Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Social Security Office (SSO) Report of State Buy-in Problems; *Use:* A State may enter into an agreement to provide Medicare protection to individuals who are members of a Buy-in coverage group, as specified in the State's Buy-in agreement. When problems arise that cannot be resolved through the normal data exchange process, clerical actions are required. This collection is intended to help identify and resolve beneficiary complaints and inquiries regarding State Buy-in eligibility. *Form Number:* CMS–1957 (OMB control number: 0938–0035); *Frequency:* On occasion; *Affected Public:* Individuals and households; *Number of Respondents:* 1,400; *Total Annual Responses:* 1,400; *Total Annual Hours:* 467. (For policy questions regarding this collection contact Keith Johnson at 410–786–1148.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–10777 Filed 5–28–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0197]

Statistical Approaches To Establishing Bioequivalence; 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 ''Statistical Approaches to Establishing Bioequivalence.'' This guidance provides recommendations to sponsors and applicants planning to use equivalence criteria in analyzing bioequivalence (BE) studies for investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and amendments and supplements to these applications. The guidance discusses statistical approaches for BE comparisons and focuses on how to use these approaches both generally and in specific situations. This guidance finalizes the draft guidance of the same title issued on December 5, 2022, and replaces the guidance of the same title issued on February 2, 2001.

DATES: The announcement of the guidance is published in the **Federal Register** on May 29, 2026.

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–2001–D–0197 for ''Statistical Approaches to Establishing Bioequivalence.'' 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 20993–0002, 301–796–9193, *David.Coppersmith@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Statistical Approaches to Establishing Bioequivalence.'' This guidance provides recommendations to sponsors and applicants planning to use equivalence criteria in analyzing in vivo or in vitro BE studies for INDs, NDAs, ANDAs, and amendments and supplements to these applications. The guidance discusses statistical approaches for BE comparisons and focuses on how to use these approaches both generally and in specific situations.

These specific situations include statistical methods for narrow therapeutic index drugs and highly variable drugs; recommendations for missing data and outlier detection; and a discussion of statistical methods regarding assessment of in vitro BE, including population BE and statistical approaches for in vitro release tests, in vitro permeation tests, and in vitro abuse-deterrent formulation comparative studies.

This guidance finalizes the draft guidance entitled ''Statistical Approaches to Establishing Bioequivalence'' issued on December 5, 2022 (87 FR 74426) and replaces the guidance entitled ''Statistical Approaches to Establishing Bioequivalence'' issued on February 2, 2001 (66 FR 8805). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include updates to provide clarifying information on estimands and intercurrent events, sample size determinations, and outlier data. The final guidance incorporates additional information on statistical analysis using population BE and statistical analysis using modified population BE, which was previously included in product-specific guidances. The final guidance also incorporates additional information on the statistical analysis for the reference scaled average BE for narrow therapeutic index drugs and highly variable drugs, which was previously included in the draft guidance for industry entitled ''Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA'' issued on August 23, 2021 (FDA issued a final guidance for industry of the same title 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 ''Statistical Approaches to Establishing Bioequivalence.'' 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 part 312 relating to the submission of INDs and bioavailability/BE (BA/BE) studies or pharmacogenomic data and the collections of information in part 320 for ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans'' have been approved under OMB control numbers 0910–0014 and 0910–0291. The collections of information in 21 CFR part 314 relating to the submission of NDAs, ANDAs, and supplemental applications and applicable BA/BE requirements have been approved under OMB control number 0910–0001. The collections of information that support Good Laboratory Practice for Non-Clinical Laboratory Studies have been approved under OMB control number 0910–0119. The recordkeeping requirement for current good manufacturing practices sample retention in 21 CFR 211.170 has been approved under OMB control number 0910–0139. 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 relating to good clinical practice have been approved under OMB control number 0910–0014.

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. 2026–10705 Filed 5–28–26; 8:45 am]

BILLING CODE 4164–01–P

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 May 29, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: