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 1, 2008, from 8 a.m. to 5 p.m.


Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFDB–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.

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]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FR Doc. E8–20578 Filed 9–4–08; 8:45 am]

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 In the Federal Register of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, “Bioequivalence Recommendations for Specific Products,” explaining the process that would be used to make product-specific BE recommendations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

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


Jeffrey Shuren, Associate Commissioner for Policy and Planning.

[FR Doc. E8–20564 Filed 9–4–08; 8:45 am]
SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

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. Risedronate Sodium
2. Fosinopril Sodium; Lisinopril
3. Fluoxetine HCl; Olanzapine
4. Erlotinib HCl
5. Morphine Sulfate


IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments or submissions 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]

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).