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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.

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 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@aao.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.

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