into interstate commerce (including importation) of infant formula that is safe and nutritionally adequate but that may not comply with all FDA statutory and regulatory requirements. Consistent with the policies described in the May 2022 Enforcement Discretion Guidance, certain manufacturers have submitted information to FDA to substantiate the safety and nutritional adequacy of specific infant formula products and, following FDA's thorough review of the information provided, are marketing such products under FDA's exercise of enforcement discretion.

This guidance sets forth our current thinking on circumstances under which we intend to exercise temporary enforcement discretion for certain infant formula products beyond November 14, 2022, and to advise infant formula manufacturers marketing products in accordance with letters of enforcement discretion issued under the May 2022 Enforcement Discretion Guidance about: (1) the type of information to provide to FDA; and (2) our timing expectations related to such information, if they would like us to consider the continued exercise of enforcement discretion with respect to their products. This guidance document will remain in effect until October 18, 2025, and FDA expects that all infant formula products will comply with applicable U.S. requirements by the end of the enforcement discretion period.

We issued this guidance without prior public comment under section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2) because we determined that prior public participation is not feasible or appropriate, as this guidance provides time-sensitive clarifications regarding FDA's intent to exercise enforcement discretion with respect to specific formula products that are currently fulfilling the needs of infants in the United States.

As with all FDA guidance documents, the public may comment on the guidance at any time.

II. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

III. Paperwork Reduction Act of 1995

FDA requested, and OMB has approved, emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). Immediate implementation of the information collection is critical to providing predictability, stability, and continuity in the infant formula market, specifically with respect to those products currently available to infants in the Unites States under FDA's exercise of enforcement discretion. Because we believe that routine procedures, which allow for a 60-day comment period, would prevent our ability to immediately implement the information collection, we requested a waiver from the requirement to publish a 60-day notice for the information collection (see 5 CFR 1320.13(a)(2)(iii)).

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ONE-TIME ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submit information in accordance with timing and content schedule discussed in guidance document for both exempt and non-exempt infant formulas	115	1	115	24	2,760
Letter of Intent	15	1	15	5	75
Plan to Meet Applicable Infant Formula Requirements	15	1	15	90	1,350
Total					4,185

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on submissions received in response to the May 2022 Enforcement Discretion Guidance, for which we account for 115 respondents, each of whom submitted one request. We assume it requires an average of 24 hours to prepare each submission, and therefore calculate a total of 2,760 burden hours (115 requests × 24 hours). Of those 115 respondents, we have currently issued 12 letters of enforcement discretion but may issue additional letters through November 14, 2022. We therefore assume that a total of 15 respondents will initiate requesting enforcement discretion and final a letter of intent. We assume this requires an average of 5 hours to prepare, for a total of 75 burden hours (15 letters × 5 hours). We estimate these same 15 respondents will then submit a compliance plan and assume each plan will require an average of 90 hours to prepare, for a total of 1,350 burden hours (15 plans × 90 hours).

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21794 Filed 10–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0589]

General and Plastic Surgery Devices Panel of the Medical Devices 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 General and Plastic Surgery Devices Panel of the Medical Devices Advisory 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 virtually on October 26, 2022, from 9 a.m. Eastern Time to 6:15 p.m. Eastern Time and October 27, 2022, from 9 a.m. Eastern Time to 3 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions, including information regarding special accommodations due to a disability, 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–2022–N–0589. Please note that late, untimely filed comments will not be considered. The docket will close on November 28, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 28, 2022. 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 11, 2022, 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–2022–N–0589 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 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. 5216, 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 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 platform. On day 1, October 26, 2022, in the morning, the committee will discuss and make recommendations on the classification proposal for tissue expanders and accessories, which are currently unclassified preamendments devices, to be class III (general controls and premarket approval) and class II (general and special controls), and mammary sizers, which are currently

unclassified preamendments devices, to be class II (general and special controls). In the afternoon on the first day, the committee will discuss and make recommendations on the classification proposals for wound dressings with animal-derived materials, absorbable synthetic wound dressings, and hemostatic wound dressings with or without thrombin, which are all currently unclassified preamendments devices, to be class II (general and special controls).

On day 2, October 27, 2022, the committee will discuss and make recommendations on the classification proposals for nail prostheses, which are currently unclassified preamendments devices, to be class I (general controls); and ultrasonic surgical instruments, single-use reprocessed ultrasonic surgical instruments, and neurosurgical ultrasonic instruments, which are all currently unclassified preamendments devices, to be class II (general and special controls).

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 is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the 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 11, 2022, will be provided to the committee. Oral presentations from the public will be scheduled on October 26, 2022, between approximately 9:30 a.m. and 10 a.m. Eastern Time, and 2 p.m. and 2:30 p.m. Eastern Time, and on October 27, 2022, between approximately 9:30 a.m. and 10 a.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 September 30, 2022. 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 3, 2022.

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. app. 2).

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21746 Filed 10–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Innate Immunity and Inflammatory Responses.

Date: November 2, 2022.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bakary Drammeh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805–P, Bethesda, MD 20892, (301) 435–0000, *drammehbs@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: November 2, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kathryn Partlow, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1016D, Bethesda, MD 20892, (301) 594–2138, *partlowkc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Epidemiology and Population Sciences.

Date: November 3–4, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Randolph Christopher Capps, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1009J, Bethesda, MD 20892 (301) 435–1042 *cappsrac@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel The Cellular and Molecular Biology of Complex Brain Disorders.

Date: November 3, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Adem Can, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, (301) 435–1042, *cana2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; The Blood-Brain Barrier, Neurovascular System and CNS Therapeutics.

Date: November 3, 2022.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mariam Zaka, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1009J,