4164-01-P

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Combined Food and Drug Administration and Sponsor Oncologic Drugs Advisory Committee Briefing Document; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Combined FDA and Sponsor Oncologic Drugs Advisory Committee (ODAC) Briefing Document." This draft guidance provides recommendations to sponsors regarding use and development of a combined version of the ODAC briefing document, as part of the Oncology Center of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DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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.

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