21 CFR part; guidance; or FDA form	Topic	OMB Control No.
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
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: December 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27825 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–1118]

Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 Public Health Emergency; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request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SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of the draft guidance entitled ''Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID–19) Public Health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 a phased transition process with respect to devices that fall within enforcement policies issued during the COVID–19 PHE, including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices. FDA is concurrently issuing a companion guidance to describe FDA's recommendations for this transition process with respect to devices issued Emergency Use Authorizations (EUAs) during the COVID–19 PHE. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 23, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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 collection of information 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–1118 for ''Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued 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 That Fall Within Enforcement Policies Issued 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 guidance applies to devices that fall within the enforcement policies described in List 1 of the draft guidance. FDA is concurrently issuing a companion guidance to describe FDA's recommendations for this transition process with respect to devices issued EUAs during the COVID–19 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) that fall within enforcement policies.

FDA is proposing a 180-day transition period that will begin on the implementation date and end on the date that the guidances in List 1 of the draft guidance are withdrawn. FDA requests public comment on this timeline from all interested stakeholders. FDA believes a phased approach over the course of 180 days following the implementation date as set forth in this guidance can help foster compliance with applicable statutory and regulatory requirements once the relevant enforcement policies are no longer in effect.

This 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 That Fall Within Enforcement Policies Issued 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.

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 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 That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (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 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 That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency

OMB Control Numbers 0910–0120 and 0910–0231—Revision

The following paragraphs discuss the one-time burdens associated with information collections found in the draft guidance, ''Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (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
Total					993

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

Notification of intent: In Section V.C.(1) 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 their intent to submit a marketing submission or not. The guidance recommends that manufacturers of such devices include in this notification, general information (*e.g.,* contact information); the title of the relevant enforcement policy guidance; submission number(s) for related premarket submissions; a list of all model numbers or other device identifying information; whether the manufacturer plans to submit a marketing submission; and, if not planning to submit a marketing submission, the manufacturer should discuss, as applicable, its plan to discontinue distribution of the device, to restore the device to a previously FDA-cleared or -approved version (if applicable), to provide a physical copy or electronic updated labeling, and any other efforts to address or mitigate potential risks of devices that remain distributed after the transition period has ended and the guidances in List 1 of the draft guidance have been withdrawn. If the device was previously FDA-cleared or -approved and a modified version was distributed as described in a policy in a guidance in List 1 of the draft guidance, the manufacturer should submit this information as a premarket notification (*i.e.,* 510(k)) or premarket approval application (PMA) ''amendment'' to the manufacturer's existing device submission that was previously cleared or approved. FDA recommends that manufacturers notate the following on the cover letter of the submission: ''Attention: Notification of Intent''. Based on the number of devices that may be marketed under the immediately in effect guidance enforcement policies, 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.D.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 the enforcement policy currently in U.S. distribution, and a benefit-risk based plan for disposition of distributed product as detailed in the draft guidance.

Considering the amount of devices that may fall within enforcement policies, 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 340 products. Based on the recommended content of a transition plan, we estimate that the average burden per response is 2 hours.

Labeling mitigation: The draft guidance indicates that when manufacturers of certain reusable devices do not intend to continue to distribute their devices beyond the transition period, 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 withdrawal of the relevant guidance 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) that were distributed before the withdrawal of the relevant guidance remain distributed. Such devices should either be restored by the manufacturer to the previously FDA-cleared or -approved 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 believe these reusable devices represent about half of the marketing submissions (170).

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 transition period before FDA withdraws the guidances identified in List 1 would sufficiently allow for an appropriate transition period that avoids exacerbating product shortages and supply chain disruptions.

2. Suggestions to add or remove guidances documents to or from List 1 of the draft guidance.

3. FDA's proposal to extend the effectiveness of the guidances in List 1 of the draft guidance either for 180 days or for at least 225 days, if the PHE declaration under section 319 of the Public Health Service Act expires before the finalization of this guidance.

Dated: December 20, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27892 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–2019–D–5606]

Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions; Guidance for Industry 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 ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions.'' FDA has developed this guidance document to assist in the preparation of premarket notification submissions (510(k)) for arthroscopy pump tubing sets intended for multiple patient use. This guidance outlines the device design considerations, risk mitigation strategies, and testing recommendations for arthroscopy pump tubing sets intended for multiple patient use. This guidance also clarifies the terminology used to describe arthroscopy pump tubing sets intended for multiple patient use.

DATES: The announcement of the guidance is published in the **Federal Register** on December 23, 2021.

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