

Dated: February 20, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04536 Filed 2-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 8, 2013, from 8:30 a.m. to 6 p.m.

Location: Hilton Washington, DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993-0002, Natasha.Facey@fda.hhs.gov, 301-796-5290, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 8, 2013, the committee will discuss, make recommendations, and vote on information regarding the premarket

approval application for the Trulign Toric posterior chamber intraocular lens sponsored by Bausch and Lomb. The Trulign Toric posterior chamber intraocular lens is intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision and reduction of residual refractive cylinder. Trulign Toric provides approximately one diopter of monocular accommodation, which allows for near, intermediate, and distance vision without spectacles.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 1, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 22, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 26, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee

meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 20, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04534 Filed 2-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request Healthy Communities Study; How Communities Shape Children's Health (HCS)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 30, 2012, Pages 71426-71427 allowed 60-days for public comment. Two (2) comments were 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.

Proposed Collection

Title: Healthy Communities Study; How Communities Shape Children's Health (HCS). *Type of Information Collection Request:* Revision—OMB#

0925–0649. *Need and Use of Information Collection:* The HCS will address the need for a cross-cutting national study of community programs and policies and their relationship to childhood obesity. The HCS is an observational study of communities that aims to (1) determine the associations between community programs/policies and body mass index (BMI), diet, and physical activity for children; (2) identify the community, family, and child factors that modify or mediate the associations between community programs/policies and BMI, diet, and physical activity in children; and (3) assess the associations between programs/policies and BMI, diet and physical activity in children in communities that have a high proportion of African American, Latino,

and/or low-income residents. A total of 264 communities and over 21,000 elementary and middle school children and their parents will be part of this study. A HCS community is defined as a high school catchment area. The study examines quantitative and qualitative information obtained from community-based initiatives; community characteristics (e.g., school environment); measurements of children’s physical activity levels and dietary practices; and children’s and parents’ BMIs. Results from the Healthy Communities Study may influence the future development and funding of policies and programs to reduce childhood obesity. Furthermore, HCS results will be published in scientific journals and will be used for the development of future research

initiatives targeting childhood obesity. *Frequency of Response:* One time. *Affected Public:* Families or households; businesses, other for-profit, and non-profit. *Type of Respondents:* Parents, children, community key informants (who have knowledge about community programs/policies related to nutrition, physical activity, and weight of children), food service personnel, physical education instructors, school liaisons, and physicians or medical secretaries. The annual reporting burden is as follows: *Estimated number of respondents:* 69,010; *Estimated Number of Responses per Respondent:* 1; and *Estimated Total Burden Hours Requested:* 29,657. The annualized cost to respondents is estimated at \$381,841. There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours requested
Parents (screening)	39,600	1	10/60	6,732
Parents/Caregivers	7,128	1	1.56	11,120
Second Parents	3,564	1	7/60	428
Parents who refuse to participate	880	1	10/60	150
Children	7,128	1	1.04	7,413
Key Informants (screening)	3,520	1	5/60	282
Key Informants	1,056	1	2.25	2,376
Food Service Personnel	352	1	5/60	28
District Food Service Administrator/Manager	88	1	30/60	44
Physical Education Instructors	352	1	15/60	88
School Liaisons	352	1	25/60	148
Physicians/medical secretaries	4,990	1	10/60	848
Total	69,010	29,657

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and

instruments contact: Dr. Sonia Arteaga, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892–7936, or call non-toll free number (301) 435–0377 or Email your request, including your address to: hcs@nhlbi.nih.gov.

Comments 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.

Dated: February 19, 2013.

Lynn Susulske,
NHLBI Project Clearance Liaison, National Institutes of Health.
Michael S. Lauer,
Director, DCVS, National Institutes of Health.
 [FR Doc. 2013–04528 Filed 2–26–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Clinical Myttheries: A Video Game About Clinical Trials

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 June 13, 2012, page 35407 and allowed 60-days for public comment. No public comments were 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,