

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance for industry, IRBs, and clinical investigators entitled “Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.” The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. However, eligibility criteria are sometimes more restrictive than necessary, and expanding eligibility criteria to be more inclusive is one trial design consideration that may improve the diversity of clinical trial populations. This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. Specifically, this draft guidance includes recommendations regarding the appropriate use of washout periods and concomitant medication exclusions and is intended to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

A clinical trial’s eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients’ access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug.

Appropriately broadening cancer trial eligibility criteria can improve the generalizability of trial results and provide a more detailed characterization of the therapy’s benefit-risk profile across the patient population likely to use the drug in clinical practice.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115).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 “Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.” 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 Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances](https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information/biologics/biologics-guidances), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA–2023–D–5303]

Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer’s Goods From Detention Without Physical Examination; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration is reopening the comment period for the draft guidance for industry entitled “Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer’s Goods From Detention Without Physical Examination; Draft Guidance for Industry; Availability” that published in the **Federal Register** of February 12, 2024. We are taking this action in response to a request to extend the comment period to allow additional time for interested parties to submit comments.

DATES: FDA is reopening the comment period for the draft guidance for industry announced in the **Federal Register** on February 12, 2024 (89 FR 9852). Submit either electronic or written comments on the draft guidance by June 25, 2024, to ensure that we consider your comments before we begin work on the final 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-2023-D-5303 for "Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer's Goods From Detention Without Physical Examination; Draft Guidance for Industry." 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." We will review this copy, including the claimed confidential information, in our 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://](https://www.regulations.gov)

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.

FOR FURTHER INFORMATION CONTACT:

Steven Bloodgood, Division of Seafood Safety (HFS-325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-5316, email: Steven.Bloodgood@fda.hhs.gov; or Holli Kubicki, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 2024 (89 FR 9852), the Food and Drug Administration (FDA or we) published a notice announcing the availability of a draft guidance for industry entitled "Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer's Goods From Detention Without Physical Examination; Draft Guidance for Industry." We provided a 60-day comment period for the draft guidance.

We have received a request for a 60-day extension of the comment period for the draft guidance to provide additional time to review and comment on the rationale for the sampling recommendations in the draft guidance. In the interest of balancing the public health importance of the sampling recommendations in the draft guidance

and granting additional time to submit comments before we finalize the draft guidance, we have concluded that it is reasonable to reopen the comment period for 60 days, until June 25, 2024. We are reopening the comment period because the request for an extension of the comment period arrived too late for us to extend the comment period. We believe that an additional 60 days allows adequate time for interested persons to submit comments.

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-1377]

Cancer Clinical Trial Eligibility Criteria: Performance Status; Draft Guidance for Industry, Institutional Review Boards, Clinical Investigators; 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, institutional review boards (IRBs), and clinical investigators entitled "Cancer Clinical Trial Eligibility Criteria: Performance Status." This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of cancer. Specifically, this draft guidance includes recommendations regarding expanding eligibility criteria to include patients with a wider range of performance status.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2024 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: