

implementation, support, and scale up of the NEICE. The NEICE is a national electronic system for quickly and securely exchanging the data and documents required by the Interstate Compact on the Placement of Children (ICPC) to place children with foster, adoptive, and kinship families across state lines. APHSA has been the recipient of funding from the ACYF/CB for the development and national implementation of the NEICE since its inception as a pilot project funded by the Partnership Fund for Program Integrity Innovation at the Office of Management and Budget and administered by CB in November 2013. This 20-month pilot proved successful and led to a new sole source cooperative agreement for the expansion of the pilot to all 52 jurisdictions of the AAICPC nationwide. This funding was further extended and supplemented to continue to support the expansion of the project nationally with the current funding period expiring September 29, 2024. This within scope awarding agency-initiated non-competitive supplement with extension is essential to allow the remaining states to join the system and to provide ongoing support and upgrades necessary for an electronic system. In addition, the Family First Prevention Services Act of 2018 requires all states to join an electronic exchange system by October 1, 2027, and NEICE is on track to support states in meeting this requirement.

It is CB's intention to provide funding of up to \$1,600,000 beginning September 30, 2024. The state members of the AAICPC contribute annual membership and connection fees; however, these are currently not adequate to meet the full operational costs of managing the national system. The APHSA is well-positioned to continue to scale the project nationally and to assure the continued optimal maintenance of the NEICE.

Statutory Authority: Title II, section 203(b) of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978 (42 U.S.C. 5113(b)(3)), as most recently amended by CAPTA Reauthorization Act of 2010.

Anthony Petrucci,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2024-20827 Filed 9-12-24; 8:45 am]

BILLING CODE 4184-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-4057]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of Public Docket; Request for Comments—ProSense Cryoablation System

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 General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's 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 November 7, 2024, from 9 a.m. to 6 p.m. eastern time.

ADDRESSES: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301-948-8900. The hotel's link can be found at: <https://www.ihg.com/holidayinn/hotels/us/en/gaithersburg/wasrv/hoteldetail>.

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-2024-N-4057. The docket will close on December 9, 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 December 9, 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 October 17, 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-2024-N-4057 for "General and Plastic Surgery Devices Panel of the Medical Devices 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 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 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: Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, 301-636-0510, Candace.Nalls@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 the Agency’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 coming to the meeting.

SUPPLEMENTARY INFORMATION: Agenda: On November 7, 2024, the Committee will discuss, make recommendations, and vote on clinical information related to a *De Novo* request for the ProSense Cryoablation System sponsored by IceCure Medical Ltd. The discussion will focus on the sponsor’s proposed indication: “for use in the treatment of patients with early stage, low-risk breast cancer for the treatment of breast cancer with adjuvant endocrine therapy.” 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, and the background material will be posted on FDA’s website after the meeting. Background material will be available at the location of the advisory committee meeting and at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

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 October 17, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled on November 7, 2024, between approximately 1:45 p.m. and 2:45 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 October 10, 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 October 15, 2024. Persons attending FDA’s advisory committee meetings are

advised that FDA is not responsible for providing access to electrical outlets.

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 Ann Marie Williams at Annmarie.Williams@fda.hhs.gov or 301-796-5966 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.*).

Dated: September 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-20889 Filed 9-12-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-3878]

New Drugs Regulatory Program Modernization: Integrated Assessment of Marketing Applications and Integrated Review Documentation; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is seeking public comments on the “New Drugs Regulatory Program Modernization: Integrated Assessment of Marketing Applications and Integrated Review Documentation.” The purpose is to seek public comments/feedback on the Integrated Review documentation generated by the Integrated Assessment of Marketing Applications for new drug products developed as part of the New Drugs Regulatory Program Modernization. The Agency hopes to receive public feedback on how this Integrated Review documentation can continue supporting our stakeholders’ needs.

DATES: Submit either electronic or written comments on the notice by December 12, 2024.