

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jeffrey Siegel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3154, Silver Spring, MD 20993-0002, 301-796-2280; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210; or

Sahar M. Dawisha, Office of In Vitro Diagnostic Devices, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., rm. 374, Rockville, MD 20850, 240-276-0717.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Systemic Lupus Erythematosus—Developing Medical Products for Treatment." This guidance is intended to assist sponsors in the clinical development of medical products for the treatment of SLE. The guidance addresses the overall development program and clinical trial designs as well as specific information on claims, study design, study duration, efficacy endpoints, and response criteria.

In the **Federal Register** of March 29, 2005 (70 FR 15868), FDA announced the availability of a draft guidance entitled "Systemic Lupus Erythematosus—Developing Drugs for Treatment." FDA received a number of comments on the draft guidance, which were considered and incorporated, as appropriate, when finalizing the guidance. The recommendations regarding medical product development for lupus nephritis were removed from this guidance and placed into a separate guidance, the availability of which is announced elsewhere in this issue of the **Federal Register**. Additional organ-specific guidances will be developed in the future. Other changes that were made include the addition of more specific examples of trial design and study endpoints, updating the science, and minor editorial changes to clarify specific issues. In addition, input was obtained from the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on developing medical products for the treatment of SLE. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB Control No. 0910-0014; the collections of information in 21 CFR part 314 have been approved under OMB Control No. 0910-0001; the collections of information in 21 CFR part 601 have been approved under OMB Control No. 0910-0338; and the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910-0078.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <http://www.regulations.gov>.

Dated: June 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-N-2010-0001]

Blood Products 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: Blood Products 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 July 26, 2010, from 8 a.m. to approximately 5:30 p.m. and July 27, 2010, from 8 a.m. to approximately 1 p.m.

Location: Hilton Washington DC/North, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Bryan Emery or Pearlina Muckelvene, Center for Biologics and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 26, 2010, in the morning session, the committee will hear updates on the following topics: June 10 and 11, 2010, meeting of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability; December 14 and 15, 2009, FDA workshop on emerging arboviruses; May 11 and 12, 2010, FDA workshop on emerging infectious diseases; and the Q fever epidemic in the Netherlands. The committee will also hear informational presentations on Xenotropic Murine Leukemia Virus-Related Virus. In the

afternoon session, the committee will discuss issues related to the risk of *Babesia* infection by blood transfusions and the status of laboratory tests. On July 27, 2010, the committee will discuss blood donor hemoglobin/hematocrit qualifications standards, iron status, and interdonation interval.

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 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 July 19, 2010. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:30 p.m. and between 4 p.m. and 4:45 p.m. on July 26, 2010, and between approximately 10:30 a.m. and 11 a.m. on July 27, 2010. Those desiring to make 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 9, 2010. 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 12, 2010.

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 Bryan Emery 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: June 15, 2010.

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-2010-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 July 30, 2010, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: James Engles, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1566, Silver Spring, MD 20993-0002, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512396. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn

about possible modifications before coming to the meeting.

Agenda: On July 30, 2010, the committee will discuss, make recommendations, and vote on a premarket approval application for the Glaukos iStent Trabecular Micro-Bypass Stent, Model GTS-100 L/R, sponsored by Glaukos Corp. The device is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in subjects with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. For this device, the patients should have normal gonioscopic anatomy and a visually significant cataract eligible for phacoemulsification. The patient's glaucoma should be considered mild to moderate Primary Open Angle Glaucoma, or the secondary open angle glaucomas, Pigmentary Glaucoma and Pseudoexfoliation Glaucoma. Patients with other causes of secondary open angle glaucoma or angle closure glaucomas are not eligible for use of this device. Patients' IOP should be controlled on 1-3 glaucoma medications and patients should not previously have had surgery for glaucoma.

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 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 July 22, 2010. Oral presentations from the public will be scheduled approximately between 1 p.m. and 2 p.m. or immediately following lunch. Those desiring to make 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, 2010. 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