or class of persons into the United States is being prohibited;

(3) The conditions under which that prohibition on introduction will be effective, in whole or in part, including any relevant exceptions that the Director determines are appropriate;

(4) The means by which the prohibition will be implemented; and

(5) The serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

V. Determination and Implementation

Based on the foregoing, I hereby determine that Ebola disease, a highly transmissible quarantinable communicable disease, is confirmed present in the DRC and Uganda. There is a material risk that the outbreak will spread to South Sudan. I also determine that the prevalence of Ebola disease in these foreign countries constitutes a serious danger of the introduction of this disease into the United States due to the limited screening and testing and mitigation measures currently available. Finally, I determine that a temporary 30-day suspension of the right to introduce covered aliens is necessary to protect the public health from the serious danger of the introduction of Ebola disease into the United States, pending completion of a thorough public health assessment of the unique public health risk profile posed by Ebola disease and the development of a comprehensive mitigation and containment strategy in consultation with other stakeholders.

I consulted with the Department of State, DHS, and other federal departments as needed before I issued this Amended Order and requested that DHS aid in the enforcement of this Amended Order because CDC does not have the capability, resources, or personnel needed to do so.[11] As part of the consultation, DHS developed operational plans for implementing this Amended Order. These plans are consistent with the language of this Amended Order.

Although this Amended Order is not a rule subject to notice and comment under the Administrative Procedure Act (APA) and is issued with immediate effect, in order to ensure that the forthcoming public health risk assessment is informed by public input, the Order is being issued with a simultaneous 30-day comment period.

* * * * *

In testimony whereof, the Assistant Secretary for Health, U.S. Department of Health and Human Services, has hereunto set his hand at Birmingham, AL this 22nd day of May, 2026.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data so that the public can provide input that may inform the forthcoming public health risk assessment and whether any subsequent exercise of this authority is necessary.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

Authority

The authority for these orders is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268), as amended.

Brian Christine,

Assistant Secretary for Health (ASH) and Head of the United States Public Health Service (USPHS) Commissioned Corps, Department of Health and Human Services.

[FR Doc. 2026–10701 Filed 5–27–26; 8:45 am]

BILLING CODE 4163–18–P

[11] 42 U.S.C. 268; 42 CFR 71.40(d).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1957]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 29, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

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