

Lynne.Yao@fda.hhs.gov; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993-0002, 301-796-5259, [jill.adleberg@fda.hhs.gov](mailto:jill.adleberg@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a guidance for industry entitled “E11A Pediatric Exploration.” The guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to <https://www.ich.org/>).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA’s

guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of August 29, 2022 (87 FR 52788), FDA published a notice announcing the availability of a draft guidance entitled “E11A Pediatric Extrapolation.” The notice gave interested persons an opportunity to submit comments by October 28, 2022.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in August 2024.

This guidance finalizes the draft guidance issued on August 29, 2022. The final guidance includes clarification and minor formatting changes to its recommendations on pediatric extrapolation concepts and approaches. The guidance was restructured for easier navigability and includes additional details on key concepts like study designs, modeling approaches, and the role of biomarkers. Additionally, the final guidance includes updates to the figure on the continuum of pediatric extrapolation.

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 “E11A Pediatric Extrapolation.” 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

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 relating to submission of investigational new drug applications, including efficient approaches to clinical trial design and study protocols, have been approved under OMB control number 0910-0014. The collections of information relating to submission of new drug applications have been approved under OMB control number 0910-0001. The collections of information relating to 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.regulations.gov>, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: December 16, 2024.

**P. Ritu Nalubola,**

Associate Commissioner for Policy.

[FR Doc. 2024-31026 Filed 12-27-24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-D-4490]

### Combined Food and Drug Administration and Sponsor Oncologic Drugs Advisory Committee Briefing Document; Draft Guidance for Industry; 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 draft guidance for industry entitled “Combined FDA and Sponsor Oncologic Drugs Advisory Committee (ODAC) Briefing Document.” This draft guidance provides recommendations to sponsors regarding use and development of a combined version of the ODAC briefing document, as part of the Oncology Center of Excellence’s (OCE) Project Point/Counterpoint initiative. This single document includes information that customarily would be contained in separate briefing documents prepared individually by the Sponsor and FDA. Project Point/Counterpoint is an option for advisory committee meetings for oncology products. Sponsors in non-oncology therapeutic areas who want to discuss whether a combined advisory committee briefing document may be appropriate for their applications should contact the relevant review division. This briefing document format may provide efficiencies by allowing Sponsors and FDA to choose to use a single document that provides the views of the Sponsor and FDA on key issues.

**DATES:** Submit either electronic or written comments on the draft guidance by February 28, 2025 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-2024-D-4490 for "Combined FDA and Sponsor Oncologic Drugs Advisory Committee (ODAC) Briefing Document." 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:** Jennifer Gao or Jamie Brewer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-4683 or 240-

402-4463; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-5923.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a draft guidance for industry entitled "Combined FDA and Sponsor Oncologic Drugs Advisory Committee (ODAC) Briefing Document." This guidance provides recommendations to sponsors regarding use and development of a combined version of the briefing document for matters before the ODAC, as part of the OCE Project Point/Counterpoint initiative. This single briefing document includes information that customarily would be contained in separate briefing documents prepared individually by the Sponsor and FDA. Project Point/Counterpoint is an option for advisory committee meetings for oncology products. Sponsors in non-oncology therapeutic areas who want to discuss whether a combined advisory committee briefing document may be appropriate for their applications should contact the relevant review division.

Sponsors and FDA customarily prepare their own separate ODAC briefing documents. This can lead to repetition of information (*i.e.*, trial design, endpoints, eligibility criteria, etc.) and increases the number of documents that ODAC committee members need to review. Additionally, ODAC committee members may need to go back and forth from each briefing document to consider the Sponsor's and FDA's position on each issue. Project Point/Counterpoint may provide efficiencies by allowing Sponsors and FDA to choose to use a single document that provides the views of the Sponsor and FDA on key issues.

The combined briefing document was first piloted for use at an ODAC meeting in December 2019. This format decreases the number of documents ODAC members must review by providing the applicant's and FDA's positions in one document. It serves as a stand-alone document containing the background information and an objective description of the data for the clinical trial or topic under discussion at ODAC, followed by the positions of the Sponsor and FDA.

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 "Combined FDA and Sponsor

Oncologic Drugs Advisory Committee (ODAC) Briefing Document.” 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

FDA tentatively concludes that this draft guidance contains no collection of information. 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: December 18, 2024.

### P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31305 Filed 12–27–24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2024–N–5717]

#### Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Supplemental New Drug Application 218276 S–004 for FABHALTA (iptacopan) Oral Capsules in the Treatment of Adults With C3G

**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 Cardiovascular and Renal Drugs Advisory Committee (the Committee). The general function of the Committee 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 24, 2025, from 9 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–5717. The docket will close on February 21, 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 21, 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 February 7, 2025, will be provided to the Committee. 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–5717 for “Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Supplemental New Drug Application (sNDA) 218276 S–004 for FABHALTA (iptacopan) Oral Capsules in the Treatment of Adults with C3G.” 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 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