

### B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2024 program fees under the new fee schedule in August 2023. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are due on October 2, 2023.

FDA will issue invoices in December 2024 for products that qualify for FY 2024 program fee assessments after the October 2023 billing.

### C. Fee Waivers and Refunds

To qualify for consideration for a waiver or reduction under section 736(d) of the FD&C Act, an exemption under section 736(k) of the FD&C Act, or the return of an application or program fee paid under section 736 of the FD&C Act, including if the fee is claimed to have been paid in error, a person must submit to FDA a written request justifying such waiver, reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: July 24, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-15911 Filed 7-27-23; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-D-0466]

#### Clinical Considerations for Studies of Devices Intended To Treat Opioid Use Disorder; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder.” Design of clinical studies for devices intended to treat opioid use disorder (OUD) is challenging. This guidance provides recommendations for the design of pivotal clinical studies for devices intended to treat opioid use disorder (“OUD device studies”) and used to support marketing submissions. These recommendations are applicable

to the design and development of clinical studies to provide a reasonable assurance of safety and effectiveness for a device intended to treat OUD. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by October 26, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2023-D-0466 for “Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder.” 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 “Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder” to the Office of Policy, Guidance and Policy Development, 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:** Megha Reddy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2568, Silver Spring, MD 20993-0002, 240-402-2980.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The opioid overdose crisis is a serious and complex challenge facing the United States. The Agency has already taken significant steps to decrease unnecessary exposure to opioids, prevent new cases of opioid use disorder (OUD) and support the treatment of people with OUD. The Center for Devices and Radiological Health (CDRH) is committed to helping to end this national crisis. This guidance provides recommendations for the design of pivotal clinical studies for devices intended to treat OUD (hereafter “OUD device studies”) and used to support marketing submissions. These recommendations are applicable to the design and development of clinical studies to provide a reasonable

assurance of safety and effectiveness for a device intended to treat OUD. OUD device studies designed using the recommendations set out in this guidance may advance the treatment of OUD by providing scientific evidence that aids FDA in determining whether there is a reasonable assurance that a device intended to treat OUD is safe and effective. These recommendations may change as more information becomes available, and the research community gains experience with different designs in relation to OUD device studies.

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 this topic. 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 CDRH guidance documents is available at [https://www.fda.gov/medical-devices/device-advice-comprehensive-](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products)

[regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products](https://www.fda.gov/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 “Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00019017 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA guidance have been approved by OMB as listed in the following table:

Guidance	Topic	OMB control No.
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-submissions ..	0910-0756

Dated: July 24, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2023-N-2897]

**Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2024**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2024 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and

renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that are applying to be directly accredited by FDA.

**DATES:** This fee is effective on October 1, 2023, and will remain in effect through September 30, 2024.

**FOR FURTHER INFORMATION CONTACT:** Olufunmilayo (Funmi) Ariyo, Food and Drug Administration, 404 Powder Mill Rd., Beltsville, MD 20705-4304, 240-402-4989; or the FSMA Fee Staff, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, [FSMAFeeStaff@fda.hhs.gov](mailto:FSMAFeeStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 307 of FSMA (Pub. L. 111-353), Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies<sup>1</sup> conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly

<sup>1</sup> For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578-74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term “third-party certification body” rather than the term “third-party auditor” used in section 808(a)(3) of the FD&C Act.