reflect resident experience rather than changing a term that is commonly used in abuse investigations by other entities.

Comment: Three respondents recommended modification to the psychological abuse complaint code to include social media posts and posting of photographs.

Response: The current reporting tips include oral, written, or gestured language and are sufficient to include social media posts. Photos are also included in the reporting tips.

Comment: Three respondents recommended adding language to complaint types in the category of autonomy, choice, and rights to address emergence of artificial intelligence to monitor residents.

Response: This issue requires further review and will be considered for future revisions.

Comment: One respondent suggested adding a reporting tip to complaint type F10- Rehabilitation services to instruct Ombudsmen how to report contractures as gross neglect.

Response: Further review is needed, and this suggestion will be considered for future revisions.

Comment: One respondent recommended that instruction be added to select staffing as a secondary complaint and to broaden the definition of staffing.

Response: The use of secondary complaint codes when a resident or complainant has not expressed staffing as a complaint would be a significant change in practice with potential unintended consequences. This requires further review and may be considered in future revisions. The existing definition of J03—Staffing is sufficiently inclusive of staffing vacancies.

Comment: Two respondents recommended adding language to the definition and examples for complaint type L01—Resident representative or family conflict to include other visitors with different types of relationships.

Response: The complaint type as currently defined is specific to the nature of the relationships of family members and individuals that residents choose to be their representative; adding others could dilute the meaning of the data element.

Comment: Two respondents requested the addition of a new complaint type for reporting resident-to-resident altercations that are not willful abuse.

Response: ACL is not adding or removing data elements with this renewal but will consider this recommendation in the future after analysis of impact and alternatives within the existing collection.

Comment: Three respondents recommended adding a new category of complaints and individual complaint types about discrimination.

Response: ACL is not adding or removing elements but will seek additional input and consider this change in the future after analysis of impact.

Comment: Two respondents suggested adding a new complaint category to allow for short-term collection of data for a special purpose.

Response: ACL is not adding or removing elements with this renewal but will consider the recommendation after analysis of impact and alternatives.

Comment: One respondent asserted that complaint/case terminology in data elements S01–S06 is confusing.

Response: The data elements are text fields and provide flexibility for the State Ombudsman to describe complaints as they determine best. Technical assistance will be provided.

Comment: One respondent requested clarification about reporting hours donated by volunteers when the volunteer receives travel reimbursement.

Response: The Older Americans Act allows for reimbursement and travel is included in the current examples and reporting tips.

Comment: One respondent requested clarification about removal or remediation of conflicts of interest.

Response: How conflicts of interest are addressed is a matter of rule (45 CFR 1324.21(b)) implementation and technical assistance will be provided as part of broader regulatory guidance.

Comment: One respondent suggested the addition of a code for a specific type of expenditure.

Response: ACL is not adding or removing data elements with this revision of NORS but will consider this change in the future.

Comment: One respondent suggested clarification of local funds expended.

Response: The instruction is written as intended and technical assistance will be provided.

Comment: Four respondents recommended changes to routine access visitation reporting.

Response: Routine access visits as defined are an important measure of resident access to their advocate separate from visits to handle complaints, as well as a measure of the impact of program funding. ACL will explore this request further and consider a change in the future; data elements are not being changed in this revision.

Comment: Three respondents commented that instructions are vague about how to report the number of facilities and that closures have an impact on how routine access visits are measured on a quarterly basis.

Response: The examples and tips are specific that the count of facilities is as of the last day of the federal fiscal year. Routine access is based upon the count of facilities as of the last day of the fiscal year. The data element is defined as intended, routine access does not include facilities that open after the first quarter or close before the fourth quarter of the fiscal year. Technical assistance will be provided.

Comment: One respondent requested a new data element for reporting facility closures.

Response: At this time ACL is not adding or removing elements but will consider this change in the future after analysis of impact and alternatives.

Comment: Two respondents requested new Ombudsman program staffing data elements—statewide turnover rates, years of experience of Ombudsman representatives, and the staff-to-bed ratio of staff.

Response: At this time ACL is not adding or removing elements but will consider this change in the future after analysis of potential methods of collection.

Estimated Program Burden

ACL estimates the burden of this collection of information as follows:

Fifty-two grantees report to ACL using NORS.

a. Number of respondents—52
b. Frequency of response—1
c. Total annual responses—52
d. Hours per response—214
e. Total burden hours—11,153

Dated: October 28, 2024.

Maura Calsyn,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–25358 Filed 10–30–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0093]

M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms; International Council for Harmonisation; 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 ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms'' and the supplemental document entitled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Questions and Answers.'' The guidance and supplemental questions and answers document were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance describes the scientific and technical aspects of study design and data analysis to support bioequivalence (BE) assessment of orally administered immediate-release solid oral dosage forms of pharmaceutical drugs, such as tablets, capsules, and granules/powders for oral suspension. The supplemental questions and answers document provides clarity to concepts covered in the guidance and rationales behind to facilitate implementation. The guidance is intended to provide globally harmonized scientific recommendations for conducting BE studies during both the development and postapproval phases of immediate-release solid oral dosage forms. The guidance replaces the draft guidance ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms'' issued on February 1, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on October 31, 2024.

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–2023–D–0093 for ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms'' and ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms Questions and Answers.'' 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: *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: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms'' and the supplemental document entitled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Questions and Answers.'' The guidance and supplemental questions and answers document were prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and

maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of February 1, 2023 (88 FR 6750), FDA published a notice announcing the availability of a draft guidance entitled ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms; International Council for Harmonisation.'' The notice gave interested persons an opportunity to submit comments by April 3, 2023.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in July 2024.

This guidance finalizes the draft guidance issued on February 1, 2023. The final guidance includes clarification on the scientific and technical aspects of study design and data analysis to support BE assessment for orally administered immediate-release solid oral dosage forms. The supplemental questions and answers document provides further clarification and examples of the technical aspects of the main guidance in order to effectively implement the guidance. The internationally harmonized guidance and questions and answers document aim to increase the efficiency of drug development and accelerate the availability of safe and effective orally administered immediate-release solid oral dosage forms.

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 ''M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms''. The guidance and supplemental questions and answers document do not establish any rights for any person and are 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 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 314.94 for content and format for BE studies submitted under abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information for the implementation of improved quality and integrity of the study data approaches pertaining 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.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: October 23, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25355 Filed 10–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Revised Draft Guidances 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 additional revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The draft guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by December 30, 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:

- *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