TABLE 1—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [1] [2]
Labeling following recommendations in ''Questions and Answers About Dietary Guidance Statements in Food Labeling''	556	4	2,224	1	2,224	$3,422,736

[1] One time relabeling costs.
[2] There are no operating and maintenance costs associated with this collection of information.

The estimates in table 1 are based on our experience with similar labeling programs. We estimate that each year 556 manufacturers will relabel their products following recommendations found in the draft guidance. This estimate assumes manufacturers will remove Dietary Guidance Statements from their labels following recommendations in the draft guidance, as well as those that will add Dietary Guidance Statements to their labels. We estimate that each manufacturer will relabel 4 products for 2,224 total annual disclosures (556 manufacturers × 4 labels). Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 2,224 hours (2,224 disclosures × 1 hour). We estimate that there will be an annual capital cost of $3,422,736 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time burden.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. HHS and USDA. 1980 Dietary Guidelines for Americans. February 1980. Available at: *https://health.gov/dietaryguidelines/1980.asp.*
2. HHS and USDA. Dietary Guidelines for Americans, 2020–2025. 9th Edition. December 2020. Available at: *https://www.dietaryguidelines.gov/.*

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06304 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–D–1118 and FDA–2020–D–1138]

Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency; Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff; 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 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, device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the COVID–19 public health emergency (PHE) to ''normal operations.'' To provide a clear policy for all stakeholders and FDA staff, the Agency is issuing this guidance to describe FDA's general recommendations for a phased transition process with respect to devices that fall within certain enforcement policies issued during the COVID–19 PHE declared by the Secretary of Health and Human Services (the Secretary) under the Public Health Service Act (PHS Act), including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices. This guidance applies to devices that fall within enforcement policies in guidances included in List 1 of this guidance. The phased transition process outlined in this guidance will begin on the ''implementation date.'' The implementation date is the day the PHE expires or 45 days after the finalization of this guidance, whichever comes later. Because the COVID–19 section 319 PHE declaration is anticipated to expire at least 45 days after the finalization of this guidance, or May 11, 2023, the implementation date is that date. The guidances in List 1 of this guidance will no longer be in effect after the 180-day transition period ends.

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–1118 for ''Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency'' or the Docket No. FDA–2020–D–1138 for ''Center for Devices and Radiological Health (CDRH): 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 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: Ryan Ortega, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4618, Silver Spring, MD 20993–0002, 240–402–2303.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, the Secretary issued a declaration of a PHE related to COVID–19 in accordance with section 319 of the PHS Act (section 319PHE) (42 U.S.C. 247d) and mobilized the Operating Divisions of the Department of Health and Human Services (HHS).[1] FDA issued various guidance documents that describe enforcement policies for certain devices that are intended to support the emergency response to the COVID–19 pandemic.

Given the magnitude of the response to the COVID–19 pandemic, FDA recognizes that a phased approach may help to facilitate an orderly and transparent transition to normal operations. The Agency is issuing this guidance to describe FDA's general recommendations for a phased transition process with respect to devices that fall within certain enforcement policies issued during the COVID–19 PHE, including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices. This guidance applies to devices that fall within the enforcement policies described in List 1 of the guidance. FDA is concurrently issuing a companion transition guidance to describe FDA's recommendations for devices issued Emergency Use Authorizations related to COVID–19.

As described in this guidance, a 180-day transition period will begin on the implementation date. The implementation date is the date the COVID–19 section 319 PHE expires or 45 days after the finalization of this guidance, whichever comes later. Because the COVID–19 section 319 PHE declaration is anticipated to expire at least 45 days after the finalization of this guidance, or on May 11, 2023, the implementation date is that date. FDA believes the phased approach over the course of 180 days following the implementation date as set forth in this guidance can help foster compliance with applicable legal requirements once the relevant enforcement policies are no longer in effect.

A notice of availability of the draft guidance appeared in the **Federal Register** of December 23, 2021 (86 FR 72973). FDA considered comments received and revised the guidance as appropriate in response to the comments, including providing clarity on the 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, and revisions to example scenarios.

