4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration/American Glaucoma Society Workshop on the Validity, Reliability, and Usability of Glaucoma Imaging Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

Summary: The Food and Drug Administration (FDA) is announcing a public workshop entitled "FDA/American Glaucoma Society (AGS) Workshop on the Validity, Reliability, and Usability of Glaucoma Imaging Devices." FDA is co-sponsoring the workshop together with the AGS, a nonprofit organization that supports glaucoma specialists and scientists through the advancement of education and research. The purpose of this public workshop is to provide a forum for discussing the validity, reliability, and usability of glaucoma imaging devices. The primary topic to be discussed relates to imaging of the posterior segment of the eye (e.g., retinal nerve fiber layer, optic nerve head, ganglion cell layer) using Optical Coherence Tomography (OCT, time-domain and spectral-domain), with particular emphasis on normative databases and the diagnostic performance of OCT for therapeutic glaucoma products (regulatory considerations) and clinical decision making (clinical practice considerations).

Date and Time: The public workshop will be held on October 5, 2012, from 8 a.m. until 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD

20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Brad Cunningham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993. Phone: 301-796-6620, FAX: 301-847-8126, email: bradley.cunningham@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 $200 for AGS members and $300 for non-AGS members. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 17, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. the morning of the workshop (October 5, 2012). AGS will charge an on-site registration fee of $400.

If you need special accommodations due to a disability, please contact Ms. Cindy Garris at Cynthia.Garris@fda.hhs.gov or 301-796-5861, no later than September 17, 2012.

To register for the public workshop, please visit the AGS Web site at: https://www.formstack.com/forms/?1237628-fpPvbj6eU2. 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 meeting/public workshop from the posted events list.) Those interested in attending but unable to access the electronic registration should fax the PDF form on the AGS website (http://www.americanglaucomasociety.net/client_data/files/2012/259_fdaagsworkshopregistrationform.pdf) to 415-561-8531 to register. Please complete either the online registration form or the PDF form with the 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. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Persons interested in viewing the webcast must register online by September 17, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 1, 2012. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

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, 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

Advances in glaucoma diagnostic devices have been rapid and these devices are of increasing importance in the diagnosis and clinical management of glaucoma. Device hardware is often upgraded and innovative software, such as measurement algorithms, image registration, and normative databases, is being added to existing hardware configurations. The optimal endpoints and strategies for assessing the safety and effectiveness of these new diagnostic tools in the management of glaucoma are unclear.

While there are several ophthalmic assessments (e.g., imaging, perimetry, tonometry, etc.) and ocular spaces (e.g., posterior segment, anterior chamber angle, etc.) relevant to the diagnosis and management of glaucoma, the primary topic of this workshop is the imaging of the posterior segment (e.g., retinal nerve fiber layer, optic nerve head, ganglion cell layer, etc.) with Optical Coherence Tomography (OCT, time-domain and spectral-domain).

II. Topics for Discussion at the Public Workshop

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

- Issues related to the use of OCT technology (time domain and spectral domain) in the diagnosis and treatment of glaucoma.

- Approaches to verify/validate new diagnostic technologies and their associated claims as well as factors that affect the quality of their images and measurements.
- Normative/reference databases and their impact on the diagnostic use of OCT devices.

Dated: September 5, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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