November 15, 2023. During the 60-day comment period, ACL received five public comments. A portion from two public comments which directly related to the collection of routine customer feedback and ACL's response are listed in the below table. To view unrelated comments in entirety, visit *www.reginfo.gov/public/do/PRAMain and select* the proposed information collection record.

Commenter	Comment	ACL response
Harris T. Capps, Major US AF, retired.	Feedback to ACL should be a part of an HHS, and an ACL quality management program to serve as a powerful tool for monitoring, evaluating, and improving processes, products, and services, ultimately contributing to the organization's overall success. It can provide: a. Performance Evaluation c. Identification of Issues/Problems Transparency and Communication d. Continuous Improvement, especially regarding Customer Satisfaction & Quality of Services, etc.	Thank you for your service. ACL acknowledges receipt of comment. This proposed data collection will collect Routine Customer Feedback related to ACL program data under the below listed topics. Thank you for providing feedback on (1) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates; and (2) ways to enhance the quality, utility, and clarity of the information to be collected.
Rebecca Underwood	How will the participants be selected for small discussion groups, focus groups, and panel discussion groups?	Thank you for providing feedback on your concerns related to the selection of participants in customer satisfaction small discussion groups, focus groups, and panel discussion groups. Please note the terms of usage for this type of information collection requires the collection is targeted to the solicitation of opinions from respondents who have experience with the program services provided or may have experience with the program in the future. Such services as technical assistance, general solicitation, and suggestions for public meeting topics. Terms of usage for a Generic/Fast Track information collection do not cover the same terms applicable to program specific collections of information when data is most likely publicly reported, please visit *https://acl.gov/* Data, Research, and Issues tab to view such findings.

Estimated Program Burden

ACL estimates the burden of this collection of information as follows: The annual burden hours (2,521) requested, and the anticipated number of respondents (10,086) are based on the number of potential customer feedback respondents. Over the course of a three-year clearance for this generic information collection, ACL estimates a three-year burden drawdown amount of 7,564.5 burden hours and 30,258 respondents.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Annual number of respondents	Number of responses per respondent	Burden hours per response	Total annual burden hours
ACL Potential Customer or Stakeholder.	ACL Generic Clearance for the Collection of Routine Customer Feedback.	10,086	1	.25	2,521

Dated: March 26, 2024.

Alison Barkoff,

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

[FR Doc. 2024–06789 Filed 3–29–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3953]

Providing Regulatory Submissions in Electronic Format: Investigational New Drug Application Safety Reports; 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 ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' This guidance finalizes the draft guidance of the same name published on October 30, 2019, and describes the electronic format sponsors will be required to use when they electronically submit investigational new drug application (IND) safety reports to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) for serious and unexpected suspected adverse reactions, as required by FDA regulations. FDA is establishing the electronic format requirements described in this guidance under the Federal Food, Drug, and Cosmetic Act

(FD&C Act). The requirements in the guidance will be effective 24 months after the date of publication (April 1, 2026). Certain sponsors will be required to submit the specified IND safety reports electronically to FDA using the FDA Adverse Event Reporting System (FAERS) as structured data elements, which will provide sponsors with a reporting format that is consistent with the International Council for Harmonisation (ICH) E2B format guidelines and reporting requirements to other regulatory agencies.

DATES: The announcement of the guidance is published in the **Federal Register** on April 1, 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–2019–D–3953 for ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Suranjan De, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4307, Silver Spring, MD 20993–0002, 240–402–0498; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' This guidance finalizes the draft guidance of the same name published on October 30, 2019 (84 FR 58158), and describes the electronic format sponsors will be required to use when they electronically submit IND safety reports to CDER and CBER for serious and unexpected suspected adverse reactions, as required under 21 CFR 312.32(c)(1)(i). FDA is establishing the electronic format requirements described in this final guidance under section 745A(a) of the FD&C Act (21 U.S.C. 379k–1(a)). Certain sponsors will be required to submit the specified IND safety reports electronically to FDA using FAERS as structured data elements. This will provide sponsors with a reporting format that is consistent with the ICH E2B format guidelines and reporting requirements to other regulatory agencies. Additional technical specification documents and instructions for submitting IND safety reports, including ''Electronic Submission of IND Safety Reports Technical Conformance Guide'' and the technical specifications document entitled ''Technical Specifications Document—FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products,'' are available on the FDA Adverse Event Reporting System (FAERS) Electronic Submissions—E2B(R3) Standards web page (available at: *https://www.fda.gov/*

drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions-e2br3-standards).

The electronic format requirements specified in this guidance will be effective 24 months after the publication of this guidance (April 1, 2026). Before the effective date of this requirement, FDA will accept the IND safety reports described in this guidance to FAERS as part of a voluntary submission program.

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 ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' 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.

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 under 21 CFR 312.10 for submitting waiver requests and in 21 CFR 312.32 for submitting IND safety reports and reporting serious and unexpected suspected adverse events have been approved under OMB control number 0910–0014. The collections of information for submitting Forms FDA 3500 and 3500A, and for FDA adverse event reporting and electronic submissions using the Electronic Submission Gateway and the Safety Reporting Portal have been approved under OMB control number 0910–0291. The collections of information for submitting periodic adverse drug experience reports have been approved under OMB control number 0910–0230. The collections of information for submitting FAERS reports have been approved under 0910–0308.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06736 Filed 3–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a webcast on April 30, 2024. This virtual meeting will be open to the public. Registration is required for the public to attend the meeting, provide comment, and/or distribute material(s) to the ACMH members. Instructions regarding participating in the call and providing written or verbal public comments will be provided after meeting registration occurs.

DATES: The ACMH meeting will be held on April 30, 2024 from 11 a.m. to 12:30 p.m. EDT. If the Committee completes its work before 12:30 p.m., the meeting will adjourn early.

Any individual who wishes to participate in the virtual meeting should register using the Zoom registration link provided below by 5 p.m. EDT on April 24, 2024.

ADDRESSES: The meeting will be held virtually and will be accessible by webcast. Instructions regarding webcast access and providing written or verbal public comments will be given after meeting registration occurs.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, OMH, HHS, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240–453–6816; email: *OMH-ACMH@hhs.gov*.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on the development of goals and program activities related to OMH's duties.

The topics to be discussed during the virtual meeting will be finalizing the recommendations on how OMH and HHS can support community awareness, education and engagement on HHS efforts to implement the revised Office of Management and Budget (OMB) Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15). The final recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to implementation of the revised OMB standards. Information on OMB's Interagency Technical Working Group on Race and Ethnicity Standards can be found on this website: *spd15revision.gov*.

Information about the meeting will be posted on the HHS Office of Minority Health (OMH) website: *www.minorityhealth.hhs.gov*. Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Working Groups*.

Any individual who wishes to attend the meeting must register via the Zoom registration link, *https://www.zoomgov.com/meeting/register/vJIscuuhqzIqHX5wssDFc84ZH-6jdn4NgZg,* by 5 p.m. EDT on April 24, 2024. Each registrant should provide their name, affiliation, phone number, email address, if they plan to provide either written or verbal comment, and whether they have requests for special accommodations, including sign language interpretation. After registering, registrants will receive an automated email response with the meeting connection link. The meeting connection link is unique to each registrant and should not be shared.

Members of the public will have an opportunity to provide comments at the meeting. Individuals should indicate during registration whether they intend to provide written or verbal comment. Public comments will be limited to two minutes per speaker during the time allotted. Written statements are limited to two pages. If the two-page limit is exceeded, the full statement will not be included. Registered members of the public who plan to submit and distribute electronic or printed public statements or material(s) related to this meeting's topic should email the material to *OMH-ACMH@hhs.gov* at least five (5) business days prior to the meeting.