

FDA Public Advisory Committee Meeting

March 25 and 26, 2019

Meeting Information for the Public

FDA recognizes the importance of the Public Advisory Committee Meetings to be transparent as the panel weighs the risks versus benefit of medical devices and provides the Agency with recommendations to protect the health and safety of the public. FDA expects significant attendance from the public and advises attendees to plan appropriately. The FDA Conference Center has limited seating and will do its best to accommodate the public. However, if the Conference Center reaches capacity, FDA will have to close admission to the public; FDA will provide the public with URL information to access the meeting live from the internet. FDA recommends that you arrive early to avoid long lines and inconveniences. Please know FDA space is limited and will not be able to accommodate personal luggage. FDA is providing the public with meeting information for planning purposes to encourage a positive meeting environment.

White Oak Campus Information: The below links will provide you information on the following:

- [FAQs: Public Meetings at FDA White Oak Campus](#)
- [Ground Transportation](#)
- [Airport Information](#)
- [Lodging Near the White Oak Conference Center](#)
- [Driving Directions and Parking, FDA White Oak Campus](#)
- [Security at the White Oak Conference Center](#)

Public Conduct During FDA Advisory Committee Meetings:

The FDA would like to ensure that advisory committee meetings proceed in an orderly fashion, are conducted in a safe and secure environment, that the right of free speech is protected, and that the ability of FDA Advisory Committees and Panels to accomplish their objectives is not disrupted. Therefore, the following procedures will be followed:

- An interested person who wishes to be assured of the right to make an oral presentation during the Open Public Hearing portion of an advisory committee meeting should register with FDA before the meeting. See 21 CFR 14.29(b).
- Open Public Hearing participants who are designated to speak may be questioned only by the Chair or other members of the Committee.
- Audience members may not present comments or questions to the Committee unless recognized by the Chair.
- Attendees may be subject to security screening, such as presenting identification, passing through metal detectors, and inspection of briefcases, packages, etc.
- Attendees at the meeting are asked to maintain order and not display behavior that is disruptive to the meeting (i.e., shouting from the audience, loud outbursts).

- The committee Chair or Designated Federal Officer will note on the record any disruptive behavior and will ask the person to cease the behavior or else leave the meeting room.
- We ask that attendees not approach the advisory committee table area before, during, or after the meeting without permission from a Designated Federal Officer/Executive Secretary.
- Flash photography and posters will not be permitted in the meeting room.

Open Docket:

FDA recognizes that this will be a well-attended meeting. We further recognize that the public will want to continue to provide FDA with their input on this very important topic. Please know the link below is active and will file your comments as part of the FDA record on the risks and benefits of breast implants. This site will be closed for comments on April 26, 2019. Please know all submission will be public.

<https://www.regulations.gov/docket?D=FDA-2019-N-0426>

With regards to written comments submitted to the FDA, submitters should know that FDA has presented all comments to the Advisory Panel members and FDA staff for their review. Submitters should also know that FDA will not post the written statements because of privacy issues.

Open Public Hearing Speakers:

Registered Open Public Hearing Speakers MUST check-in at the registration table when they arrive at the FDA Conference Center.

Webcasting:

FDA recognizes that this meeting will be well attended and is providing live feed of the meeting for the public's convenience. Please click on the link below to access the live feed.

March 25, 2019 (DAY 1):

<http://fda.yorkcast.com/webcast/Play/a6baa43b37004ecab288779ac3a263bd1d>

March 26, 2019 (DAY 2)

<http://fda.yorkcast.com/webcast/Play/8f0ba1b148174747b4dbd0ec916167f11d>

The webcasting will go live at 7 AM and the Advisory Committee Panel meeting will begin at 8 AM.

Office of Media Affairs: General press and media information contact number is (301) 796-4540. Ms. Stephanie Caccamo will be the point of contact for press and media inquiries and can be reached at Stephanie.Caccamo@fda.hhs.gov

CDRH External Outreach Contact: The Division of Industry and Consumer Education (DICE) will address external outreach questions; or call 1 (800) 638-2041, press 1 to speak to the consumer team.

Food Access:

Please know there will be limited access to food in the FDA Conference Center. **FDA recommends that if you want to have a lunch box at the Conference Center to place your food order when you arrive or at your earliest convenience. There will be a table near the entrance of the conference center to take lunch box orders.** Sodexo is the contract catering service for the FDA and will facilitate food services in the following manner:

- On March 25th and 26th, Sodexo will stand up a kiosk from 7 A.M. – 9:30 A.M. to take advance orders and payment for lunch boxes
- On March 25th, day-1, Sodexo will stand-up a kiosk at 12:30 to pick up your pre-paid lunch box
- On March 26th, day-2, Sodexo will stand up a kiosk at 12:40 to pick up your pre-paid lunch box
- Sodexo will have the cantina window open from 7 A.M. thru the first break of the Advisory Committee meeting. The cantina will offer for sale, coffee, tea, drinks, snacks, sandwiches etc.

Sodexo is providing the following lunch options for \$11.00:

Wraps:

Turkey & Cheddar Wrap
Roast Beef & Cheddar Wrap
Tuna & Cheddar Wrap
Ham & Swiss Wrap
Roasted Veggie Wrap

Salads:

Chef Salad
Caesar Salad
Garden Salad

Note: each lunch box with include an apple, chips, cookie and beverage.