



AGENDA

FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting

August 13, 2025

(VIRTUAL)

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Advisory Panel (the Panel) for the purposes of discussing a new indication for use for dermal filler devices in the décolletage area and making 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), premarket and post-market study assessments for benefit and risk, removal of dermal filler implant material, and patient preference.

The panel meeting will be held in a virtual format over the course of one day and includes time for open public comment, questions by the panel, and panel deliberation.

9:00 a.m.	Call to Order and Opening Remarks Panel Introductions	Hobart Harris, M.D., MPH Panel Chair
9:05 a.m.	Conflict of Interest Statement	Evella Washington Designated Federal Official
9:10 a.m.	Opening Remarks	Bleta Vuniqui Acting Office Director CDRH/OPEQ/OHTIV

Benefits and Risks associated with the décolletage injection location

FDA Presentation

9:15 a.m.	Clinical and regulatory overview of Dermal Fillers	Taili T. Mata, Ph.D. CDRH/OPEQ/OHTIV
9:25 a.m.	Benefits and risks of dermal fillers with new indications for use in the décolletage area	Sung Yoon, M.D., FACS CDRH/OPEQ/OHTIV

9:40 a.m.

Patient Preference Information

Olufemi Babalola, Ph.D.
CDRH/OSPTI/OEID/DPCD

9:50 a.m.

Clarifying Questions from the Panel

9:55 a.m.

External Speakers

Juan Daccach, M.D.
Vice President, Global Product Safety
Merz Aesthetics

Joseph Brown, Ph.D.
Chief Technology and Operations
Officer
Sofregen, Inc.

Scott Hollenbeck, M.D.
Lead Medical Advisor for inSoma Bio
and the Chair of the Department of
Plastic and Maxillofacial Surgery at the
University of Virginia

**Natalie M. Curcio, M.D., MPH,
MMHC, FAAD –(LIVE)**
American Academy of Dermatology
Association (AADA)

**M. Laurin Council, M.D., MBA,
FAAD, FACMS**
American Society for Dermatologic
Surgery (ASDS)

Sachin M. Shridharani, M.D., FACS
The Aesthetic Society

Karol A. Gutowski, M.D., FACS
American Society of Plastic Surgeons
(ASPS)

Scot Bradley Glasberg, M.D.
American Society of Plastic Surgeons
(ASPS)

*** Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.

11:15 a.m.	Clarifying questions from panel	
11:25 a.m.	Break	
11:30 a.m.	Open Public Hearing*	
12:30 p.m.	Clarifying questions from Panel	Hobart Harris, M.D., MPH Panel Chair
12:40 p.m.	<i>Lunch</i>	
1:40 p.m.	FDA Questions to the Panel	Jodie Giordano, Ph.D. CDRH/OPEQ/OHTIV
1:45 p.m.	Panel Deliberations	Hobart Harris, M.D., MPH Panel Chair
3:30 p.m.	Adjourn	Hobart Harris, M.D., MPH Panel Chair

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