21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: December 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27823 Filed 12–22–21; 8:45 am]

BILLING CODE 4164–01–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for Medical Devices Issued Emergency Use Authorizations During the Coronavirus Disease 2019 Public Health Emergency; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' FDA recognizes that it will take time for device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the declared public health emergency (PHE) 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 during the COVID–19 PHE, including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 23, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the proposed collection of information in the draft guidance by February 22, 2022.

ADDRESSES: You may submit comments on any guidance 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) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' 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 draft guidance document entitled ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency'' 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:

With regard to the draft guidance: Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–5155; or 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.

With regard to the proposed collection of information: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance applies to devices that have been issued EUA under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3) on the basis of a device-related COVID–19 EUA declaration. This draft 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. 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.

Given the magnitude of the COVID–19 PHE, FDA recognizes that some 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' 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.

FDA is concurrently issuing a companion draft guidance to describe FDA's recommendations for transitioning devices that fall within enforcement policies issued during the COVID–19 PHE.

II. Electronic Access

Persons interested in obtaining a copy of the draft 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 draft guidance 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) During the COVID–19 Public Health Emergency'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 21012 and complete title to identify the draft guidance you are requesting.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency OMB Control Number 0910–0595; Revision

The following paragraphs discuss the one-time burdens associated with information collections found in the draft guidance, ''Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the COVID–19 Public Health Emergency.''

The draft 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. The information collections proposed in the draft guidance would assist the Agency in resource planning for marketing submission review and providing increased support to manufacturers. The information collections also include recommended information to provide in labeling for certain devices to inform potential users of the device's regulatory status, including physical labeling for life-supporting/life-sustaining devices.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification of intent	100	1	100	1	100
Transition plan	340	1	340	2	680
Labeling mitigation for reusable devices	170	1	170	1.25	213
Labeling mitigation for devices under FDA review after the EUA termination date	340	1	340	1.25	425
Total					1,418

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Notification of intent: In section V.A of the draft guidance, '' 'Notifications of Intent' for Certain Reusable Life-Supporting or Life-Sustaining Devices,'' FDA recommends that manufacturers of certain life-supporting or life-sustaining 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. The draft guidance recommends that manufacturers of such devices include in this notification: (1) General information (*e.g.,* contact information); (2) the EUA request number; (3) a list of all model numbers or other device identifying information; (4) whether the manufacturer plans to submit a marketing submission; and (5) if not planning to submit a marketing submission, the manufacturer should discuss, as applicable, its plan to stop 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 report.'' FDA recommends that manufacturers notate the following on the cover letter of the submission: ''Attention: Notification of Intent.''

Based on the current EUA submissions and authorizations, we estimate we will receive 100 notifications of intent for certain life-supporting or life-sustaining devices. Considering the recommended content of a notification, we estimate that the average burden per response is 1 hour.

Transition implementation plan: Section V.B.1 of the draft guidance recommends that manufacturers who intend to continue distribution of their device include with their marketing submissions a ''transition implementation plan'' that addresses the manufacturers' plans for devices already distributed in the case of a positive decision or a negative decision on its marketing submission. The ''transition implementation plan'' should include information regarding the estimated number of devices distributed under an EUA currently in U.S. distribution, and a benefit-risk based plan for disposition of distributed product as detailed in the draft guidance.

Considering the current EUA submissions and authorizations, the amount of these products that are 510(k) exempt, and the amount of respondents we estimate are likely to pursue marketing submission, we estimate that we will receive transition plans for approximately two-thirds of these products, or about 340 products. Based on the recommended content of a transition plan, we estimate that the average burden per response is 2 hours.

Labeling mitigation for reusable devices: The draft guidance indicates that when manufacturers of certain reusable devices do not intend to distribute their device beyond the EUA termination date, FDA does not intend to object to the disposition of already distributed devices (*i.e.,* FDA does not intend to request market removal), as detailed in the draft guidance.

The draft guidance states that FDA does not intend to object to reusable, non-life-supporting/non-life-sustaining devices that were distributed before the EUA termination date remaining distributed and being used by their end user. Such devices should either be restored by the manufacturer to the previously FDA-cleared or approved version or have publicly available labeling that accurately describes the product features and regulatory status (*i.e.,* that the product lacks FDA clearance or approval). In addition, the draft guidance recommends that 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 be restored by the manufacturer to the previously FDA-cleared or approved version of the device, or have both publicly available and a physical copy of labeling that specifies that the device lacks FDA clearance or approval. We estimate that, on average, updating the labeling will take approximately 1 hour and 15 minutes. We estimate 170 respondents, which is about one-third of devices currently under an EUA issued during the COVID–19 PHE, will make such labeling available.

Labeling mitigation for devices under FDA review after the EUA termination date: 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. We believe updating this labeling will also take approximately 1 hour and 15 minutes per device. We estimate that the majority of devices for which manufacturers pursue a marketing submission may remain under FDA review for clearance or approval during the period after the EUA termination date.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

TABLE 2—GUIDANCES AND COLLECTIONS

21 CFR part or guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing.	0910–0625
806	Corrections and Removals	0910–0359
830 and 801.20	Unique Device Identification	0910–0720
800, 801, and 809	Medical Device Labeling	0910–0485
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595

IV. Other Issues for Consideration

As discussed in the draft guidance, FDA understands that it will take time for device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the declared PHE to normal operations. FDA encourages all stakeholders to comment on the following topics:

1. Whether the 180-day period proposed for advance notice of termination of each EUA declaration pertaining to devices would sufficiently allow for an appropriate transition period that avoids exacerbating product shortages and supply chain disruptions.

2. Whether FDA's issuance of this draft guidance with a proposed transition policy and requesting public comment may help the Agency to satisfy, or otherwise determine how to best satisfy, while also effectively managing Agency resources, the requirement in section 564(b)(2)(B) of the FD&C Act to consult with a manufacturer that was issued an EUA for an unapproved product on the appropriate disposition of the product.

Dated: December 20, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27891 Filed 12–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1128]

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations; Draft Guidance for Industry, Investigators, and Other Stakeholders; 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 draft guidance for industry, investigators, and other stakeholders entitled ''Digital Health Technologies for Remote Data Acquisition in Clinical Investigations.'' This guidance provides recommendations to sponsors, investigators, and other stakeholders on the use of digital health technologies (DHTs) to acquire data remotely from participants in clinical investigations evaluating medical products. DHTs may take the form of hardware and/or software and may be used to gather health-related information from study participants and transmit that information to study investigators and/or other authorized parties to evaluate the safety and effectiveness of medical products.

DATES: Submit either electronic or written comments on the draft guidance by March 23, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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