DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. [2004N–0089]

Antimicrobial Drug Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Infectious Diseases Society of America (IDSA) and the International Society of Anti-Infective Pharmacology (ISAP), regarding clinical trial design of antimicrobial agents. The public workshop is intended to provide information for and gain perspectives from advocacy groups, interested health care providers, academia, and industry organizations on various aspects of antimicrobial drug development, including a discussion of microbiological surrogate endpoints in clinical trials to evaluate treatments of infectious diseases and issues regarding dose selection in the drug development process for antimicrobials. The input from this public workshop will help to develop topics for further exploration.

Date and Time: The public workshop will be held on Thursday, April 15, 2004, and Friday, April 16, 2004, from 9 a.m. to 5 p.m.

Location: The public workshop will be held in the Center for Drug Evaluation and Research Advisory Committee conference room, 5630 Fishers Lane, rm. 1066, Rockville, MD. Seating is limited and available only on a first-come, first-served basis. Please note there is very limited parking in the vicinity of 5630 Fishers Lane, but it is near the Twinbrook Metro station. Please bring picture identification in order to clear building security.

Contact Person: John Powers or Leo Chan, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2350.

Registration: Because seating is limited, we are asking interested persons to register on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, organization, address, telephone, fax number, and e-mail address) to *antimicrobial@cder.fda.gov* by April 7, 2004. Persons without access to the Internet may call 301–827–2350 to register. There is no registration fee for the public workshop. Space is limited; therefore, interested parties are encouraged to register early.

Persons needing a sign language interpreter or other special accommodations should notify the contact person at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with IDSA and ISAP, regarding antimicrobial drug development. This public workshop will focus on general considerations in designing clinical trials for antimicrobial products. Additional topics include the utility of microbiological surrogate endpoints in clinical trials to evaluate treatments of infectious diseases and issues regarding dose selection in the drug development process for antimicrobials.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: You may request a copy of the transcript in writing from the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the public workshop at a cost of 10 cents per page. You may also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Division of Dockets Management Public Reading Room, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at *http://www.fda.gov/ohrms/dockets/dockets.htm*.

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5191 Filed 3–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Blood Products Advisory Committee. This meeting was announced in the **Federal Register** of February 25, 2004 (69 FR 8666). The amendment is being made to reflect a change in the *Location* portion of the document. The street address of the hotel was originally posted as 2 Montgomery Ave. The correct street address is 2 Montgomery Village Ave. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 25, 2004, FDA announced that a meeting of the Blood Products Advisory Committee would be held on March 18 and 19, 2004. On page 8666, in the first column, the *Location* portion of the document is amended to read as follows:

Location: Holiday Inn, Gaithersburg, 2 Montgomery Village Ave., Gaithersburg, MD 20877.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 3, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–5239 Filed 3–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0553]

Draft Guidance for Industry on Vaccinia Virus—Developing Drugs to Mitigate the Complications Associated With Vaccinia Virus Used for Smallpox Vaccination; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Vaccinia Virus—Developing Drugs to Mitigate the Complications from Smallpox Vaccination.'' In this draft guidance, FDA provides recommendations on the development of drugs to be used to treat complications that may occur from smallpox vaccination with vaccinia virus. This draft guidance is intended to help research sponsors plan and design appropriate nonclinical and clinical studies during the development of these drugs.

DATES: Submit written or electronic comments on the draft guidance by May 10, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lewis Schrager, Center for Drug Evaluation and Research (HFD–970), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7265, or Debra Birnkrant, CDER (HFD–530) 301–827–2330.

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; or

Steve Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Vaccinia Virus—Developing Drugs to Mitigate the Complications from Smallpox Vaccination.'' This draft guidance provides recommendations on the development of drugs to be used to treat complications that may occur from smallpox vaccination with vaccinia virus. The study of vaccinia complications poses challenges in drug development, such as sparse human data. Therefore, this draft guidance focuses on the design and characterization of animal models and of clinical trials and on the use of combinations of animal and human data. In addition, this draft guidance addresses data collection encompassing both preterrorism event controlled vaccination and postterrorism event emergent vaccination. It also addresses the collection of long-term and special population safety data.

This level 1 draft guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance represents the agency's current thinking on developing drugs to mitigate the complications associated with vaccinia virus used for smallpox vaccination. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes or regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain this document at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5241 Filed 3–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The National Diabetes Education Program Comprehensive Evaluation Plan

Summary: Under provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), 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 September 9, 2003, pages 53176–53177, 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 Institute 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: The National Diabetes Educations Program Comprehensive Evaluation Plan. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goals of the NDEP are to improve the treatment and health outcomes of people with diabetes, to promote early diagnosis, and, ultimately, to prevent the onset of diabetes. The NDEP objectives are: (1) To increase awareness of the seriousness of diabetes, its risk factors, and strategies for preventing diabetes and its complications among people at risk for diabetes; (2) to improve understanding about diabetes and its control and to promote better self-management behaviors among people with diabetes; (3) to improve health care providers' understanding of diabetes and its control and to promote an integrated approach to care; (4) to promote health care policies that improve the quality of and access to diabetes care.

Multiple strategies have been devised to address the NDEP objectives. These have been described in the NDEP Strategic Plan and include: (1) Creating partnerships with other organizations concerned about diabetes; (2) developing and implementing awareness and education activities with special emphasis on reaching the racial and ethnic populations disproportionately affected by diabetes; (3) identifying, developing, and disseminating educational tools and resources for the program's diverse audiences; (4) promoting policies and activities to improve the quality of and access to diabetes care.

The NDEP evaluation will document the extent to which the NDEP program has been implemented, and how successful it has been in meeting program objectives. The evaluation relies heavily on data gathered from existing national surveys such as National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey