

and supplements other FDA documents that discuss the specific contents of premarket submissions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection or detection and differentiation of influenza viruses. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1638 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB Control No. 0910-0120; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB Control No. 0910-0130; the collections of information in 21 CFR part 814 have been approved under OMB Control No. 0910-0231; the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910-0078; and the collections of information associated with CLIA waiver submissions and described in the draft guidance document for industry and FDA staff, "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications" have been approved under OMB Control No. 0910-0598.

V. 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.

Dated: February 11, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8-2826 Filed 2-14-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0065 (formerly Docket No. 2005D-0203)]

Guidance for Industry on Safety Testing of Drug Metabolites; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Safety Testing of Drug Metabolites." This guidance provides recommendations to industry on when and how to identify and characterize drug metabolites whose nonclinical toxicity needs to be evaluated. It also provides recommendations on the timing and type of nonclinical studies that should be conducted to investigate the potential for clinical toxicity of drug metabolites. This guidance applies to small molecule nonbiologic drug products under development. This guidance finalizes the draft guidance published on June 6, 2005.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Aisar Atrakchi, Center for Drug Evaluation and Research (HFD-130), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4384, Silver Spring, MD 20993-0002, 301-796-1036.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Safety Testing of Drug Metabolites." This guidance addresses drug metabolites of small molecule nonbiologic drug products and does not apply to some cancer products. It applies to drug metabolites that are not adequately evaluated in standard toxicology testing with the parent drug. This can happen if the metabolite is present only in humans or if it is present at higher levels (referred to in the guidance as "disproportionate drug metabolite") in humans than in any of the animal toxicology test species. The guidance provides recommendations on the timing and types of nonclinical safety

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]

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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.