

[www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm). (Select this public workshop from the posted events list.)

*Streaming Webcast of the Public Workshop:* The morning session but not the afternoon session of this public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. EDT, March 14, 2014. 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 March 24, 2014. 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](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](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**

Cataract surgery is the most commonly performed elective procedure in the United States with over 3 million patients being implanted with an IOL. Over the past two decades, IOLs have undergone significant design changes allowing them to correct for a spectrum of visual distances and refractive errors. As IOL technology evolves, some endpoints for the evaluation of the technology are also evolving. Endpoints and strategies for assessing the relative safety and

effectiveness of these innovative lens designs are in various stages of development. At this workshop, not only will some of these novel endpoints and the challenges with assessments of these endpoints be identified, but these endpoints also will be prioritized for further discussion, development, and validation. Breakout sessions following the didactic portion of the workshop will allow for more in-depth group discussions of potential approaches to address these challenges.

The workshop seeks to involve industry and academia in addressing the challenges in the development of novel endpoints for premium IOLs. By bringing together all of the relevant stakeholders, which include clinicians, researchers, industry representatives, and regulators, to this workshop, we hope to facilitate the improvement of regulatory science in this rapidly evolving product area.

FDA and AAO recognize the unique opportunity this workshop provides for all stakeholders of the ophthalmic device community and that the knowledge and education provided from this workshop will further strengthen our mission of protecting 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:

- Safety assessments for premium IOLs and how they could differ from those for monofocal IOLs.
- Patient-Reported Outcome (PRO) measures and the need to develop and validate them for assessing the safety and effectiveness of premium IOLs.
- Objective assessments of accommodation and their challenges.
- Subjective assessments of accommodation and Extended Depth of Focus (EDF) and their challenges.

These topics will be presented by experts in the associated area and the afternoon will allow for more in-depth discussions of the given topics in small breakout sessions.

Dated: December 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Office of Inspector General**

##### **Statement of Delegation of Authority**

Notice is hereby given that I have delegated to the Inspector General, Office of Inspector General, the authority vested in the Secretary of Health and Human Services under section 1116(e)(1) of the Social Security Act (42 U.S.C. 1316(e)(1)) to conduct reconsiderations of disallowances of any item or class of items for which Federal financial participation is claimed under section 1903 of the Social Security Act (42 U.S.C. 1396b) for the establishment or operation of a Medicaid Fraud Control Unit. This authority may be redelegated to the Principal Deputy Inspector General. This delegation excludes the authority to issue regulations.

This delegation is effective upon date of signature.

Dated: December 12, 2013.

**Kathleen Sebelius,**

*Secretary.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Institute of Biomedical Imaging and Bioengineering (NIBIB) Announcement of Requirements and Registration for the 2014 NIBIB Design by Biomedical Undergraduate Teams (DEBUT) Challenge**

**Authority:** 15 U.S.C. 3719.

**SUMMARY:** The National Institute of Biomedical Imaging and Bioengineering (NIBIB) DEBUT Challenge is open to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems. NIBIB's mission is to improve health by leading the development and accelerating the application of biomedical technologies. The goals of the DEBUT Challenge are (1) to provide undergraduate students valuable experiences such as working in teams, identifying unmet clinical needs, and designing, building and debugging solutions for such open-ended problems; (2) to generate novel, innovative tools to improve healthcare, consistent with NIBIB's purpose to support research, training, the dissemination of health information, and other programs with respect to