Dated: August 25, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–19799 Filed 8–30–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Animal Models and Correlates of Protection for Plague Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: ''Animal Models and Correlates of Protection for Plague Vaccines.'' The purpose of this workshop is to provide a public forum to discuss the animal models that may be most appropriate for evaluating new plague vaccines; the critical immune responses that may correlate with protection against plague; and the kinds of experimental and clinical assays that will need to be developed to measure these critical immune responses both in animals and in humans. The workshop will develop information that may be critical to the design of the pivotal studies required to assess plague vaccine efficacy.

Date and Time: This 1 1/2-day public workshop will be held on October 13, 2004, from 8:30 a.m. to 5 p.m., and October 14, 2004, from 8:30 a.m. to 12 noon.

Location: The workshop will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

The Marriott Gaithersburg Washingtonian Center is located approximately 30 minutes from Ronald Reagan Washington National and Washington Dulles International airports. Directions to the hotel can be found at *http://marriott.com/property/propertyPage/WASWG*.

Contact Person: *Regarding the public workshop*: Robert J. Watson, Science Applications International Corp., 5340 Spectrum Dr., suite N, Frederick, MD 21703, 301–228–3148, FAX: 301–698–5991, e-mail: *robert.j.watson@saic.com*.

Regarding this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

Registration: Registration is required; however, there is no registration fee for this public workshop. The deadline for registration is Wednesday, October 6, 2004. There will be no onsite registration. Information about the workshop and online registration can be found at *https://www.seeuthere.com/event/m2c640–122589588204*.

If you need special accommodations due to a disability, please contact Robert Watson (see *Contact Person*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: FDA's Center for Biologics Evaluation and Research; the National Institutes of Health, National Institute of Allergy and Infectious Diseases; and the Department of Health and Human Services, Office of Research Development and Coordination are sponsoring a public workshop. The workshop will be divided into interactive sessions in which leaders in the plague research field will present topics of particular relevance to plague vaccines. The sessions will include the following topics: (1) Introduction to the ''Animal Rule,'' (2) pathogenesis of plague, (3) plague vaccines and assessment of immune responses, (4) human disease and relevant animal models, and (5) implementation of the ''Animal Rule'' for plague vaccines. In addition, an expert panel will discuss the issues that will be critical for the development and eventual licensure of plague vaccines. The workshop's goal is to expedite the development and licensure of new plague vaccines by providing information critical to the development of the following: (1) Appropriate animal models, (2) immuno-assays, and (3) testing plans for vaccine evaluation.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page. Additionally, the transcript will be placed on the FDA Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: August 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19776 Filed 8–30–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Advisory Committee; Tentative Schedule of Meetings for 2004; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the tentative schedule of meetings for 2004. This document was announced in the **Federal Register** of December 31, 2003 (68 FR 75574 through 75577). The amendment is being made to reflect the following change: The Center for Food Safety and Applied Nutrition is canceling the tentatively scheduled meeting for the Dietary Supplements Subcommittee of the Food Advisory Committee on September 14 and 15, 2004.

FOR FURTHER INFORMATION CONTACT: Carolyn E. Jeletic, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2397.

SUPPLEMENTARY INFORMATION: You may also obtain up-to-date meeting information by calling the Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area).

Dated: August 24, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

[FR Doc. 04–19777 Filed 8–30–04; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), is announcing 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 goal of the public workshop is 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.

Date and Time: The public workshop will be held on October 7, 2004, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at The Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–3841, FAX: 301–827–3079, e-mail: *Whelan@cber.fda.gov*.

Registration: Mail, fax, or e-mail the registration information (including name, title, affiliation, address, and telephone and fax numbers) to Melanie Whelan (see *Contact Person*) by September 30, 2004. Because seating is limited, we recommend early registration. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Melanie Whelan (see *Contact Person*) at least 7 days in advance.

Comments: Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 written or electronic comments by September 23, 2004. Submit electronic comments to *http://www/fda.gov/dockets/ecomments*. Submit a single copy of electronic comments or two 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.

SUPPLEMENTARY INFORMATION: The goal of this workshop is to provide a public forum for input and discussion concerning opportunities for the enhancement of scientific knowledge and tools for safety, efficacy, and product quality that can be used to more effectively and efficiently develop and evaluate new biological products in the areas described.

On March 16, 2004, FDA released a report addressing the recent slowdown in innovative medical therapies submitted to FDA for approval entitled ''Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products'' at *http://www.fda.gov/oc/initiatives/criticalpath/*. That report describes the urgent need to create the scientific and technological ''tools'' to modernize the medical product development process—the Critical Path—to make medical product development more predictable and less costly.

The Center for Biologics Evaluation and Research (CBER) is seeking input from government and nongovernment research organizations, medical professional organizations, health care practitioners, patients, disease interest groups, pharmaceutical and biological product manufacturers and their industry organizations, and others with interests in facilitating development of the biological products that CBER regulates. The workshop will cover delineation of opportunities in key technologies and medical science knowledge needed to contribute to science based evaluation of the safety and efficacy of those biological products, and innovative development processes to manufacture them. FDA will discuss and welcomes input concerning all applicable areas of science including, but not limited to, bench laboratory investigations, clinical research and clinical trial design and execution, facility and manufacturing process research, statistical and epidemiological research, and computer science and computer modeling research. The workshop will not cover discussions of biological product discovery and invention or regulatory policies. The workshop will include presentations by FDA speakers and breakout sessions with panels composed of both FDA staff and non-FDA stakeholders, with an opportunity for public questions and comments.

FDA will post the agenda for this public workshop, when finalized on CBER's Web sites at *http://www.fda.gov/cber/scireg.htm* and *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Transcripts: Please note that transcripts of the workshop will not be prepared.

Dated: August 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19778 Filed 8–30–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine 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: Veterinary Medicine 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 13, 2004, from 8:30 a.m. to 5 p.m.

Location: DoubleTree Hotel, Plaza III, 1750 Rockville Pike, Rockville, MD.

Contact Person: Aleta Sindelar, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4515, e-mail: *asindela@cvm.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512548, for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on the microbial food safety of an antimicrobial drug application currently under review for use in food-producing animals in accordance with the Center for Veterinary Medicine's guidance for industry #152.

The background material for this meeting will be posted on the Internet no later than 1 business day before the meeting at*http://www.fda.gov/cvm/default.html*. A limited number of paper copies of the background information will be available at the registration table.

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 by October 1, 2004. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by October 1, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of