

and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1277 or 301-827-1281, 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 the morning of November 1, 2013, the committee will meet in open session to discuss MP Biomedicals' biologic license application for the MP Diagnostics HTLV Blot 2.4, a Western Blot intended for use as a confirmatory test for blood donors. In the afternoon, the committee will hear update presentations on the following topics: (1) The April 2013 FDA public workshop on multiplex detection of transfusion transmissible agents and blood cell antigens in blood donations and (2) FDA safety communications on new boxed warnings for immune globulin products and hydroxyethyl starch solutions. Following the update presentations, the committee will meet in open session to hear presentations on the research programs of the Laboratory of Biochemistry and Vascular Biology, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

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:** On November 1, 2013, from 8 a.m. to approximately 4 p.m., the meeting is open to the public. 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 October 24, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. Afternoon presentations will be scheduled between approximately 3:30 p.m. and 4 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 October 16, 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 October 17, 2013.

**Closed Committee Deliberations:** On November 1, 2013, from approximately 4 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. Seating for this meeting may be limited, so the public is encouraged to watch the free Web cast if you are unable to attend. The Web cast will be available at 8 a.m. on November 1, 2013, at the link provided.

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 Bryan Emery 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/ucm111462.htm> for procedures on public conduct during advisory committee meeting.

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

Dated: September 9, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-22423 Filed 9-13-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Antiviral Drugs 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:** Antiviral Drugs 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 October 25, 2013, from 8 a.m. to 5 p.m.

**Location:** Sheraton Silver Spring Hotel, Cypress Ballroom, 8777 Georgia Ave., Silver Spring, MD. The hotel phone number is 301-589-0800.

**Contact Person:** Karen Abraham-Burrell, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [AVAC@fda.hhs.gov](mailto:AVAC@fda.hhs.gov), 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:** The committee will discuss new drug application (NDA) 204671, sofosbuvir (an NS5B polymerase inhibitor), manufactured by Gilead Sciences, Inc., with a proposed indication for the treatment of chronic hepatitis C infection, in combination with other agents in adult patients with genotypes 1 to 6 and/or adult patients awaiting liver transplantation.

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 October 9, 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 October 1, 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 October 2, 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 Karen Abraham-Burrell 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/ucm111462.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: September 10, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-22427 Filed 9-13-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-day Comment Request: Family Life, Activity, Sun, Health, and Eating (FLASHE) Study (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 June 28, 2013, Vol. 78, No. 125, page 28996 and allowed 60-days for public comment. One public comment was received on June 29, 2013 which commented on the expense and topic of the study. An email response was sent on July 8, 2013 stating "Your comments will be taken into consideration. The Division of Cancer Prevention at the NCI supports research that studies the potential impact from a cell, tissue or organism and the pathways associated with disease process." The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: NIH Desk Officer.

**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:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Linda Nebeling, Ph.D., Division of Cancer

Control and Population Sciences, National Cancer Institute, 9609 Medical Center Drive, Room 3E102, Bethesda, MD 20892-9671 or call non-toll-free number 240-276-6855 or Email your request, including your address to: [nebelin@mail.nih.gov](mailto:nebelin@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**Proposed Collection:** Family Life, Activity, Sun, Health, and Eating (FLASHE) Study (NCI), 0925-NEW, Expiration Date xx/xx/xxxx, National Cancer Institute (NCI), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The FLASHE study seeks to examine psychosocial, generational (parent-adolescent), and environmental correlates of cancer preventive behaviors. FLASHE will examine the science of cancer and obesity prevention by examining correlates of cancer preventive behaviors, mainly diet, activity, and sedentary behaviors (but also examining other behaviors such as sleep, sun-safety, and tobacco) in new ways not previously addressed comprehensively on other surveys. The survey's goal is to advance understanding of the dynamic relationship between the environment, psychosocial factors, and behavior from a dyadic perspective. Data collected will ultimately be a public use dataset and resource to the research community. FLASHE will be collecting data from parents and their adolescent children through a web survey with a final sample size of 2,500 dyads with motion sensing data collected in a subsample of 900 adolescents.

OMB approval is requested for 2 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,243.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Form name                           | Type of respondent                   | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total annual burden hours |
|-------------------------------------|--------------------------------------|-----------------------|------------------------------------|--|---------------------------|
| Enrollment and Consent .....        | Parents (enrolling self) .....       | 1,250                 | 1                                  | 10/60                                  | 208                       |
|                                     | Parents (enrolling adolescent) ..... | 1,250                 | 1                                  | 10/60                                  | 208                       |
|                                     | Adolescents (assenting self) .....   | 1,250                 | 1                                  | 5/60                                   | 104                       |
| Web survey with demographics .....  | Parents .....                        | 1,250                 | 1                                  | 20/60                                  | 417                       |
|                                     | Adolescents .....                    | 1,250                 | 1                                  | 20/60                                  | 417                       |
| Web survey without demographics ... | Parents .....                        | 1,250                 | 1                                  | 15/60                                  | 313                       |
|                                     | Adolescents .....                    | 1,250                 | 1                                  | 15/60                                  | 313                       |
| Wear Log .....                      | Adolescents .....                    | 450                   | 7                                  | 5/60                                   | 263                       |