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]

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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.