

To meet its review performance goals in accordance with CDER good review management principles and practices for products covered by the Prescription Drug User Fee Act, CDER generally initiates inspection planning early in the application review process (*i.e.*, during the filing determination and review planning phase). CDER's inspection planning includes the selection of clinical investigator sites and other regulated entities for on-site inspections, and the preparation of assignment memos and background packages that CDER provides to OII investigators, who perform FDA's BIMO inspections. CDER uses the data and information described in this guidance to plan BIMO inspections, including: (1) to facilitate the timely identification of sites for inspection and (2) to ensure the availability of information needed to conduct BIMO inspections by OII investigators.

This guidance finalizes the draft guidance entitled "Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions" issued on February 16, 2018 (83 FR 7043). The draft guidance superseded the previously issued draft guidance for industry "Providing Submissions in Electronic Format—Summary Level Clinical Site Data for CDER's Inspection Planning" issued on December 19, 2012 (77 FR 75174).

We reviewed all comments received on the draft guidance issued on February 16, 2018, and revised several sections of the guidance. The updates include:

- Clarified, throughout the guidance, which NDA and BLA supplements the requirements in the guidance apply to.
- Clarified that clinical sites that screened, consented, or enrolled trial participants are to be included in the table listing all clinical sites that participated in clinical studies.
- Clarified that the request for a list of all entities that the sponsor has used to conduct clinical trial related activities includes both entities the sponsor has contracted without a transfer of regulatory obligations and those to whom the sponsor has transferred regulatory obligations.
- Deleted specific directions related to eCTD formatting and optional submission of a BIMO Reviewer's Guide and clarified that specifications for these items are now included in the technical specifications document.
- Additional comments received, which were related to the technical specifications document "Bioresearch Monitoring Technical Conformance

Guide," have been addressed separately in prior revisions to that document.

In section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k-1(a)), Congress granted explicit authorization to FDA to specify, in guidance, the electronic format for submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the Public Health Service Act (42 U.S.C. 262(a) or (k)). Accordingly, to the extent that this guidance provides such requirements, as indicated by the use of the words *must* or *required*, this guidance will not be subject to the usual restrictions in FDA's good guidance practices regulations (GGPs), such as the requirement that guidances not establish legally enforceable responsibilities (see 21 CFR 10.115(d); see also the guidance for industry "Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act" issued on December 18, 2014 (79 FR 75570)).

To comply with GGPs and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidance documents should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance document because it is not an accurate description of this guidance. Insofar as this guidance specifies the format for electronic submissions pursuant to section 745A(a) of the FD&C Act, 24 months after the issuance of this guidance, electronic submission of certain data and information in the standardized formats described in the guidance will be required.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of

information contained in 21 CFR part 601 relating to the submission of biologics license applications have been approved under OMB control number 0910–0338.

## III. Electronic Access

Persons with access to the internet may obtain the 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: December 2, 2024.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2024–N–5331]

#### Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Extended-Release/Long-Acting Opioid Analgesic Postmarketing Requirement

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee (the Committees). The general function of the Committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on February 5, 2025, from 8 a.m. to 5 p.m. Eastern Time.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2024-N-5331. The docket will close on February 4, 2025. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before January 22, 2025, will be provided to the Committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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-2024-N-5331 for "Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Extended-Release/Long-Acting (ER/LA) Opioid Analgesic (OA) Postmarketing Requirement (PMR)." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." FDA 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 the 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.

#### **FOR FURTHER INFORMATION CONTACT:**

Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-7699, email: [DSaRM@fda.hhs.gov](mailto:DSaRM@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

#### **SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committees will discuss the findings of the completed ER/LA OA PMRs 3033-1 and 3033-2 (link to Release and Reissue letter: <https://www.fda.gov/media/95546/download>).

These PMRs are prospective (3033-1) and retrospective (3033-2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online

teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The online presentation of materials will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committees. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before January 22, 2025, will be provided to the Committees. Oral presentations from the public will be scheduled between approximately between 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before January 13, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by January 14, 2025. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a

disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: December 2, 2024.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; HRSA Ryan White HIV/AIDS Program Part F Regional AIDS Education and Training Center Program Activities

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day

comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than January 8, 2025.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments," or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-3983.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* HRSA Ryan White HIV/AIDS Program Part F Regional AIDS Education and Training Center Program Activities, OMB No. 0906-xxxx—New.

*Abstract:* The Ryan White HIV/AIDS Program's (RWHAP) AIDS Education and Training Center (AETC) Program, authorized under title XXVI of the Public Health Service Act, supports a network of regional centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating people with HIV. The RWHAP Regional AETC Program's purpose is to increase the number of health care providers who are effectively educated and equipped to counsel, diagnose, treat, and medically manage people with HIV. The RWHAP Regional AETC Program recipients are required to report data on the training activities and trainees to HRSA once a year. HRSA is requesting the approval of new AETC data collection forms to accurately capture data relating to Regional AETC activities, participants, and site information for both Practice Transformation (PT) and Interprofessional Education (IPE) sites as well as involvement in the HIV care and treatment workforce (1-year post-participation), knowledge gained through participating in an activity, and satisfaction with the activity. The RWHAP Regional AETC Program recipients will gather data on the training activities they conduct using six data collection instruments. The Individual Participant Record is completed at least once every reporting period by participants actively engaging in Regional AETC activities. This form includes Regional AETC participant demographic, workplace, and clients-served data for the participant's