FDA expects that the DUNS number will continue to be submitted by the same respondents, with the same frequency, as part of the same electronic registration submission previously approved under the PRA, and the Agency will continue to use the information for the same purposes, in furtherance of its mission to protect the public health.

While FDA anticipates that firms will submit DUNS as UFI, the draft guidance also instructs firms who want to submit an alternative identifier to contact FDA. FDA estimates that no more than one respondent per year will invoke this option. FDA estimates that it would require on average 1 hour for a company to contact FDA and identify its proposed alternative UFI. If FDA determines that the alternative is one the Agency's systems can accommodate, and that satisfies the statutory goal of uniquely identifying the firm's facilities, FDA anticipates that the firm would include that alternative UFI in place of the DUNS, with no net change in the burden of a registration submission. We invite comment on these estimates.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, or http://www.regulations.gov.*

Dated: August 29, 2013.

Leslie Kux,

Commissioner for Policy.

[FR Doc. 2013–21630 Filed 9–5–13; 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 of public workshop.

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 indepth 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.

Date and Time: The public workshop will be held on October 11, 2013, 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 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: 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: 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 October 10, 2013, 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 (www.aao.org/IOLworkshop). 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 451–561–8540 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.

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 September 30, 2013.

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: 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, September 27, 2013. 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 7, 2013. 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 (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

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 indepth 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 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 and their challenges.

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

Dated: September 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21711 Filed 9–5–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Mental Health Services Survey (N–MHSS) (OMB No. 0930–0119)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality (CBHSQ), is requesting a revision to the National Mental Health Services Survey (N–MHSS) (OMB No. 0930–0119), which expires on June 30, 2015. The N–MHSS provides national and state-level data on the number and characteristics of mental health treatment facilities in the United States, annually, and national and state-level data on the number and characteristics of persons treated in these facilities, biennially.

An immediate need under N–MHSS is to update the information about facilities on SAMHSA's online Behavioral Health Treatment Services Locator (see: *http://findtreatment.samhsa.gov*), which was last updated with information from the abbreviated N–MHSS (N–MHSS-Locator Survey) in 2012. A full-scale N–MHSS will be conducted in 2014 and 2016 to collect (1) the information about facilities needed to update the online Locator, such as the facility name and address, specific services offered, and special client groups served, and (2) additional information including client counts and the demographics of persons treated in these facilities. An abbreviated N–MHSS (N–MHSS-Locator Survey) will be conducted in 2015 to update the information about facilities on the online Locator. A data collection in conjunction with adding new facilities to the online Locator as they become known to SAMHSA is also being requested. Both the 2015 N–MHSS-Locator Survey and the addition of new facilities to the online Locator will use the same N–MHSS-Locator Survey instrument.

This requested revision seeks to change the content of the currently