studies that should be conducted for drug metabolites that are present at greater than 10 percent of the parent drug systemic exposure as measured in plasma.

A draft version of this guidance was made available for public comment in 2005 (70 FR 32839, June 6, 2005). All of the public comments we received have been considered and the guidance was revised as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the safety testing of drug metabolites. 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 and regulations.

II. 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 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. Electronic Access

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

Dated: February 8, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2827 Filed 2–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs 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 a meeting of the Anti-Infective Drugs Advisory Committee. This meeting was announced in the **Federal Register** of January 11, 2008 (73 FR 2055). The amendment is being made to reflect a change in the *Date and Time* and *Agenda* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Sohail Mosaddegh, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 11, 2008, FDA announced that a meeting of the Anti-Infective Drugs Advisory Committee would be held on February 27 and 28, 2008. On page 2056, in the first column, the *Date and Time* and *Agenda* portions are amended to read as follows:

Date and Time: The meeting will be held on February 27, 2008, from 8 a.m. to 5 p.m.

Agenda: On February 27, 2008, the committee will discuss new drug application (NDA) 022–110, telavancin powder for reconstitution and intravenous administration, Theravance, Inc., proposed for the treatment of complicated skin and skin structure infection.

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

Dated: February 11, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–2824 Filed 2–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Molecular and Cellular Sciences Special Emphasis Panel.

Date: February 28, 2008.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Noni Byrnes, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5130, MSC 7840, Bethesda, MD 20892, (301) 435–1023, *byrnesn@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Stress.

Date: February 29, 2008.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Christine L. Melchior, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1713, *melchioc@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Innate Immunity and Inflammation.

Date: March 7, 2008.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.