

• *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

• *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24-8, Atlanta, Georgia 30329-4027, Attn: August 30-31, 2021 ACIP Meeting.

*Instructions:* All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the <https://www.regulations.gov> suitability policy will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS-H24-8, Atlanta, GA 30329-4027; Telephone: 404-639-8367; Email: [ACIP@cdc.gov](mailto:ACIP@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Notice is hereby given of a change in the meeting of the Advisory Committee on Immunization Practices (ACIP); August 24, 2021, 10:00 a.m.-5:00 p.m., EDT (times subject to change), in the original FRN.

The virtual meeting was published in the **Federal Register** on Wednesday, August 18, 2021, Volume 86, Number 157, pages 46256-46257.

The virtual meeting is being amended to change the dates to August 30, 2021 and August 31, 2021, update meeting times and supplemental information.

In accordance with 41 CFR 102-3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID-19 pandemic and rapidly evolving COVID-19 vaccine development and regulatory processes. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: <http://www.cdc.gov/vaccines/acip/index.html>. In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

*Purpose:* The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications

to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

*Matters To Be Considered:* The agenda will include discussions on Pfizer's COVID-19 vaccine, and additional discussions on mRNA booster doses. A recommendation vote on Pfizer's COVID-19 vaccine is planned. No Vaccines for Children (VFC) votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit <https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html>.

*Meeting Information:* The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: <http://www.cdc.gov/vaccines/acip/index.html>.

#### Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

*Oral Public Comment:* This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

*Procedure for Oral Public Comment:* All persons interested in making an oral public comment at the August 30, 2021, ACIP meeting must submit a request at <http://www.cdc.gov/vaccines/acip/meetings/> no later than 11:59 p.m., EDT, August 28, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by August 29, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

*Written Public Comment:* The docket is currently open to receive written comments. Written comments must be received on or before August 31, 2021.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2021-18453 Filed 8-24-21; 11:15 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0008]

#### General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**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 the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on October 20, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this 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>.

**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, [candace.nalls@fda.hhs.gov](mailto:candace.nalls@fda.hhs.gov), 301-636-0510, 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 the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 20, 2021, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the SurgiMend PRS Acellular Bovine Dermal Matrix (SurgiMend PRS ABDM) by Integra LifeSciences Corporation. The proposed Indication for Use, as stated in the PMA, is as follows: SurgiMend PRS Acellular Bovine Dermal Matrix is intended for use as soft tissue support in post-mastectomy breast reconstruction. SurgiMend PRS Acellular Bovine Dermal Matrix is specifically indicated for immediate, two-stage, submuscular, alloplastic breast reconstruction.

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 and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/general-and-plastic-surgery-devices-panel>. Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio 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. Written submissions may be made to the contact person on or before October 6, 2021. Oral presentations from the public will be scheduled on October 20, 2021, between approximately 2 p.m. Eastern Time and 3 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include 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 September 28, 2021. 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 sessions. The contact person will notify interested persons regarding their request to speak by September 29, 2021.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto: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](mailto: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: August 20, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-18394 Filed 8-25-21; 8:45 am]

**BILLING CODE 4164-01-P**

---

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-N-0806]

**Advisory Committee; Nonprescription Drugs Advisory Committee; Renewal**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of federal advisory committee.

---

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the renewal of the Nonprescription Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Nonprescription Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the August 27, 2023, expiration date.

**DATES:** Authority for the Nonprescription Drugs Advisory Committee will expire on August 27, 2021, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301 837-7126, [NDAC@fda.hhs.gov](mailto:NDAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Nonprescription Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and