

*Estimated Total Annual Burden*

Hours: 4,058.68.

*Authority:* 42 U.S.C. 653(m)(2) and 44 U.S.C. 3554.

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-0481]

#### Standardized Format for Electronic Submission of Marketing Application Content for the Planning of Bioresearch Monitoring Inspections for Center for Drug Evaluation and Research Submissions; Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of the guidance for industry entitled “Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions.” This guidance describes the electronic submission of certain data and information in standardized formats. This information is used by the Center for Drug Evaluation and Research (CDER) in the planning of, and by FDA’s Office of Inspections and Investigations (OI) in the conduct of, BIMO inspections.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 9, 2024.

**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-2018-D-0481 for “Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://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 “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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillendale 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-0980.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled “Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring Inspections (BIMO) for CDER Submissions.” This guidance describes the electronic submission of certain data and information in standardized formats. CDER uses the data and information described in the guidance to plan BIMO inspections. The guidance addresses major (*i.e.*, pivotal) studies used to support safety and efficacy claims in new drug applications (NDAs), biologic license applications (BLAs) regulated by CDER, as well as supplements containing new clinical study reports.

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.