accepted by FDA only through FDMS at http://www.regulations.gov.

Dated: August 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20564 Filed 9–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 23, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301–589–5200.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: Diem.Ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The Committee will discuss the clinical development of radionuclide imaging products for the detection of amyloid to assist in the diagnosis of Alzheimer's Disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 8, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 30, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 1, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 27, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–20577 Filed 9–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369] (formerly Docket No. 2007D–0168)

Publication of Guidances for Industry Describing Product-Specific Bioequivalence Recommendations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). 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,'' explaining the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Submit written or electronic comments on the draft product-specific BE recommendations listed in this notice by December 4, 2008.

ADDRESSES: Submit written requests for single copies of the individual BE guidances 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 draft product-specific BE recommendations 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 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.

[FR Doc. E8–20580 Filed 9–4–08; 8:45 am]

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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).