

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards. As explained previously in this document, FDA estimates that no more than 500 regulatory jurisdictions will participate in the Program Standards in any given year. FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both forms. FDA bases its estimate on the small number of data elements on the two forms and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3519 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3520 for a total of 500 annual responses. Each of these submissions is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit three requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 250 hours.

Dated: January 29, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-02191 Filed 1-31-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### **American Glaucoma Society/Food and Drug Administration Workshop on Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "American Glaucoma Society (AGS)/FDA Workshop on Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery." This workshop will address the current challenges in the assessment of implantable minimally

invasive glaucoma surgical (MIGS) devices with a focus on clinical trial design and conduct. Glaucoma experts will present evidence to better define the appropriate patient population, as well as the appropriate evaluation of effectiveness and safety for MIGS devices. The primary goal of the workshop is to discuss the appropriate clinical trial design and conduct for MIGS devices in order to facilitate bringing these innovative technologies to the U.S. marketplace.

**Date and Time:** The public workshop will be held on February 26, 2014, from 1 p.m. to 6 p.m. Materials may be picked up starting at 12 noon.

**Location:** The public workshop will be held at the Washington Marriott at Metro Center, 775 12th St. NW., Washington, DC 20005.

**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, 301-796-5620, FAX: 301-847-8126, email: [michelle.tarver@fda.hhs.gov](mailto:michelle.tarver@fda.hhs.gov).

**Registration:** AGS will charge a registration fee to cover its share of the expenses associated with the workshop. The registration fee is \$150 for AGS members and \$300 for non-members in advance. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop may register online or by telephone. The deadline for online registration is February 10, 2014, at 5 p.m. EDT. There will be onsite registration on the day of the public workshop with the cost of onsite registration being \$150 for AGS members and \$500 for non-members. Early registration is recommended because facilities are limited.

If you need special accommodations due to a disability, please contact Ms. Susan Monahan at [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) or 301-796-5661 no later than February 3, 2014.

To register for the public workshop, please visit the AGS Web site (<http://www.americanglaucomasociety.net/professionals/events/>). Those interested in attending but unable to access the electronic registration site should contact AGS Customer Service to register at 415-561-8587 or 866-561-8558 (toll free). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. If there are any questions with registration, please contact the AGS administrative offices at 415-561-8587 or email to the attention of Amber Mendez at [ags@ao.org](mailto:ags@ao.org). Registrants will

receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Food and beverages will be available for purchase by participants during the workshop breaks.

For more information on the workshop, please see the FDA's Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

**Streaming Webcast of the Public Workshop:** This public workshop will not be Webcast.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Glaucoma is estimated to be the second leading cause of blindness worldwide. Management of this often chronic disease is a challenge for both patients and health care providers, requiring the use of multiple modalities including drops, lasers, and surgery. In recent years, innovative devices have been developed to decrease the risk of glaucoma surgery. These MIGS devices have moved the option for surgical intervention towards less severe forms of the disease. Hence, the appropriate clinical trial design and conduct for the evaluation of the safety and effectiveness of MIGS devices has become a topic of debate. At this workshop, we will discuss the important clinical trial components including subject enrollment criteria, safety parameters, and effectiveness endpoints. The workshop seeks to involve industry and academia in addressing the challenges in the development of appropriate clinical trials to adequately evaluate safety and

effectiveness for implantable MIGS devices. By bringing together relevant stakeholders, we hope to facilitate the improvement of regulatory science in this rapidly evolving product area.

FDA and AGS recognize the unique opportunity this workshop provides for all stakeholders of the ophthalmic device community to work together to improve trial design for the assessment of new MIGS devices, and, thereby, strengthen contributions to improved patient care and the protection of the public health.

## II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Definition of MIGS and overview of these procedures;
- defining the patient population for implantable MIGS devices;
- determining effectiveness endpoints for implantable MIGS devices; and
- determining the appropriate safety parameters for implantable MIGS devices.

These topics will be presented by experts in the associated area, and will be discussed by panelists with extensive experience conducting glaucoma clinical research.

Dated: January 28, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-02146 Filed 1-31-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0124]

### Science Board to the Food and Drug Administration: Request for Nominations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations to serve on the Science Board to FDA (Science Board).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Nominations received on or before March 5, 2014, will be given first

consideration for membership on the Science Board. Nominations received after March 5, 2014 will be considered for nomination to the Board should nominees still be needed.

**ADDRESSES:** You may submit your information by logging into the FDA advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4286, Silver Spring, MD 20993-0002, 301-796-4627, email: [martha.monser@fda.hhs.gov](mailto:martha.monser@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations to the Science Board. The Science Board will meet approximately three times a year. All meetings will be announced in the **Federal Register** at least 15 days prior to each public meeting.

### I. General Function of the Committee

The Science Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board will provide advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs.

### II. Desired Expertise

FDA is specifically seeing persons knowledgeable in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and

other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, combination products and relevant areas of behavioral and social science. Members shall be chosen from academia and industry. The Science Board may also include technically qualified federal members.

### III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Science Board. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, including a current business address and/or home address, telephone number, and email address if available. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 29, 2014.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2014-02155 Filed 1-31-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Drug Abuse; Amended Notice of Meeting

Notice is hereby given of changes in the meeting of the National Institute on Drug Abuse Special Emphasis Panel, February 6, 2014, 10:00 a.m. to February 6, 2014, 12:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, which was published in the **Federal Register** on January 10, 2014, 79, 8 FRN2014-00301.

The date of the meeting is changed to February 11, 2014. The meeting is closed to the public.

Dated: January 28, 2014.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-02103 Filed 1-31-14; 8:45 am]

**BILLING CODE 4140-01-P**