to the demographic subgroups of age, race, and ethnicity. However, this is outside of the scope of the revised guidance but, where applicable, the guidance was updated with links to other guidances and information related to these other demographic subgroups.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on evaluation of sex-specific data in medical device clinical studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* Persons unable to download an electronic copy of ''Evaluation of Sex-Specific Data in Medical Device Clinical Studies,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1727 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 812.25(c) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449.

V. 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.*

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19939 Filed 8–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Revamping Microbiological Test Methods for Contact Lenses Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), the American Academy of Ophthalmology (AAO), the American Academy of Optometry (AAOpt), the American Optometric Association (AOA), and the Contact Lens Association of Ophthalmologists, Inc. (CLAO), are cosponsoring a public workshop entitled ''Revamping Microbiological Test Methods for Contact Lenses, Products, and Accessories.'' The purpose of this workshop is to discuss adequate testing of contact lens care products for disinfection efficacy against emerging pathogens as well as common infectious etiologies. Participants will explore the pros and cons of the various proposals for disinfection efficacy testing and aid in developing general recommendations. The workshop will assist in informing the regulatory science for evaluating contact lenses and disinfection efficacy of associated care products as well as improving test methods to mitigate potential infections.

DATES: *Date and Time:* The public workshop will be held on September 12, 2014, from 8 a.m. to 5 p.m. Sign-in will open at 7:30 a.m.

ADDRESSES: *Location:* The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), 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.*

FOR FURTHER INFORMATION CONTACT: *Contact Person:* Jeffrey Brocious, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2252, Silver Spring, MD 20993, 240–402–3797, email: *Jeffrey.Brocious@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Registration is $250 for members of the AAO, AAOpt, AOA, or CLAO; or $400 for non-members and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 5, 2014, at 4 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.

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 August 28, 2014.

To register for the public workshop, please visit *http://www.clwkshop.org/.* 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 Ms. Cindy Groff at *cgroff@convergence-us.com.* 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: The public workshop will

also be Webcast. Persons interested in viewing the Webcast must register online by September 5, 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 September 5, 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 (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

To ensure that safe and effective contact lenses and associated care products are introduced into the U.S. marketplace, FDA has issued guidance documents, recognized standards that describe the appropriate test methods, and held workshops. In 2009, FDA held a workshop entitled ''Microbiological Testing for Contact Lens Care Products'' that was cosponsored by AAO, AAOpt, AOA, and CLAO (Ref. 1). Representatives from industry, academia, professional organizations, and regulatory agencies discussed variables to consider when developing disinfection efficacy test methods against *Acanthamoeba* keratitis (AK) as well as current contact lens disinfection tests and limitations.

Although the 2009 workshop began gathering information, there has been a persistent increase in the number of AK cases (Ref. 2). This persistent rise in the number of AK cases has prompted concern about the safety of contact lens care products. While most experts present at a 2008 Ophthalmic Devices Advisory Panel meeting agreed that *Acanthamoeba* should be added as a challenge organism to disinfection efficacy testing methods, consensus has not been reached on the appropriate method for performing this testing (Ref. 3).

At this workshop, the concerning rise in the keratitis associated with *Acanthamoeba* will be discussed as well as the emergence of other pathogens in contact lens related keratitis. The progress made in the development of *Acanthamoeba* test methods will be summarized. The goal of the workshop is to determine uniform testing methods for *Acanthamoeba* disinfection efficacy as well as to discuss methods for conducting real-world simulated testing of contact lens care products. The meeting will bring together scientists, clinicians, and industry experts to discuss critical aspects of disinfection efficacy testing.

The FDA/AAO/AAOpt/AOA/CLAO Workshop will provide FDA with an important opportunity to interact with stakeholders and gain knowledge and information on methods to test commonly used medical devices and would assist the Agency in carrying out its mission to promote and protect 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, the following as they relate to contact lenses and their associated care products:

- Emerging infectious pathogens in contact lens related keratitis;
- role of soil in disinfection efficacy testing; and
- *Acanthamoeba* disinfection efficacy test methods.

These topics will be presented by experts in the associated area with more in-depth discussions of the given topics during panel sessions.

III. References

The following references have been placed on display in the Division of Dockets Management (see *Transcripts*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Public workshop in 2009, ''Microbiological Testing for Contact Lens Care Products,'' **Federal Register** notice, available at *http://www.gpo.gov/fdsys/pkg/FR-2008-12-16/pdf/E8-29741.pdf.*

2. Yoder, J.S. et al., ''*Acanthamoeba* Keratitis: The Persistence of Cases Following a Multistate Outbreak,'' *Ophthalmic Epidemiology,* vol. 19, pp. 221–225, 2012.

3. Ophthalmic Devices Advisory Panel meeting (2008) minutes, available at *http://www.fda.gov/ohrms/dockets/ac/08/minutes/2008-4363m1.pdf.*

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19938 Filed 8–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The National Diabetes Education Program (NDEP) Comprehensive Evaluation Plan

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 19, 2014, pages 15351 and 15351 [FR DOC #: 2014–06064], and allowed 60 days for public comment. There was 1 public comment received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@*