[1] Secretary of HHS, Determination That a Public Health Emergency Exists (hereinafter referred to as ''section 319 PHE declaration'') (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.*

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 ''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. Guidances Identified in List 1 of This Guidance

As part of FDA's commitment to support continuity and response efforts to the COVID–19 pandemic, the transition plan outlined in this guidance takes into account that the guidances in List 1 of this guidance will no longer be in effect after the 180-day transition period ends, or after November 7, 2023.

Generally, the guidances that set forth COVID–19-related enforcement policies for certain devices initially stated that they were intended to remain in effect only for the duration of the section 319 PHE declaration. As FDA announced in the **Federal Register** on March 13, 2023,[2] many of these guidance documents—the guidances in List 1—have been revised to state that they are intended to continue in effect for 180 days after the section 319 PHE declaration expires unless a different intended duration is set forth in the finalized version of this guidance. A different intended duration is not being set forth in this guidance. The implementation date is the date the section 319 PHE declaration expires, and the guidances are intended to continue in effect for 180 days after that date.

In finalizing this guidance, FDA added the following guidances to List 1: ''Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (Revised)'' [3] and ''Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID–19) Public Health Emergency.'' [4] These guidances were added to help facilitate an appropriate transition period for these devices away from the policies adopted and operations implemented during the COVID–19 PHE to normal operations. FDA removed the following guidances from List 1: ''Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID–19 Public Health Emergency,'' [5] ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (Revised),'' [6] ''Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency,'' [7] [8] and ''Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' [9] FDA has removed these guidances from List 1 because: (1) the policy in the guidance should not continue in effect beyond the expiration of the COVID–19 PHE or (2) the guidance was extended beyond the expiration of the COVID–19 PHE and FDA intends to retain the policy with appropriate changes. See the **Federal Register** notice entitled ''Guidance Documents Related to Coronavirus Disease 2019 (COVID–19).'' [10]

III. 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 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 GUI00021011 and complete title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act (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.*

[2] See ''Guidance Documents Related to Coronavirus Disease 2019 (COVID–19)'' (88 FR 15417), available at *https://www.federalregister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirus-disease-2019-covid-19.*

[3] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health.*

[4] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-shields-surgical-masks-and-respirators-during-coronavirus-disease-covid-19.* Bifurcation of the ''Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the COVID–19 Public Health Emergency (Revised)'' guidance was announced in the **Federal Register** notice on March 13, 2023. The guidance relating to face shields, surgical masks, and respirators is on List 1, and the guidance related to face masks and barrier face coverings, as noted below, is outside the scope of this guidance.

[5] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-quality-standards-mammography-quality-standards-act-during-covid-19-public-health.*

[6] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during.*

[7] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public.*

[8] See footnote 4.

[9] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public.*

[10] See footnote 2.

21 CFR part	Another guidance referenced in this guidance	OMB control No.	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	
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. 2023–06291 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–2023–N–1007]

Over-the-Counter Monograph Drug User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates under the over-the-counter (OTC) monograph drug user fee program (OMUFA) for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests. This notice publishes the OMUFA fee rates for FY 2023.

DATES: These fees are effective on October 1, 2022, and will remain in effect through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Brandon Lee, Mitra Ramson, and the User Fees Support Staff, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov,* 202–510–1643.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), as added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), authorizes FDA to assess and collect: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests. These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include various FDA activities associated with OTC monograph drugs and inspection of facilities associated with such products.

For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act);
- An OTC monograph drug facility (MDF) is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act);
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act); and
- An OTC monograph order request (OMOR) is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2023 shall be assessed with respect to each facility that is identified as an OTC monograph drug facility during the fee-liable period from January 1, 2022, through December 31, 2022.[1] Consistent with the statute, FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees for FY 2023 are due on June 1, 2023 (see section 744M(a)(1)(D)(ii) of the FD&C Act).[2]

[1] Under section 744M(a)(1) of the FD&C Act, "Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility". For purposes of FY 2023 facility fees, that time period is January 1, 2022, through December 31, 2022.

[2] Assuming that, as we anticipate, the FY 2023 fee appropriation will occur prior to June 1, 2023. Under section 744M(a)(1)(D)(ii), the FY 2023 facility fees are due on the later of: (1) the first business day of June 2023 (*i.e.,* June 1, 2023) or (2)