office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Sally Hojvat, Center for Devices and Radiological Health (HFZ–312), Food and Drug Administration,2098 Gaither Rd, Rockville, MD 20850, 301–594–5940, ext. 114; or

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to facilitate the movement of new IVD technology from the investigational stage to the marketing stage by providing information about the development and conduct of IVD studies that will be submitted to the agency to support premarket notifications and applications. Because many IVD studies are exempt from most of the IDE regulations at part 812 (21 CFR part 812) (§ 812.2(c)(3)), both industry sponsors and FDA staff often have questions concerning the relevant requirements and appropriate methods for such studies. This draft guidance provides information about such studies as well as general information about the development, conduct, and responsibilities associated with all IVD studies. The Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) both have regulatory oversight of IVD devices. Information in this draft guidance is relevant to IVD devices regulated by either center under subchapter H of 21 CFR Chapter I.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on IVD device studies. 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 requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Draft Guidance for Industry and FDA Staff; In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1587 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 PRA). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR 807.87 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 810 have been approved under OMB control number 0910–0432; the collections of information under part 812 have been approved under OMB control number 0910–0078; the collections of information in part 814 (21 CFR part 814), subparts B and E, have been approved under OMB control number 0910–0231; the collections of information in part 814, subpart H, have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. 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.

Dated: October 18, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–20982 Filed 10–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 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 document were developed using the process described in that guidance.

DATES: Submit written or electronic comments on the draft product-specific BE recommendations by January 23, 2008. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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 either *http://www.fda.gov/dockets/ecomments* or *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, 7500 Standish Pl., Rockville, MD 20855, 301–827–0495.

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.

In that same issue of the **Federal Register** (72 FR 30386), FDA also announced that 200 product-specific BE recommendations were being made available on FDA's Web site at *http://www.fda.gov/CDER/GUIDANCE/bioequivalence/default.htm*. However, a number of the recommendations listed in that notice were not posted on the Web site. In addition, some of the recommendations posted on the Web site were omitted from the **Federal Register** notice. Finally, four recommendations announced in the May 31, 2007, notice and posted on the Web site were incorrect and have now been corrected. This document clarifies the notice of May 31, 2007 (72 FR 30386), as follows:

A. Recommendations Listed in the May 31, 2007, **Federal Register** *Notice That Were Not Posted on the Web Site*

(1) Ganciclovir
(2) Ibuprofen; Pseudoephedrine HCl
(3) Felbamate (multiple dosage forms)
(4) Leflunomide

These drugs are now available on the Web site.

B. Recommendations Posted on the Web Site That Were Not Listed in the May 31, 2007, **Federal Register** *Notice*

(1) Fosinopril Sodium
(2) Hydrochlorothiazide and Irbesartan
(3) Levonorgestrel
(4) Lidocaine
(5) Loratadine
(6) Phenytoin Sodium (multiple RLDs)
(7) Phenytoin
(8) Terazosin HCl

C. Recommendations Listed in the May 31, 2007, **Federal Register** *Notice and Posted on the Web Site That Were Incorrect*

(1) Mycophenolate mofetil tablet 50723, corrected the analytes to measure
(2) Mycophenolate mofetil capsule 50722, corrected the analytes to measure
(3) Erlotinib HCl tablet, deleted the IND requirement
(4) Hydrochlorothiazide and losartan potassium tablets, added waiver strength 12.5 mg/100mg

The recommendations listed in sections I.A, B, and C of this document are available for comment by (see **DATES**).

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain these BE recommendations at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 19, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21062 Filed 10–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Institute on Aging Special Emphasis Panel, Reverse Site Visit.

Date: November 26–27, 2007.

Time: 5 p.m. to 4 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: Louise L. Hsu, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496–7705, *hsul@exmur.nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel, ''Aging Brain Vasculature''.

Date: November 30, 2007.

Time: 12 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: William Cruce, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212,