Ethan D. Cohen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 1204, Silver Spring, MD 20993–0002, 301–796–2485;

For clinical concerns:

Bernard P. Lepri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2404, Silver Spring, MD 20993–0002, 301–796–6501.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance addresses the investigation of medical devices intended to manage permanent vision impairment resulting from ocular pathology such as retinitis pigmentosa. Vision impairment, or low vision, is vision that is not correctable to normal levels by spectacles, contact lenses, medications, surgery, or other techniques and devices. It is irreversible loss of vision due to disease, not refractive errors (myopia, astigmatism, presbyopia). This guidance is intended to assist device manufacturers who plan to conduct clinical investigations of devices indicated for the treatment of vision impairment in support of premarket approval (PMA) applications, humanitarian device exemptions, or premarket notification (510(k)) submissions. The guidance describes FDA's recommendations for human clinical trials that involve the use of any type of retinal prosthesis device, including, but not limited to, visual prosthetic devices implanted on or beneath the retina, and those on or beneath the outer surface of the globe that use electrical stimulation to provide some level of visual perception for persons suffering from degenerative retinal conditions. This document does not apply to prostheses that stimulate the optic nerve or other higher brain areas such as the visual cortex or the lateral geniculate nucleus.

In the **Federal Register** of April 17, 2009 (74 FR 17872), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by July 16, 2009. Six comments were received with each comment making multiple recommendations on changes to the content of the guidance document. The comments included recommended changes to primary, secondary, and functional vision endpoints and changes to the recommended clinical study design. In response to these comments, FDA has clarified the appropriate context for recommended endpoints and a sponsor's options with respect to use of a given endpoint. FDA also revised and clarified the recommendation regarding use of sham controls.

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 IDE applications for retinal prostheses. 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 using 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.* To receive ''Investigational Device Exemption (IDE) Guidance for Retinal Prostheses,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1809 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously 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 part 812 have been approved under OMB control number 0910–0078; collections of information in part 814 (21 CFR part 814), subpart H, have been approved under OMB control number 0910–0332; collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130; and collections of information in part 814, subpart E, have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**), or electronic comments to *http://www.regulations.gov.* 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: February 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05125 Filed 3–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 January 2, 2013 (Volume 78, Page 105) and allowed 60-days for public comment. Two public comments were received and responded to. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection

plans and instruments, contact: Nina Goodman, Public Health Advisor, Office of Communications and Education (OCE), NCI, NIH, 6116 Executive Blvd., Suite 400, Rockville, MD 20892, call non-toll-free number (301) 435–7789 or email your request, including your address to: *goodmann@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: A Generic Submission For Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources, 0925–0046, Expiration Date 2/28/2013, Reinstatement without Change, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection, diagnosis, and treatment to a wide variety of audiences and organizations, it is beneficial for NCI through its Office of Communications and Education (OCE), to pretest NCI communications strategies, concepts, and messages while they are under development. This pretesting, or formative evaluation, helps ensure that the messages, communication materials, and information services created by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since NCI's OCE is also responsible for the design, implementation, and evaluation of education programs over the entire cancer continuum, and management of NCI initiatives that address specific challenges in cancer research and treatment, it is also necessary to ensure that customers are satisfied with programs. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many educational programs and products that OCE and NCI produce. OCE will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and web surveys) methodologies to conduct this formative and customer satisfaction research, allowing NCI to: (1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective communication tools and strategies; (2) use a feedback loop to help refine, revise, and enhance messages, materials, products, and programs—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and (3) expend limited program resource dollars wisely and effectively. The participants may include, but are not limited to, cancer patients, their families, the general public, health providers, the media, voluntary groups, scientific and medical organizations (affected public could include individuals or households; businesses or other for profit; not-for-profit institutions; and Federal Government; State, Local, or Tribal Government).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden, over three years for this generic request are 6,600 hours.

3-YEAR ESTIMATED BURDEN HOURS (GENERIC REQUEST)

Category of respondents	Form name	Number of respondents	Frequency of response per respondent	Time per response (in hours)	Burden hours
Individuals, Households, Local, State, and Federal Governments, and Private Sector.	Focus Groups, Individual In-Depth Interviews, Brief Interviews, Surveys, Website Usability Testing.	33,000	1	12/60	6,600

Dated: February 27, 2013.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, NCI, NIH.

[FR Doc. 2013–05164 Filed 3–5–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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 of Child Health and Human Development Special Emphasis Panel; Multigenic Disease Models.

Date: March 20, 2013.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Cathy J. Wedeen, Ph.D., Scientific Review Officer, Division of Scientific Review, OD, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01–G, Bethesda, MD 20892, 301–435–6878, *wedeenc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 28, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–05109 Filed 3–5–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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