Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12412 Filed 7–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1731]

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

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 August 13, 2025, from 9 a.m. to 3:30 p.m. Eastern Time.

ADDRESSES: Please note that all meeting participants will be joining this advisory committee meeting via an online teleconferencing 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–2025–N–1731. The docket will close on September 13, 2025. 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 August 13, 2025. 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 July 23, 2025, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event 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–2025–N–1731for ''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: Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2404, Silver Spring, MD 20993–0002, *Evella.Washington@fda.hhs.gov,* 301–796–6683, 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: On August 13, 2025, the Committee will discuss a new indication for use for dermal filler devices in the décolletage area and will make recommendations regarding risks associated with new indications for use such as in the décolletage area, the potential impact of filler material on imaging studies and clinical exams (*e.g.,* breast cancer screening), pre-market and post-market study assessments for benefit and risk, removal of dermal filler implant material, and patient preference.

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 and/or video conferencing meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.html.* 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 July 23, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled on August 13, 2025, between approximately 11:30 a.m. and 12:30 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 July 14, 2025. 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 July 15, 2025.

For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202–690–6343. 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. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: June 27, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12421 Filed 7–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an *in vivo* Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment or Prevention of B Cell Mediated Autoimmune Diseases

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patents applications listed in the Supplementary Information section of this notice to Capstan Therapeutics, Inc. (Capstan), a company located in San Diego, California, the United States of America.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before July 18, 2025 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Abritee Dhal, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276–6154; Email: *abritee.dhal@nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application 62/006,313 (HHS Reference E–042–2014–0–US–01), filed 2 June 2014;
2. PCT Application PCT/US2015/033473 (HHS Reference E–042–2014–0–PCT–02), filed 1 June 2015;
3. Australian Patent 2015270912 (HHS Reference E–042–2014–0–AU–03), issued 17 December 2020;
4. Canadian Patent Application 2951045 (HHS Reference E–042–2014–0–CA–04), filed 1 June 2015;
5. Chinese Patent ZL201580033802.5 (HHS Reference E–042–2014–0–CN–05), issued 31 August 2021;
6. European Patent 3149044 (HHS Reference E–042–2014–0–EP–06), issued 21 October 2020 and validated in the following jurisdictions:
   a. Germany (HHS Reference E–042–2014–0–DE–19);
   b. Spain (HHS Reference E–042–2014–0–ES–20);
   c. France (HHS Reference E–042–2014–0–FR–21);
   d. The United Kingdom (HHS Reference E–042–2014–0–GB–22);
   e. Italy (HHS Reference E–042–2014–0–IT–23); and
   f. Ireland (HHS Reference E–042–2014–0–IE–24);
7. Israeli Patent 249305 (HHS Reference E–042–2014–0–IL–07), issued 1 October 2021;
8. Indian Patent 406961 (HHS Reference E–042–2014–0–IN–08), filed 19 May 2022;
9. Japanese Patent 6797693 (HHS Reference E–042–2014–0–JP–09), issued 20 November 2020;
10. South Korean Patent 2016–7036828 (HHS Reference E–042–2014–0–KR–10), issued 20 May 2024;
11. Mexican Patent 383150 (HHS Reference E–042–2014–0–MX–11), issued 3 June 2021;
12. New Zealand Patent 727167 (HHS Reference E–042–2014–0–NZ–12), issued 8 October 2024;