• 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: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies.'' This guidance provides instructions for the electronic submission of expedited ICSRs from IND-exempt BA/BE studies to FAERS. An ICSR captures information necessary to support the reporting of an adverse event related to an individual subject that is associated with the use of an FDA-regulated product.[1] The electronic submission of the ICSRs from IND-exempt BA/BE studies is a voluntary option for submitting these required reports.

In the **Federal Register** of September 29, 2010 (75 FR 59935), FDA published a final rule that revised the IND safety reporting requirements for human drug and biological products under 21 CFR 312 and added safety reporting requirements for persons conducting IND-exempt BA/BE studies under § 320.31 (21 CFR 320.31).[2] A serious adverse event experienced by a study subject during the conduct of an IND-exempt BA/BE study must be submitted on Form FDA 3500A or in an electronic format that FDA can process, review, and archive.[3]

Previously, to meet the requirements under § 320.31(d)(3) applicable to IND-exempt BA/BE studies, submitters sent expedited premarket safety reports directly to the Office of Generic Drugs (OGD) by email, telephone, or facsimile. This guidance provides recommendations on how to electronically submit ICSRs to FAERS as an alternate avenue for submitting reports to OGD.

This guidance finalizes the draft guidance entitled ''Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies'' issued on August 3, 2022 (87 FR 47431). FDA did not receive any comments to the docket. Editorial changes were made to improve clarity and incorporate the FAERS enhancements to enable electronic submissions of ICSRs from IND-exempt BA/BE studies.

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 ''Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies.'' 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 in 21 CFR part 312 for IND applications and 21 CFR 320.31 for IND-exempt BA/BE safety reporting requirements for human drug and biological products have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 314 for safety report submissions for applications for FDA approval new drug application have been approved under OMB control number 0910–0001.

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.*

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06726 Filed 4–1–24; 8:45 am]

BILLING CODE 4164–01–P

[1] See additional information on Individual Case Safety Reports available at *https://www.fda.gov/industry/fda-resources-data-standards/individual-case-safety-reports.*

[2] BA and BE studies that meet the conditions for exemption under 21 CFR 320.31 are not conducted under an IND and are not subject to the IND safety reporting requirements. The safety reporting requirements under § 320.31(d)(3) apply to persons conducting BA or BE studies that are exempt from the IND requirements.

[3] § 320.31(d)(3).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, 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 18, 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 ACMH members. Any individual who wishes to participate in the virtual meeting should register using the Zoom registration link provided below by 5:00 p.m. EDT on April 12, 2024. Instructions regarding participating in the call and providing written or verbal public comments will be provided after meeting registration occurs. 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.*

DATES: The ACMH meeting will be held on April 18, 2024 from 9:00 a.m. to 10:30 a.m. EDT. If the Committee completes its work before 10:30 a.m., the meeting will adjourn early.

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 include finalizing: (1) meeting notes of the February 13–14, 2024 ACMH meeting; and (2) recommendations on how OMH and HHS can support community awareness, education and engagement on HHS efforts to implement 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.*

Any individual who wishes to attend the meeting must register via the Zoom registration link, *https://www.zoomgov.com/meeting/register/vJItce2spj0jHw9b9h15hNrFezljtnit0_g,* by 5:00 p.m. EDT on April 12, 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.

Dated: March 25, 2024.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2024–06855 Filed 4–1–24; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Mashantucket Pequot Tribal Nation in the State of Connecticut

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Final notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Mashantucket Pequot Tribal Nation to include the counties of Fairfield, Hartford, Litchfield, Middlesex, New Haven, Tolland, and Windham in the State of Connecticut. The final PRCDA for the Mashantucket Pequot Tribal Nation now includes the Connecticut counties of Fairfield, Hartford, Litchfield, Middlesex, New Haven, New London, Tolland, and Windham. The sole purpose of this expansion is to authorize additional Mashantucket Pequot Tribal Nation members and eligible IHS beneficiaries to receive purchased/referred care (PRC) services.

DATES: This expansion is effective as of the publication date of this notice.

ADDRESSES: This notice can be found at *https://www.federalregister.gov.* Written requests for information should be delivered to: CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 10E85C, Rockville, MD 20857, or by phone at (301) 443–0969 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The IHS provides services under regulations in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the relative medical priority of the services to be provided, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation. 42 CFR 136.22(a)(6). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may from time to time, redesignate areas within the United States for inclusion in or exclusion from a PRCDA. 42 CFR 136.22(b). The regulations require that certain criteria must be considered before any