TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual indepth interviews	360	1	360	0.75 (45 minutes)	270
General public focus group interviews	144	1	144	1.50 hours	216
Intercept interviews: Central location	200	1	200	0.25 (15 minutes)	50
Intercept interviews: Telephone	4,000	1	4,000	0.08 (5 minutes)	320
Self-Administered surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	0.50 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	0.17 (10 minutes)	204
Total (general public)	8,704				1,860
Physician focus group interviews	144	1	144	1.50 hours	216
Total (physician)	144				216
Total (overall)	8,848				2,076

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30149 Filed 12–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Food and Drug Administration/ American Academy of Ophthalmology Workshop on Developing Novel Endpoints for Premium Intraocular Lenses; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''FDA/ American Academy of Ophthalmology (AAO) Workshop on Developing Novel Endpoints for Premium Intraocular Lenses.'' The main topic of this workshop is the current challenges in the assessment of innovative intraocular lens (IOL) designs with a focus on endpoint methodologies used in evaluating IOL safety and effectiveness. Experts in subjects ranging from patient reported outcomes to objective measures of accommodation will give talks on the latest developments in the field. Participants will then engage in in-depth discussions of the pros and cons of various methods used to assess premium IOLs, and work to devise a plan to further promote innovation in this device area. The primary goal of the workshop is to improve the regulatory science for evaluating premium IOLs, which in turn may enhance the efficiency with which safe and effective premium IOLs get to the market. This public workshop is being rescheduled due to the government shutdown.

Date and Time: The public workshop will be held on March 28, 2014, from 8:30 a.m. to 5:30 p.m. Materials may be picked up starting at 7:30 a.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 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: Michelle Tarver, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5620, FAX: 301–847–8126, email: *michelle.tarver@fda.hhs.gov*.

Registration: AAO will charge a registration fee to cover its share of the expenses associated with the workshop. The registration fee is $250 for Academy members and $400 for non-members. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online. The deadline for online registration is March 27, 2014, at 5 p.m. EDT. There will be no onsite registration on the day of the public workshop. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. To register for the public workshop, please visit the AAO Web site (*http://www.aao.org/meetings/iol_workshop.cfm*). Those interested in attending but unable to access the electronic registration site should fax the *PDF form* on the AAO Web site (*http://www.aao.org/meetings/upload/FDA_iol_workshop_reg.pdf*) to 415–561–8575. Those without Internet access should contact AAO Customer Service to register at 415–561–8540 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 AAO administrative offices at 415–561–8540. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

This public workshop is being rescheduled due to the government shutdown. It was originally scheduled for October 11, 2013. Those who registered for the original workshop date were contacted by AAO individually and offered either a complete refund or the option to have those monies applied to the rescheduled date registration. Any questions about this process should be addressed to AAO Customer Service at 415–561–8540 or 866–561–8558 (toll free).

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

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 March 14, 2014.

For more information on the workshop, please see 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: 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*. 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

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.

[FR Doc. 2013–30148 Filed 12–18–13; 8:45 am]

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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.

[FR Doc. 2013–30160 Filed 12–18–13; 8:45 am]

BILLING CODE 4152–01–P

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