

or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.nidcr.nih.gov/about>, where an agenda and any additional information for the meeting will be posted when available.

Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: March 15, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-6121 Filed 3-19-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Dental & Craniofacial Research, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

*Date:* June 6-9, 2010.

*Time:* June 6, 2010, 6 p.m. to 9 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* Pook's Hill Marriott, 5151 Pook Hill Road, Bethesda, MD 20814.

*Time:* June 7, 2010, 8 a.m. to 6:40 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 30, 30 Center Drive, Room 117, Bethesda, MD 20892.

*Time:* June 8, 2010, 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 30, 30 Center Drive, Room 117, Bethesda, MD 20892.

*Time:* June 9, 2010, 8 a.m. to 2 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, Building 30, 30 Center Drive, Room 117, Bethesda, MD 20892.

*Contact Person:* Alicia J. Dombroski, PhD, Director, Division of Extramural Activities, Natl Inst of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

Information is also available on the Institute's/Center's home page: <http://www.nidcr.nih.gov/about/CouncilCommittees.asp>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: March 15, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0133]

#### Revised Draft Guidance for Industry on Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling." The draft guidance is intended to assist sponsors planning to conduct studies to assess the influence of renal impairment on the pharmacokinetics of an investigational drug. It provides recommendations on when studies should be conducted to assess the influence of renal impairment on the pharmacokinetics of an investigational drug, the design of such studies, and how such studies should be carried out.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft

guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 21, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. 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:

Shiew-Mei Huang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3188, Silver Spring, MD 20993-0002, 301-796-1541, or;

Lei Zhang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3106, Silver Spring, MD 20993-0002, 301-796-1635.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a revised draft guidance entitled "Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling." The pharmacokinetics (PK) and pharmacodynamics of drugs primarily eliminated through the kidneys may be altered by impaired renal function to the extent that the dosage regimen needs to be changed from that used in patients with normal renal function. Although the most obvious type of change arising from renal impairment is a decrease in renal excretion of a drug or its metabolites, changes in renal metabolism can also occur. Renal impairment can also adversely affect some pathways of hepatic and/or gut drug metabolism and has been associated with other changes, such as changes in absorption, plasma protein binding, transport, and tissue distribution. These changes may be particularly prominent in patients with severely impaired renal function and have been observed even when the renal route is not the primary route of elimination of a drug. Thus, for most