This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee (formerly the Biological Response Modifiers 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 March 3, 2005, from 8 a.m. to approximately 5:15 p.m. and on March 4, 2005, from 8 a.m. to approximately 2:30 p.m.

Location: Quality Suites, 3 Research Court, Rockville, MD.

Contact Person: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 3 and 4, 2005, the Committee will discuss cellular therapies for repair and regeneration of joint surfaces. The Committee will also receive the following updates: (1) On March 3, 2005, in the afternoon, updates of research programs in the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research; (2) on March 4, 2005, in the morning, update on the FDA Critical Path Initiative.

Procedure: On March 3, 2005, from 8 a.m. to approximately 4:45 p.m. and on March 4, 2005, from 8 a.m. to approximately 2:30 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 by February 23, 2005. Oral presentations from the public will be scheduled on March 3, 2005, between approximately 11 a.m. and 11:30 a.m. and on March 4, 2005, between approximately 8:45 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 23, 2005, 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.

Closed Committee Deliberations: On March 3, 2005, from approximately 4:45 p.m. to 5:15 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 research programs in the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research.

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 Gail Dapolito at least 7 days in advance of the meeting.

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

Dated: January 19, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–1473 Filed 1–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0366]

From Concept to Consumer: Center for Biologics Evaluation and Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies; Public Workshop; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until January 27, 2006, the comment period for the notice of public workshop and request for comments published in the **Federal Register** of August 31, 2004 (69 FR 53077). FDA is reopening the comment period to allow interested persons additional time to submit comments and to receive any new information.

DATES: Submit written or electronic comments by January 27, 2006.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 31, 2004 (69 FR 53077) (August 2004 notice), FDA announced a public workshop entitled ''From Concept to Consumer: Center for Biologics Evaluation and Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies.'' The public workshop was held on October 7, 2004. The goal of the public workshop was to provide a forum for stakeholders to discuss opportunities for and potential approaches to the development of innovative scientific knowledge and tools to facilitate the development and availability of new biological products including vaccines, blood and blood products, and cellular, tissue, and gene therapies.

Interested persons were originally given until September 23, 2004, to comment on the topic of the workshop.

II. Request for Comments

Following publication of the August 2004 notice, FDA received several requests to allow interested persons additional time to comment. The requesters asserted that the time period of 23 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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: January 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1475 Filed 1–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products 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 February 16, 2005, from 8:30 a.m. to approximately 5 p.m., and on February 17, 2005, from 8:30 a.m. to approximately 2:05 p.m.

Location: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 16, 2005, the committee will review and discuss the selection of strains to be included in the influenza virus vaccine for the 2005-2006 season. On February 17, 2005, the committee will hear updates on FDA Critical Path Initiative and Research Programs in the Center for Biologics Evaluation and Research.

Procedure: On February 16, 2005, from 8:30 a.m. to 5 p.m. and on February 17, 2005, from 8:30 a.m. to 11:25 a.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 by February 9, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on February 16, 2005, and approximately 8:45 a.m. and 9:15 a.m. on February 17, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 9, 2005, 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.

Closed Committee Deliberations: On February 17, 2005, from approximately 12 noon to 2:05 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)) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will discuss individual Research Programs in the Center for Biologics Evaluation and Research and receive an update on a product under review.

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 Christine Walsh or Denise Royster at 301–827–0314 at least 7 days in advance of the meeting.

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

Dated: January 18, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–1474 Filed 1–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the second meeting of the Commission on Systemic Interoperability.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The mission of the Commission on Systemic Interoperability is to submit a report to the Secretary of Health and Human Services and to Congress on a comprehensive strategy for the adoption and implementation of health care information technology standards that includes a timeline and prioritization for such adoption and implementation. In developing that strategy, the Commission will consider: (1) The costs and benefits of the standards, both financial impact and quality improvement; (2) the current demand on industry resources to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other electronic standards, including HIPAA standards; and (3) the most cost-effective and efficient means for industry to implement the standards.

Name of Committee: Commission on Systemic Interoperability (Teleconference).

Date: February 9, 2005.

Time: 3 p.m. to 4:30 p.m.

Agenda: Healthcare Information Technology Standards.

Place: National Library of Medicine, NIH, Conference Room B, Building 38, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Ms. Jane Griffith, Deputy Director, National Library of Medicine, National Institutes of Health, Building 38, Room 2E17, Bethesda, MD 20894, (301) 496–6661.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.