GENERAL SERVICES ADMINISTRATION

[Notice–MG–2015–06; Docket No. 2015–0002; Sequence No. 7]

Office of Federal High-Performance Green Buildings; Green Building Advisory Committee; Notification of Upcoming Conference Calls

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: Notice of these conference calls is being provided according to the requirements of the Federal Advisory Committee Act. This notice provides the schedule for a series of conference calls, supplemented by Web meetings, for two task groups of the Green Building Advisory Committee. The conference calls are open for the public to listen in. Interested individuals must register to attend as instructed below under Supplementary Information.

DATES: *Task group conference call dates:* The conference calls will be held according to the following alternating schedule:

The *Energy Use Index* task group will hold biweekly conference calls on Wednesdays beginning January 13, 2016, through April 20, 2016, from 3:00 p.m. to 4:00 p.m. Eastern Daylight Time (EDT).

The *Portfolio Prioritization* task group will hold biweekly conference calls on Wednesdays beginning January 20, 2016 through April 27, 2016, from 3:00 p.m. to 4:00 p.m. Eastern Daylight Time (EDT).

FOR FURTHER INFORMATION CONTACT: Mr. Ken Sandler, Designated Federal Officer, Office of Federal High-Performance Green Buildings, Office of Government-wide Policy, General Services Administration, 1800 F Street NW., Washington, DC 20405, telephone 202–219–1121 (note: this is not a toll-free number). Additional information about the Committee, including meeting materials and updates on the task groups and their schedules, will be available on-line at *http://www.gsa.gov/gbac.*

SUPPLEMENTARY INFORMATION:

Procedures for Attendance: Contact Mr. Ken Sandler at *ken.sandler@gsa.gov* to register to listen in to any or all of these conference calls. To attend the conference calls, submit your full name, organization, email address, and phone number. Requests to listen in to the calls must be received by 5:00 p.m. Eastern Daylight Time (EDT), on Friday, January 9, 2016. (GSA will be unable to provide technical assistance to any listener experiencing technical difficulties. Testing access to the Web meeting site in advance of calls is recommended.)

Background: The Administrator of the U.S. General Services Administration established the Green Building Advisory Committee with a notice published in the **Federal Register** at 76 FR 35894, on June 20, 2011, pursuant to Section 494 of the Energy Independence and Security Act of 2007 (42 U.S.C. 17123). Under this authority, the Committee advises GSA on the rapid transformation of the Federal building portfolio to sustainable technologies and practices. The Committee reviews strategic plans, products and activities of the Office of Federal High-Performance Green Buildings, and provides advice regarding how the Office can accomplish its mission most effectively.

The *Portfolio Prioritization* task group will continue to pursue the motion of a committee member to ''propose a process for Federal agencies to consistently incorporate green building and resilience requirements into their capital investment criteria and strategies.'' The *Energy Use Index* task group will continue to pursue the motion of a committee member to ''develop guidelines for creating a new energy intensity metric [to reflect impacts of] densified facilities, centrally located workplace sites . . . and expansion of telework and hoteling.''

The conference calls will focus on how the task groups can best refine these motions into consensus recommendations from each group to the full Committee, which will in turn decide whether to proceed with formal advice to GSA based upon these recommendations. Additional background information and updates will be posted on GSA's Web site at *http://www.gsa.gov/gbac.*

Kevin Kampschroer,

Federal Director, Office of Federal High-Performance Green Buildings, General Services Administration.

[FR Doc. 2015–31485 Filed 12–14–15; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0288]

Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices.'' This leapfrog guidance document was developed to notify manufacturers of the recommended non-clinical and clinical studies to support a premarket approval application (PMA) for implantable MIGS devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–0288 for ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions:* To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2504, Silver Spring, MD 20993–0002, 301–796–5620.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document recommends non-clinical and clinical studies to support a PMA for implantable MIGS devices. Glaucoma is a progressive condition that damages the optic nerve of the eye, is associated with elevated intraocular pressure, and leads to irreversible vision loss. It is the second leading cause of visual disability and blindness in the world, with 1 in 40 adults over 40 years of age suffering from glaucoma having some visual loss. Current surgical treatments are aimed at reducing intraocular pressure and often reserved for moderate to severe disease. During the past decade, novel medical devices, called MIGS devices, have emerged. These devices are designed to treat less severe glaucoma by enhancing physiological aqueous outflow with an approach that causes minimal ocular trauma.

In the **Federal Register** of February 11, 2015 (80 FR 7614), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by May 12, 2015. FDA received and considered 12 sets of public comments and revised the guidance, where applicable. Multiple comments were received regarding the definition of glaucoma and the inclusion of pre-perimetric glaucoma. Based on discussion at the ''FDA/American Glaucoma Society Workshop on Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery,'' February 26, 2014, we do not believe that pre-perimetric glaucoma (*i.e.,* optical coherence tomography changes and optic nerve changes without any field abnormalities) should be included in these interventional studies because there are differing opinions amongst experts about whether this condition warrants surgical treatment. This guidance is a leapfrog guidance; leapfrog guidances are intended to serve as a mechanism by which the Agency can share initial thoughts regarding the content of premarket submissions for emerging technologies and new clinical applications that are likely to be of public health importance very early in product development, generally before FDA has even received any such submissions. This leapfrog guidance represents the Agency's initial thinking and our recommendations may change as more information becomes available. The current recommendations are designed to provide a conservative approach to protection of human subjects.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document

number 1400049 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The guidance document ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' refers to previously approved information collections found in FDA regulations and guidance. 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 814, subparts B and E are approved under OMB control number 0910–0231 and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' are approved under OMB control number 0910–0756.

Dated: December 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31407 Filed 12–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4561]

Head Lice Infestation: Developing Drugs for Topical Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Head Lice Infestation: Developing Drugs for Topical Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of head lice infestation. This draft guidance addresses the Agency's current thinking regarding the overall development program and clinical trial designs of drugs to support approval of an indication for topical treatment of head lice infestation. The information presented will help sponsors plan clinical trials, design clinical protocols, and conduct and appropriately monitor clinical trials.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 14, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–4561 for ''Head Lice Infestation: Developing Drugs for Topical Treatment; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions:* To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Strother D. Dixon, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5168,