

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0426]

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 be held on March 25 and 26, 2019, 8 a.m. to 6 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Information about the FDA's Meeting facility on the White Oak Campus can be found at <https://www.fda.gov/aboutfda/workingatfda/buildingsandfacilities/whiteoakcampusinformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT:

Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993-0002, Patricio.Garcia@fda.hhs.gov, 301-796-6875, 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 coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On March 25 and 26, 2019, the committee will discuss and make recommendations regarding the benefits and risks of breast implants indicated for breast augmentation and reconstruction concerning the following topics: (1) Breast implant associated anaplastic large cell lymphoma (BIA-ALCL); (2) systemic symptoms reported in patients receiving breast implants; (3) the use of registries for breast implant surveillance; (4) magnetic resonance imaging screening for silent rupture of silicone gel filled breast implants; (5) the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy; (6) the use of real-world data and patient perspectives in regulatory decision making, and (7) best practices for informed consent discussions between patients and clinicians.

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 at the location 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 appropriate advisory committee meeting link.

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 March 4, 2019. Oral presentations from the public will be scheduled on March 25, 2019, between approximately 11 a.m. and 12 noon and 2:30 p.m. to 3:30 p.m. Oral presentations from the public will be scheduled on March 26, 2019, between approximately 10 a.m. and 11 a.m. and 3 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and indicate in which session they would like to present (which day, morning or afternoon session). 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 February 27, 2019. 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 February 28, 2019.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 AnnMarie 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/ucm11462.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: February 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0573]

Blood Products 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 Blood Products Advisory Committee (BPAC). The general function of the committee is to provide advice and recommendations to the Agency on regulatory issues related to blood and products derived from blood. Matters considered at the meeting will include testing of the blood supply for Zika virus, topics relevant to blood donation by men who have sex with men, and an overview of research programs in the Laboratory of

Biochemistry and Vascular Biology. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on March 20, 2019, from 8:30 a.m. to 4:45 p.m., and March 21, 2019, from 8:30 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: <https://collaboration.fda.gov/bpac0319>.

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993-0002, 240-402-8006, Prabhakara.Atreya@fda.hhs.gov; Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6270, Silver Spring, MD 20993-0002, 240-402-8106, Joanne.Lipkind@fda.hhs.gov; or the 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 coming to the meeting. For those unable to attend in person, the meeting will also be available via webcast. The webcast will be available at the following link for both days: <https://collaboration.fda.gov/bpac0319>.

SUPPLEMENTARY INFORMATION:

Agenda: On March 20, 2019, in the morning, BPAC will meet in open session to discuss and make recommendations on strategies to reduce the risk of Zika virus (ZIKV) transmission by blood and blood components. The committee will

discuss whether universal testing of blood donations for ZIKV is an appropriate strategy considering the decline of the ZIKV epidemic in the United States and worldwide. In the afternoon, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Biochemistry and Vascular Biology in the Division of Blood Components and Devices, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

On March 21, 2019, the committee will meet in open session to discuss blood donation policies regarding men who have sex with men (MSM). The committee will hear presentations on the current epidemiology of HIV in the United States; global developments in MSM blood donor deferral policies; and data on HIV incidence and prevalence among blood donors from the Transfusion-Transmitted Infection Monitoring System. The committee will discuss a proposed HIV risk questionnaire study. In addition, the committee will discuss a proposal for the use of pathogen reduction technology as an alternative procedure to a time-based deferral for MSM.

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 at the location 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 appropriate advisory committee meeting link.

Procedure: On March 20, 2019, from 8:30 a.m. to 4 p.m., and on March 21, 2019, from 8:30 a.m. to 5 p.m., the meeting is open to the public. 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 March 13, 2019. On March 20, 2019, oral presentations from the public will be scheduled between approximately 11:10 a.m. to 11:40 a.m. and 3:15 p.m. to 3:45 p.m. On March 21, 2019, oral presentations from the public will be scheduled between approximately 11:25 a.m. and 11:55 a.m. and between 3 p.m. and 4 p.m. 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 March 5, 2019. 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 March 6, 2019.

Closed Committee Deliberations: On March 20, 2019, from 4 p.m. to 4:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

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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: February 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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