

**SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Doan T. Nguyen, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9314.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, "Bioequivalence Recommendations for Specific Products," that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at <http://www.fda.gov/CDER/GUIDANCE/bioequivalence/default.htm>. As described in that draft guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Since that notice was published we have published a correction notice concerning Bioequivalence Recommendations for Specific Products on October 25, 2007 (72 FR 60683). This notice includes draft product-specific recommendations either newly posted or updated since the **Federal Register** notice dated October 25, 2007, through April 30, 2008.

**II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available**

The following draft BE product-specific recommendations have been newly posted since the FR notice dated October 25, 2007:

- (1) Abacavir Sulfate; Lamivudine
- (2) Alendronate Sodium
- (3) Alfuzosin HCl
- (4) Alprazolam
- (5) Amoxicillin; Clavulanate Potassium (multiple RLDs)
- (6) Amprenavir
- (7) Aripiprazole
- (8) Armodafinil
- (9) Atovaquone
- (10) Azithromycin
- (11) Balsalazide Disodium
- (12) Bupropion HCl (updated)
- (13) Carbamazepine (multiple dosage forms)
- (14) Cefdinir
- (15) Cefixime
- (16) Cetirizine HCl; Pseudoephedrine HCl
- (17) Ciprofloxacin; Ciprofloxacin HCl

- (18) Ciprofloxacin HCl
- (19) Clarithromycin
- (20) Darunavir Ethanolate
- (21) Delavirdine Mesylate
- (22) Dexmethylphenidate
- (23) Diltiazem HCl (multiple dosage forms; multiple RLDs)
- (24) Divalproex Sodium
- (25) Doxycycline (multiple dosage forms)
- (26) Eprosartan Mesylate; Hydrochlorothiazide
- (27) Esterified Estrogens
- (28) Eszopiclone
- (29) Ethambutol HCl
- (30) Ethinyl Estradiol; Levonorgestrel (multiple RLDs)
- (31) Fenofibrate
- (32) Fluvastatin Sodium (multiple dosage forms)
- (33) Fosamprenavir Calcium
- (34) Glimepiride; Rosiglitazone Maleate
- (35) Lamivudine
- (36) Linezolid
- (37) Lisinopril
- (38) Lopinavir; Ritonavir
- (39) Memantine HCl
- (40) Mesalamine
- (41) Metoprolol Succinate (updated)
- (42) Minocycline HCl
- (43) Nelfinavir Mesylate
- (44) Nevirapine
- (45) Omeprazole; Sodium Bicarbonate; Magnesium Hydroxide
- (46) Oxymorphone HCl (multiple dosage forms)
- (47) Paliperidone
- (48) Paricalcitol
- (49) Phenytoin
- (50) Pimozide
- (51) Posaconazole
- (52) Quinine Sulfate
- (53) Saquinavir Mesylate (multiple dosage forms)
- (54) Solifenacin Succinate
- (55) Tenofovir Disoproxil Fumarate
- (56) Tinidazole
- (57) Tipranavir
- (58) Tolterodine Tartrate
- (59) Tramadol HCl
- (60) Trospium Chloride
- (61) Varenicline Tartrate
- (62) Zafirlukast
- (63) Zalcitabine
- (64) Zileuton
- (65) Zolmitriptan
- (66) Zonisamide

**III. Drug Products for Which Updated Draft Product-Specific BE Recommendations Are Available**

The following five product-specific recommendations previously made available on FDA's Web site have been updated:

1. Risedronate Sodium
2. Fosinopril Sodium; Hydrochlorothiazide

3. Fluoxetine HCl; Olanzapine
  4. Erlotinib HCl
  5. Morphine Sulfate
- For a complete history of previous **Federal Register** notices pertaining to product-specific BE recommendations, please go to <http://www.regulations.gov> and enter FDA-2007-D-0369.

**IV. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on any of the specific BE recommendations posted on FDA's Web site. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance, notices, and received comments are available for public examination 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 Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only at <http://www.regulations.gov>.

**V. 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.regulations.gov>.

Dated: August 27, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0450]

**Science Board to the Food and Drug Administration; Request for Nominations SUBJECT≤**

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is requesting nominations to serve on the Science Board to the FDA (Science Board).

FDA has special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations qualified candidates from these groups.

**DATES:** Nominations received on or before October 6, 2008 will be given first consideration for membership on the Science Board. Nominations received after October 6, 2008 will be considered for nomination to the Science Board should nominees still be needed.

**ADDRESSES:** All nomination for membership should be sent electronically to [CV@OC.FDA.GOV](mailto:CV@OC.FDA.GOV), or by mail to Advisory Committee Oversight & Management Staff, 5600 Fishers Lane (HF-4), rm. 15A-12, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Regarding all nomination questions for membership, the primary contact is Carlos Peña, Office of Science and Health Coordination, Office of the Commissioner, Food and Drug Administration (HF-33), 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, e-mail: [carlos.Peña@fda.hhs.gov](mailto:carlos.Peña@fda.hhs.gov). Information about becoming a member on a FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link <http://www.fda.gov/oc/advisory/default.htm>.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations to the Science Board. The Science Board will meet approximately four times a year. Meetings of the Science Board will be open to the public. All meetings will be announced in the **Federal Register** at least 15 days prior to each scheduled public meeting.

### I. General Function of the Committee

The Science Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community. Additionally, the Science Board will provide advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency sponsored intramural and extramural scientific research programs.

### II. Criteria for Members

Persons nominated for membership shall be knowledgeable in the fields of food safety, nutrition, chemistry,

pharmacology, toxicology, clinical research, or other scientific disciplines such as systems biology, wireless healthcare devices, nanotechnology, medical imaging, robotics, cell and tissue based products, regenerative medicine, and combination products. Members shall be chosen from academia and industry. The Science Board may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Science Board may also include technically qualified Federal members.

### III. Nomination Procedures

Any interested person may nominate one or more qualified person for membership on the Science Board. Self nominations are also accepted. Nominations shall include the name of the committee, complete curriculum vitae of each nominee, and their current business address and telephone number and e-mail address if available. Each nomination shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: August 27, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E8-20574 Filed 9-4-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Alternative Medicine; 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:* National Center for Complementary and Alternative Medicine, Special Emphasis Panel, Exploratory Grants for CAM Studies of Humans (R21).

*Date:* October 20-21, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Jeanette M. Hosseini, PhD, Scientific Review Officer, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594-9096, [jeanettehmail.nih.gov](mailto:jeanettehmail.nih.gov).

*Name of Committee:* National Center for Complementary and Alternative Medicine, Special Emphasis Panel, Basic and Preclinical Research on CAM.

*Date:* October 27-28, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott Gaithersburg, 204 Boardwalk Place, Gaithersburg, MD 20878.

*Contact Person:* Peter Kozel, PhD, Scientific Review Officer, NCCAM, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892-5475, 301-496-8004, [kozelpmail.nih.gov](mailto:kozelpmail.nih.gov).

Dated: August 27, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-20626 Filed 9-4-08; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### Collection of Overpayments

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This document provides notice that the Federal Emergency Management Agency (FEMA) has terminated the current procedures for the recoupment of overpayments of disaster assistance made pursuant to Section 408 of the Stafford Act, in connection with Hurricanes Katrina and Rita. Recoupment notices previously