

Science Coordination, followed by a report from the National Toxicology Program of the National Institutes of Environmental Health Sciences on current and future collaboration.

On January 30, 2014, the Arkansas Bioinformatics Consortium will present concepts and ideas on defining and meeting NCTR and FDA's scientific computing needs and discuss how it can partner with FDA to foster the development of collaborative efforts in this area. To facilitate the discussion representatives from each of the product centers will discuss their bioinformatic needs, how those needs are being addressed and areas of possible collaboration.

Following an open discussion of all the information presented, the open session of the meeting will close so that SAB members can discuss personnel issues at NCTR.

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 Web site 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 Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On January 29, 2014, from 8:45 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 January 21, 2014. Oral presentations from the public will be scheduled between approximately 12 p.m. to 2 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 January 13, 2014. 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 January 14, 2014.

Closed Committee Deliberations: On January 30, 2014, from 11 a.m. to 2 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)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Margaret Miller at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://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: December 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-30578 Filed 12-23-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 14, 2014, from 8 a.m. to 6 p.m.

Location: Gaithersburg Marriott Washingtonian Center, Salons A, B, C and D, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1609, Silver Spring, MD 20993, James.Swink@fda.hhs.gov, 301-796-6313, 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 Web site at <http://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.

Agenda: On February 14, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the Visian Toric Implantable Collamer Lens (TICL) sponsored by STAAR Surgical Company. "Visian TICL proposed indications for use:

- For adults 21–45 years of age;
- For correction of myopic astigmatism in adults with spherical equivalent ranging from $-3.0D$ to $\leq -15.0D$ with cylinder of $1.0D$ to $4.0D$;
- For the reduction of myopic astigmatism in adults with spherical equivalent ranging from greater than $-15.0D$ to $-20.0D$ with cylinder $1.0D$ to $4.0D$;
- With an anterior chamber depth (ACD) of 3.0 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5 Diopter for 1 year prior to implantation); and

• The Visian TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye."

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 Web site 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 Web site after the meeting. Background material is available at <http://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 February 7, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on February 14, 2014. 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 January 30, 2014. 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 February 3, 2014.

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 physical disabilities or special needs. If you require special 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 Web site at <http://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: December 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 21, 2014, from 8 a.m. to 3 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20993-0002, Sara.Anderson@fda.hhs.gov, 301-796-7047, 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 Web site at <http://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.

Agenda: On February 21, 2014, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009

[Docket No. FDA-2009-M-0101], relating to the regulatory classification of iontophoresis devices, one of the remaining preamendments class III devices. Iontophoresis is a method of non-invasive transdermal delivery in which a substance bearing a charge is propelled through the skin by an electric current. Iontophoresis devices generally consist of a controller, active and return electrode(s), and power supply used to deliver currents to transport drugs, soluble salts, or ionic solutions across the skin.

The regulation for iontophoresis devices (21 CFR 890.5525) currently has two parts. Part (a) of the regulation classifies iontophoresis devices as class II when indicated to introduce drugs or soluble salts to induce sweating for use in the diagnosis of cystic fibrosis or for other uses if the drug intended for use with the device bears adequate directions for the device's use with that drug. Devices identified in part (a) of the regulation will not be considered in the scope of the committee meeting. Part (b) of the regulation classifies iontophoresis devices as class III when intended to use direct current to introduce soluble salts or other drugs into the body for purposes other than those specified in part (a). Devices identified in part (b) of the regulation are the subject of the committee meeting.

On August 28, 1979, FDA published a proposed rule (44 FR 50520) for classification of iontophoresis devices for specialized uses (for the diagnosis of cystic fibrosis, fluoride uptake acceleration in dentistry, and for local anesthesia of the intact tympanic membrane) into class II and for all other uses into class III. FDA recommended class III for iontophoresis devices when used for purposes other than those specifically considered because such use presents "a potential unreasonable risk of injury without benefit to the patient because substantial data and clinical investigations do not exist to support the claims made for the devices." In addition, the Agency noted that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Subsequent to the proposed rule, FDA published a final rule (48 FR 53047) on November 23, 1983, classifying iontophoresis devices for use in the diagnosis of cystic fibrosis or other uses if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug as class II (performance standards)