0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Haja Sittana El Mubarak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5519, Silver Spring, MD 20993–0002, 301–796–6193.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations on the types of information and data that FDA believes needs to be included in a 510(k) for herpes simplex virus (HSV) types 1 and 2 serological assays. HSV serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to HSV in serum. Additionally, some of the assays consist of HSV antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify HSV directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by HSVs and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome. We revised the existing guidance by rewriting the method comparison section and the sample selection inclusion and exclusion criteria section. The revisions define and differentiate the required studies and the study populations for the assessment of the safety and effectiveness of the different types of HSV types 1 and 2 serological assays. Additionally, the revisions include several corrections and clarifications throughout the document to ensure accuracy, consistency, and ease of reading. The draft of this guidance issued on September 28, 2010 (75 FR 59726) and the comment period closed on December 27, 2010. We received no comments on the draft guidance. Elsewhere in this issue of the **Federal Register**, FDA is finalizing the amendment of the special controls guidance document and designating this guidance as the class II special control for HSV types 1 and 2 serological assays. Following the effective date in the final rule finalizing the amendment of the special controls guidance document, this revised guidance document will serve as the special control for this device and supersedes the guidance with the same name that issued on April 3, 2007 (72 FR 15888).

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the HSV types 1 and 2 serological assays classified under 21 CFR 866.3305. In order to be classified as a class II device, HSV types 1 and 2 serological assays must comply with the requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

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 ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays,'' you may either send an e-mail 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 1713 to identify the guidance you are requesting.

IV. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: August 3, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20117 Filed 8–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Immunology 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: Immunology 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 October 14, 2011, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6639, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and

follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On October 14, 2011, the committee will discuss, make recommendations, and vote on a premarket approval application for the Progensa PCA3 assay sponsored by Gen-Probe, Inc. The Progensa PCA3 assay is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended based on current standard of care, before consideration of PCA3 assay results. A lower PCA3 score is associated with a decreased likelihood of a positive biopsy.

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 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 September 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m., immediately following lunch. 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 September 22, 2011. 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 September 23, 2011.

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 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/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: August 3, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–20118 Filed 8–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Hispanic Community Health Study (HCHS)/Study of Latinos (SOL)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Hispanic Community Health Study (HCHS)/Study of Latinos (SOL). *Type of Information Collection Request:* Revision of currently approved collection. (OMB# 0925–0584). *Need and Use of Information Collection:* A baseline examination was conducted from March 3, 2008 to June 30, 2011. HCHS will follow-up new participants enrolled in the past year by telephone for dietary data, and continue to conduct annual follow-up of all participants by telephone to ascertain morbidity and mortality. Physicians/health care providers will be contacted to verify reported events for outcomes ascertainment. The Hispanic Community Health Study (HCHS)/Study of Latinos (SOL) will identify risk factors for cardiovascular and lung disease in Hispanic populations and determine the role of acculturation in the prevalence and development of these diseases. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; physicians/health care providers. The annual reporting burden is as follows: Estimated Number of Respondents: 17,284; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response: 0.3072;* and *Estimated Total Annual Burden Hours Requested: 5,309.* The annualized cost to respondents is estimated at $104,718, assuming respondents time at the rate of $15 per hour and physician time at the rate of $55 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

Type of response	Number of respondents	Frequency of responses	Average hours per response	Annual hour burden
Participant telephone Interviews:				
a. Follow-up call, Year 1	1,333	1	0.75	1,000
b. Follow-up call, Year 2	5,333	1	0.25	1,333
c. Follow-up call, Year 3,4,5,6	9,334	1	0.25	2,334
Non Participant Components:				
Physician, medical examiner, next of kin or other contact follow-up [1]	1,284	1	0.50	642
Total unique respondents	17,284			5,309

[1] Annual burden is placed on doctors and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.