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.)


Peter Lurie, Associate Commissioner for Policy and Planning.

[FR Doc. 2014–19998 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: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@
OMB will make every effort to accommodate requests for reasonable accommodations from people with disabilities. If you require a reasonable accommodation to participate in this meeting, contact Frank Holloman, Project Clearance Liaison, NIDDK, NIH, 6110 Rockledge Drive, MSC 2560, Bethesda, MD 20892, or call non-toll-free number 301–402–3587, or Email your request, including your address to: joanne_gallivan@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Ms. Joanne Gallivan, M.S., R.D., Director, National Diabetes Education Program, OCPL, NIDDK, 31 Center Drive, MSC 2560, Bethesda, MD 20892, or call non-toll-free number 301–496–6110, or Email your request, including your address to: joanne_gallivan@nih.gov. Formal requests for additional plans and instruments must be requested in writing.


Need and Use of Information Collection: The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goal of the NDEP is to reduce the burden of diabetes and pre-diabetes in the United States, and its territories, by facilitating the adoption of proven strategies to prevent or delay the onset of diabetes and its complications.

The NDEP evaluation will document the extent to which the NDEP program has been implemented and how successful it has been in meeting program objectives, outlined in the NDEP Strategic Plan. The evaluation relies heavily on data gathered from existing national surveys such as National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), among others for this information. This is a continued collection of additional primary data from NDEP target audiences on some key process and impact measures that are necessary to effectively evaluate the program. The audiences targeted by the NDEP include people at risk for diabetes, people with diabetes and their families, and the public.

OMB approval is requested for changing the data collection methodology from a random-digit-dialing (RDD) telephone survey to a probability-based web-based survey as well as an update of the survey questionnaire which has not been updated since it was first developed in 2006. There are no costs to respondents other than their time. The total estimated annualized burden hours are 833. This represents a modest increase in the burden amount from the previously approved 749 hours to 833 hours, an additional 84 hours overall. This burden reflects an increase of 5 minutes per participant due to survey content changes and an additional 400 participants.

Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Type of respondent and instrument</th>
<th>Estimated number of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Average time per response (in hours)</th>
<th>Estimated total annual burden hours</th>
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<tr>
<td>Adults—Survey instrument</td>
<td>2,500</td>
<td>1</td>
<td>20/60</td>
<td>833</td>
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</table>

Dated: July 14, 2014.

Michelle Trout,
Program Analyst, Office of the Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Meetings Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Special Emphasis Panel, October 15–16, 2014, 9:00 a.m. to 6:00 p.m., National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20817 which was published in the Federal Register on June 9, 2014, 79 FR 110, Page 32969.

The meeting of the Special Emphasis Panel will be held on October 23–24, 2014 instead of October 15–16, 2014, at 9:00 a.m. and will end at 6:00 p.m. The meeting is closed to the public.


Michelle Trout,
Program Analyst, Office of the Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders

Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings. The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Translational Research R01 Applications in Hearing and Balance.

Date: September 11, 2014.
Time: 12:30 p.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6601 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, Rockville, MD 20850, 301–402–3587, rayk@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Communication Disorders Clinical Trial Review

Date: September 17, 2014.
Time: 10:00 a.m. to 12:00 p.m.