



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1464]

Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; 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 final guidance for industry entitled “Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.” This guidance provides recommendations to applicants planning to include bioequivalence (BE) information in abbreviated new drug applications (ANDAs), ANDA amendments, and ANDA supplements. In addition, this guidance describes how to meet the BE requirements set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations. This guidance finalizes the draft guidance for industry of the same title issued on August 23, 2021.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-2013-D-1464 for “Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.” 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: David Coppersmith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1666, Silver Spring, MD 20903, 301-796-9193, David.Coppersmith@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.” This guidance provides recommendations to applicants planning to include BE information in ANDAs, ANDA amendments, and ANDA supplements. In addition, this guidance describes how to meet the BE requirements set forth in the FD&C Act and FDA regulations. This guidance is applicable to immediate-release and modified-release oral dosage forms. It is also applicable to non-orally administered drug products in which reliance on systemic exposure measures is suitable for establishing BE (e.g., transdermal delivery systems and certain rectal and nasal drug products). This guidance will also be useful to applicants planning BE studies intended to be conducted during the postapproval period for changes to a drug product approved under an ANDA.

This guidance finalizes the draft guidance for industry of the same title issued on August 23, 2021 (86 FR 47117). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) updates to align the recommendations in the guidance with the recommendations in the guidance for industry entitled “M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms” issued on October 31, 2024, (2) clarifications about study population and study design, (3) updates to in vitro dissolution testing information, and (4) removal of the appendices on the statistical analysis for the reference scaled average BE for narrow therapeutic index drugs and highly variable drugs, which were incorporated into the guidance for industry entitled “Statistical Approaches to Establishing Bioequivalence” issued concurrently with this guidance. In addition, editorial changes were made to improve clarity.

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 “Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.” 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be neither regulatory nor deregulatory.

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 in 21 CFR parts 50 and 56 relating to the protection of human subjects and investigational review boards have been approved under OMB control number 0910-0130. The collections of information in 21 CFR 201.56 and 201.57 for the Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products have been approved under OMB control number 0910-0572. The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications and bioavailability/BE (BA/BE) studies or pharmacogenomic data and the collections of information in part 320 for drug safety reporting have been approved under OMB control numbers 0910-0014 and 0910-0291. The collections of information under 21 CFR part 312.145 pertaining to good clinical practice have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications, ANDAs, and supplemental applications and applicable BA/BE requirements have been approved under OMB control number 0910-0001. The collections of information under the administrative practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the FDA under 21 CFR Part 10 and 12 are approved under OMB control number 0910-0191. The collections of information for the submission of controlled correspondence, and for meetings pertaining to ANDA approval are approved under OMB control number 0910-0727. The collections of

information pertaining to Good Laboratory Practice Regulations have been approved under OMB control number 0910-0119.

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/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-10703 Filed: 5/28/2026 8:45 am; Publication Date: 5/29/2026]