

letter to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

### III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women, and men, members of all racial and ethnic groups and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 21, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-20990 Filed 9-27-22; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-2059]

#### Providing Over-the-Counter Monograph Submissions in Electronic Format; Draft Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Providing Over-the-Counter Monograph Submissions in Electronic Format.” This guidance provides information on providing electronic submissions to FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

**DATES:** Submit either electronic or written comments on the draft guidance by November 28, 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 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-2022-D-2059 for “Providing Over-the-Counter Monograph Submissions in Electronic Format.” 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-

0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-7945.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Providing Over-the-Counter Monograph Submissions in Electronic Format.” This guidance provides information on providing electronic submissions to FDA under section 505G of the FD&C Act (21 U.S.C. 355h) (hereafter referred to as over-the-counter (OTC) monograph submissions). This guidance is intended to assist submitters by describing the electronic OTC monograph submissions requirement in section 505G(j) of the FD&C Act and providing recommendations and other information on how to send such OTC monograph submissions to FDA in electronic format.

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, which was enacted on March 27, 2020. Section 505G(j) of the FD&C Act requires that all OTC monograph submissions must be in electronic format. As required by section 505G(l)(3) of the FD&C Act, this draft guidance, when finalized, specifies the format of electronic submissions under section 505G of the FD&C Act.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document entitled “Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,” commonly referred to as the OMUFA commitment letter (the document can be accessed at <https://www.fda.gov/media/106407/download> and the document with updated goal dates for fiscal years 2021 to 2025 can be accessed at <https://www.fda.gov/media/146283/download>). In the OMUFA commitment letter, FDA committed to issuing this draft guidance under specific timelines.

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 “Providing Over-the-Counter Monograph Submissions in Electronic

Format.” 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. Paperwork Reduction Act of 1995**

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 does not apply to collections of information made under section 505G of the FD&C Act. This guidance is being issued to implement the provisions of section 505G(l)(3) of the FD&C Act, which specifies the format of electronic submissions to FDA under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 23, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-D-0987]

**Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised); Immediately in Effect Guidance for Commercial Manufacturers 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 document related to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE) entitled “Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised).” FDA is issuing this guidance to provide FDA’s revised enforcement policies and review priorities regarding certain novel coronavirus (COVID-19) tests for the duration of the public health

emergency. Rapid detection of COVID-19 cases in the United States requires wide availability of testing to control the spread of this highly contagious infection. This document supersedes “Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised)” issued November 15, 2021. The guidance identified in this notice addresses issues related to the COVID-19 PHE and has been issued in accordance with the expedited process FDA announced in the **Federal Register** of March 25, 2020, for making available to the public COVID-19-related guidances. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency’s good guidance practices.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 28, 2022.

**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.