days before the day on which the EUA declaration is terminated. The advance notice of termination of each device EUA declaration may occur simultaneously or at different times, depending on whether the circumstances underlying such declarations continue to exist (section 564(b)(2)(A) of the FD&C Act).

A notice of availability of the draft guidance appeared in the **Federal Register** of December 23, 2021 (86 FR 72978). FDA considered comments received and revised the guidance as appropriate in response to the comments, including revising the recommendation for interim labeling during the time when the device EUA declaration has been terminated and a manufacturer's marketing submission for a device is under FDA review, providing clarity on recommendations regarding physical and/or electronic copies of updated labeling, and adding clarifications regarding use of real-world evidence in marketing submissions, interactions with FDA, collaboration with stakeholders on the transition process, in vitro diagnostics, and example scenarios.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19).'' 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.

[1] Secretary of HHS, 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.* On February 9, 2023, the 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. 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.*

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID–19)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00020042 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the table below.

This guidance also contains new collections of information not approved under a current collection. These new collections of information have been granted a PHE waiver from the PRA by HHS on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

CFR cite referenced in this guidance	Another guidance referenced in this guidance	OMB control No(s).	New collection covered by PHE PRA waiver
	''Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders''.	0910–0595	
	''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program Guidance for Industry and Food and Drug Administration Staff''.	0910–0756	
	''Administrative Procedures for CLIA Categorization'' and ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and FDA Staff''.	0910–0607	
800, 801, and 809		0910–0485	
803		0910–0437	
806		0910–0359	
807, subparts A through D		0910–0625	
807, subpart E		0910–0120	
812		0910–0078	
814, subparts A through E		0910–0231	
814, subpart H		0910–0332	
820		0910–0073	
830 and 801.20		0910–0720	
860, subpart D		0910–0844	
			Notification of Intent.
			Transition Implementation Plan.
			Labeling Mitigation for Certain Reusable Devices.

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06292 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0814]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by April 26, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0256. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.