

2012 (77 FR 3777). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA's Web site concurrently with publication of this notice.

II. Drug Products for Which New Draft Product-Specific

BE Recommendations Are Available

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

A
Acyclovir (multiple reference listed drugs (RLDs)),
Amiloride,
B
Butenafine HCl (multiple RLDs), Chlorpromazine HCl,
C
Clindamycin Phosphate (multiple RLDs),
D
Dalfampridine,
Dexmethylphenidate HCl,
Dextromethorphan HBr; Quinidine Sulfate,
Diclofenac Epolamine,
Drospirenone Ethinyl Estradiol;
Levomefolate,
E
Ethinyl Estradiol; Norethindrone,
F
Fenofibrate,
Fludarabine,
Fulvestrant,
G
Glyburide (multiple RLDs),
Gransetron,
I
Ivermectin,
K
Ketoconazole (multiple RLDs),
M
Memantine HCl,
Metformin Hydrochloride; Saxagliptin,
N
Naftifine HCl (multiple RLDs),
Nitrofurantoin; Nitrofurantoin
Macrocrystalline,
O
Ondansetron,
Oxiconazole Nitrate (multiple RLDs),
P
Pimecrolimus,
Procarbazine,
Propylthiouracil,
S
Sumatriptan,
T
Tacrolimus (multiple strengths),
Tolvaptan,
Tretinoin (multiple RLDs),
V
Vardenafil HCl,

III. Drug Products for Which Revised Draft Product-Specific BE

Recommendations Are Available

FDA is announcing revised draft product-specific BE recommendations for drug products containing the following active ingredients:

B
Benzoyl Peroxide; Clindamycin Phosphate (multiple RLDs),
Bosentan,
C
Cholestyramine,
Colesevelam,
D
Dexamethasone; Tobramycin (multiple RLDs),
H
Hydrochlorothiazide; Irbesartan,
L
Loteprednol,
Loteprednol; Tobramycin,
P
Paliperidone

For a complete history of previously published **Federal Register** notices relating to product-specific BE recommendations, please go to <http://www.regulations.gov> and enter docket number FDA-2007-D-0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do 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.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. The guidance, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

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

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-6947 Filed 3-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; Novel Clinical Trial Methods.

Date: April 13, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tony L. Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892-7924, 301-435-0725, creazzotl@mail.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Research Dissemination and Implementation.

Date: April 16, 2012.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Keith A. Mintzer, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924, 301-435-0280, mintzerk@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Clinical Trials.

Date: April 16, 2012.

Time: 1 p.m. to 5 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: Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892-7924, 301-435-0288, cjoyce@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 15, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-6962 Filed 3-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Institute of Environmental Health Sciences Special Emphasis Panel; Oceans, Great Lakes, and Human Health Review Meeting.

Date: April 24–25, 2012.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Chapel Hill, One Europa Drive, Chapel Hill, NC 27517.

Contact Person: Linda K. Bass, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307, bass@niehs.nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Marine Toxins and Public Health Review Committee Review Meeting.

Date: April 25–27, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Imperial Center, One Europa Drive, Chapel Hill, NC 27517.

Contact Person: Linda K. Bass, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural

Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307, bass@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: March 16, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-6958 Filed 3-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Sleep Disorders Research Advisory Board.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sleep Disorders Research Advisory Board.

Date: April 30, 2012.

Time: 3 p.m. to 5 p.m.

Agenda: To discuss and provide updates on sleep and circadian research developments and the NIH sleep research plan. Public meeting observers should call 1-800-791-5525 to access the teleconference and the observer passcode is 5500669#. Members of the public unable to access the meeting by phone may attend in person.

Place: National Institutes of Health, 6701 Rockledge Drive, Conference Room 10167, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michael J. Twery, Ph.D., Director, National Center on Sleep Disorders Research, Division of Lung Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Suite 10038, Bethesda, MD 20892-7952, 301-435-0199, twerym@nhlbi.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on

this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.nhlbi.nih.gov/meetings/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 15, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-6955 Filed 3-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 the following meeting.

The meeting 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; Resource-related Application in Congenital Heart Diseases (R24).

Date: April 17, 2012.

Time: 1 p.m. to 3 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: Keary A Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive Room 7190, Bethesda, MD 20892-7924, 301-435-2222, copeka@mail.nih.gov

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases