



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-0093]

M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver; International Council for Harmonisation; Draft Guidance for Industry; Reopening of the Comment Period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SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the draft guidance announced in the notice entitled “M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver; International Council for Harmonisation; Draft Guidance for Industry,” published in the *Federal Register* of June 2, 2025. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the draft guidance announced in the notice published on June 2, 2025 (90 FR 23339). Submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2023-D-0093 for "M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver; International Council for Harmonisation; 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.” 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)).

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Lei Zhang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4724, Silver Spring, MD 20993-0002, LeiK.Zhang@fda.hhs.gov.

Regarding the ICH: Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993-0002, 301-348-1967, Brooke.DalSanto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 2, 2025 (90 FR 23339), FDA published a notice with a 30-day period to provide comments on the draft guidance for industry entitled, “M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strengths Biowaiver.” Interested persons were originally given until August 1, 2025, to submit comments to the docket. The Agency is reopening the comment period for the draft guidance until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The Agency is planning to host a webinar on September 11, 2025, to present an overview of the draft guidance, explain the current scientific thinking behind the draft guidance, and highlight the main areas that differ from FDA’s current guidance on selected topics. The Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments after the webinar.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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