Combined FDA and Sponsor Oncologic Drugs Advisory Committee Briefing Document

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE) Regulatory Affairs and Policy Team at oceguidanceteam@fda.hhs.gov or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2024
Clinical/Medical

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Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
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Combined FDA and Sponsor Oncologic Drugs Advisory Committee Briefing Document Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides recommendations to Sponsors regarding use and development of a combined version of the briefing document for matters before the Oncologic Drug Advisory Committee (ODAC), as part of the Oncology Center of Excellence's (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 by FDA.[2] 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 FDA review division.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Consistent with FDA's 2008 Guidance, Sponsors and FDA customarily prepare separate ODAC briefing documents.[3] 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

[1] This guidance has been prepared by the Oncology Center of Excellence (OCE), the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

[2] *See* FDA's guidance for industry *Preparation and Public Availability of Information Given to Advisory Committee Members* (August 2008) (the 2008 Guidance). That guidance document defines "sponsor" to include "industry sponsors, applicants, and petitioners. "Sponsor" has the same definition for purposes of this guidance document.

[3] *See id.*

Point/Counterpoint may provide efficiencies by allowing Sponsors and FDA to choose to use a single document that provides the views of both the Sponsor and of FDA on key issues.

The combined briefing document serves as a stand-alone document containing the relevant background information and a description of the data for the clinical trial or topic under discussion at ODAC, followed by the positions of the Sponsor and the FDA. This format includes information from the Sponsor and FDA as each issue is discussed.

III. PROCESS & RECOMMENDATIONS

- Sponsors should inform FDA of their interest in using Point/Counterpoint early on in the ODAC process, ideally at the first discussion with FDA about ODAC planning.

- FDA provides Sponsors who have expressed an interest in using the combined briefing document with a blank Project Point/Counterpoint combined briefing document template within 2 weeks of making a determination that a product will be discussed at ODAC. Sponsors are informed that an ODAC is planned as soon as possible after the submission of an application, perhaps even before receipt of the application, especially for priority reviews. For standard reviews, Sponsors are informed that an ODAC is planned no later than the filing meeting.

- The Sponsor completes their sections in the combined briefing document template, explaining their positions. The Sponsor's sections including tables and figures, should not exceed 35 pages. Any additional appendices may not exceed 20 pages in total. Formatting details (e.g., margins, font type, font size, etc.) should meet 508 compliance standards. The Sponsor should submit the combined briefing document template in both PDF and .docx formats.

- The Sponsor should submit their portion of the combined briefing document template to the appropriate FDA review division at least eight weeks prior to the scheduled ODAC. Exact timelines should be discussed with the FDA review division.

- FDA independently reviews all documents submitted by the Sponsor for the (s)NDA/BLA, including the combined briefing document template. After completing its independent review, the FDA will add its assessment in separate sections within the combined briefing document template. This permits FDA to respond directly to the Sponsor's views on any given topic for discussion and provide its independent assessment and document areas of agreement and/or disagreement from the Sponsor's views. The FDA does not edit the Sponsor's portions of the combined briefing document. If FDA disagrees with any aspect of the Sponsor's portion of the combined briefing document, the FDA will discuss this in the FDA assessment sections of the document.

- All other ODAC timelines (e.g., sharing with the Sponsor, public posting, etc.) for the combined briefing document remain the same as the timelines for the traditional briefing document process.[4]

- The Sponsor does not have a chance to see or review FDA's portion of the joint briefing document until the briefing document is finalized. The combined briefing document process is not iterative, and there is no discussion or collaboration between the Sponsor and FDA during the briefing document writing process itself. If the Sponsor has clarifying questions about how to complete their section(s) of the briefing document, they should contact the appropriate FDA review division.

- After the combined briefing document is finalized, addendum(s) and errata(s) may be issued as appropriate, as part of the standard ODAC process.[5]

[4] *See id.*
[5] *See id.*