• Grant recipients have a policy in place for appropriate separation of duties and internal controls
• Other, describe
• 10.7—Rewrite the question as ''Describe how you select local agencies for monitoring reviews. Attach a risk assessment if subrecipients are utilized.''
• 10.8—Add boxes ''Annually,'' ''Bi-annually,'' ''Tri-annually,'' and ''Other.'' Please attach a monitoring schedule if one has been developed.
• 10.9 and 10.10—Remove.
• 10.11—Revise the question to ''How many local agencies are currently on corrective action plans?''
• 10.12—Remove.

Section 11—Timely and Meaningful Public Participation

• 11.1—Add explanation that Tribes do not need to hold a public hearing but must ensure participation through other means.
• 11.2—Remove. Removing because question is duplicative of 11.6.
• 11.3—Insert an option to add rows for additional dates and locations that they held public hearings on the proposed use and distribution of their LIHEAP funds.
• 11.6—Revise the question as follows: ''What changes did you make to your LIHEAP plan as a result of public participation and solicitation of input?''

Section 12—Fair Hearing

• 12.4—Change question: ''Describe your fair hearing procedures for households whose applications are denied and/or not acted upon in a timely manner.''
• 12.5—Remove.
• 12.6—Remove.

Section 13—Reduction of Home Energy Needs

• 13.3—Add the following instructional sentence: ''Impact can be measured in many different ways by using: logic model, data tracking system, process evaluation, impact evaluation, number of households served vs applied, and performance management, etc.''
• 13.4—Add a space between ''of'' and ''direct''
• 13.5—Remove.

Section 14—Leveraging Incentive Program

• 14.3—Add a space between ''of'' and ''45''

Section 15—Training

• 15.1a-c—Change question to be consistent with each entity type (grant recipient, local agency, vendor)
○ Formal training provided virtually, on-site, and/or formal training conference
• Annually
• Biannually
• As needed
• Other, describe.

Section 17—Program Integrity

• 17.1b—Add ''Posted in local administering agencies offices.''
• 17.4—Change ''aliens'' to ''qualified non-citizens'' in intro text. The second option in the question is phrased as ''legal residence'' but it needs to be changed to ''U.S. Citizen or Qualified Non-Citizen.'' The second box option should read ''Client's submission of certain Social Security Administration cards is accepted as proof of U.S. Citizen or Qualified Non-Citizen.''
• 17.4—Rewrite the question as ''What are your procedures for ensuring LIHEAP recipients are U.S. citizens or qualified non-citizens who are eligible to receive LIHEAP benefits?''
• 17.6—Should also include how electronic files are protected in a secure location.

Section 19—Certification Regarding Drug-Free Workplace Requirements

• 19.1—Place of Performance: Add instructional sentence that this must be physical address. No PO Boxes allowed.

Section 21—New Change Assurances to Section 21

• 21.1—Add the following acknowledgment statement and a check box: ''By checking this box, the prospective primary participant is agreeing to the Assurances set out above.''

Section 22—Attachments

Add optional attachment section for the following items: Policy Manual; Subrecipient Contract; Model Plan Participation Notes for Tribes.

Respondents: States, the District of Columbia, U.S. territories, and tribal governments.

Annual Burden Estimates

The estimated time per response for the FY 2025 Model Plan has been increased based on the revisions. The estimated time per response for the FY 2026 Model Plan will reduce back after revisions are in place and respondents can duplicate response in OLDC.

Instrument	Total annual number of respondents	Total annual number of responses per respondent	Average burden hours per response	Annual burden hours for each form
LIHEAP Detailed Model Plan—FY24	207	1	.5	103.5
LIHEAP Detailed Model Plan—FY25	207	1	1	207
LIHEAP Detailed Model Plan FY26	207	1	.5	103.5
Estimated Total Burden Hours				414

Authority: 42 U.S.C. 8621.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–00965 Filed 1–18–24; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5745]

Medical Imaging Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Medical Imaging Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on March 5, 2024, from 9 a.m. to 5:30 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–5745. The docket will close on March 4, 2024. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 4, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before February 20, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–N–5745 for ''Medical Imaging Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' FDA 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 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 the 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.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, email: *MIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss efficacy and safety data submitted in support of a new drug application (NDA) 214511 for pegulicianine for injection, the optical imaging drug constituent of a drug/device combination product, submitted by Lumicell, Inc. The proposed indication for pegulicianine is for use in patients with breast cancer to assist in the detection of cancerous tissue within the lumpectomy cavity following removal of the primary specimen during lumpectomy surgery.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/*

Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before February 20, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 9, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 12, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: January 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01016 Filed 1–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Proposed 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: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) proposes 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 current PRCDA for the Mashantucket Pequot Tribal Nation includes the Connecticut county of New London. Mashantucket Pequot Tribal Nation members residing outside of the PRCDA are eligible for direct care services, however, they are not eligible for Purchased/Referred Care (PRC) services. The sole purpose of this expansion would be to authorize additional Mashantucket Pequot Tribal Nation members and IHS beneficiaries to receive PRC services.

DATES: Comments must be submitted by February 20, 2024.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a Comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Carl Mitchell, Director, Division of Regulatory and Policy Coordination, Indian Health Service, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, Maryland 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the above address.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above. If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443–1116 in advance to schedule your arrival with a staff member.

FOR FURTHER INFORMATION CONTACT: CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop: 10E85C, Rockville, Maryland 20857. Telephone (301) 443–0969 (This is not a toll free number).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

Background: The IHS provides services under regulation 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 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,