

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.*

[FR Doc. 2010-6119 Filed 3-19-10; 8:45 am]

**BILLING CODE 4140-01-P**

## 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

drugs that are likely to be administered to patients with renal impairment, including drugs that are not primarily excreted by the kidney, PK should be assessed in patients with renal impairment to provide appropriate dosing recommendations.

This draft guidance 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.

In the **Federal Register** of May 15, 1998 (63 FR 27094), FDA announced the availability of a guidance entitled "Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling." The guidance has been revised at this time to indicate that a renal impairment study will be recommended for all drugs (with a few exceptions). In the original guidance, the agency stressed the need to evaluate only drugs that are renally eliminated. A second change is that in the 1998 guidance, only the Cockcroft-Gault equation was recommended to gauge renal function. The revised draft guidance adds the Modification of Diet in Renal Disease equation as another possible gauge for renal function and for dose adjustments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on conducting PK studies in patients with impaired renal function. 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 requirement of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 201.57 have been approved under OMB control number 0910–0572.

## III. 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances> or <http://www.regulations.gov>.

Dated: March 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–6171 Filed 3–19–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

[Docket no. MMS–2010–OMM–0008]

### MMS Information Collection Activity: 1010–0114, Subpart A—General, Revision of a Collection; Comment Request

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Notice of revision of an information collection (1010–0114).

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), MMS is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request concerns the paperwork requirements in the regulations under 30 CFR 250, subpart A, "General."

**DATES:** Submit written comments by May 21, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the regulations and the forms that require the subject collection of information.

**ADDRESSES:** You may submit comments by either of the following methods listed below.

- *Electronically:* go to <http://www.regulations.gov>. In the entry titled "Enter Keyword or ID," enter docket ID MMS–2010–OMM–0008 then click search. Follow the instructions to submit public comments and view supporting and related materials. The MMS will post all comments.

- Mail or hand-carry comments to the Department of the Interior; Minerals

Management Service; Attention: Cheryl Blundon; 381 Elden Street, MS–4024; Herndon, Virginia 20170–4817. Please reference Information Collection 1010–0114 in your comment and include your name and return address.

#### SUPPLEMENTARY INFORMATION:

*Title:* 30 CFR 250, subpart A, General. *Form(s):* MMS–132, MMS–143, MMS–1123, and MMS–1832.

*OMB Control Number:* 1010–0114.

*Abstract:* The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations to administer leasing of the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations in the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition. Section 1332(6) states that "operations in the [O]uter Continental Shelf should be conducted in a safe manner by well trained personnel using technology, precautions, and other techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillages, physical obstructions to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property or endanger life or health."

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and Office of Management and Budget (OMB) Circular A–25, authorize Federal agencies to recover the full cost of services that confer special benefits. Under the Department of the Interior's (DOI) implementing policy, the Minerals Management Service (MMS) is required to charge fees for services that provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those which accrue to the public at large.

This information collection request covers 30 CFR 250, Subpart A, General. This request also covers the related Notices to Lessees and Operators (NTLs) that MMS issues to clarify and provide additional guidance on some aspects of our regulations.

Requests for MMS approval may contain proprietary information related