displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0188. The approval expires on November 30, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30461 Filed 12–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

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. These recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'', which explained 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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by March 2, 2015.

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, 10001 New Hampshire Ave., Hillandale Building, 4th floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris Andre Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4726, Silver Spring, MD 20993–0002, 240–402–7959.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received, and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on April 2, 2014 (79 FR 18561). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

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

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Acetaminophen; Aspirin; Caffeine.
	Acetaminophen; Butalbital; Caffeine; Codeine phosphate.
	Acyclovir.
	Aripiprazole.
B	Benzyl alcohol.
	Betamethasone valerate.
	Bosutinib monohydrate.
	Brimonidine tartrate; Brinzolamide.
	Buprenorphine hydrochloride; Naloxone hydrochloride.
C	Cobicistat; Elvitegravir; Emtricitabine; Tenofovir disoproxil fumarate.
	Conjugated estrogens.
D	Dapsone.
	Darunavir ethanolate.
I	Ibuprofen sodium.
L	Levothyroxine sodium (multiple reference listed drugs).
	Lidocaine; Prilocaine.
	Lomitapide mesylate.
	Lurasidone hydrochloride.
M	Metoprolol tartrate.
N	Nepafenac (multiple reference listed drugs).
P	Posaconazole.
R	Raltegravir potassium.
	Regorafenib.
S	Selegine hydrochloride.
T	Testosterone.
	Tofacitinib citrate.
	Treprostinil.
V	Vandetanib.

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

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Adapalene (multiple reference listed drugs and dosage forms).
	Adapalene; Benzoyl peroxide.
B	Brimonidine tartrate (multiple reference listed drugs).
	Brinzolamide.
D	Doxorubicin hydrochloride.
E	Ethinyl estradiol; Levonorgestrel.
H	Hydrocodone bitartrate; Ibuprofen.
K	Ketoconazole.
M	Memantine hydrochloride (multiple dosage forms).
	Methylprednisolone acetate.
N	Nebivolol hydrochloride.
	Nisoldipine.
P	Phenytoin sodium (multiple reference listed drugs).
S	Sevelamer carbonate.

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS—Continued

	Sevelamer hydrochloride.

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please go to *http://www.regulations.gov* and enter Docket No. 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). These 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 either electronic comments on any of the specific BE recommendations posted on FDA's Web site to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

V. Electronic Access

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

Dated: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30514 Filed 12–29–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2014.

ADDRESSES: Copies are available at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. You also may access the docket at *http://www.regulations.gov* for the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2014. Insert the docket number found in brackets in the heading of this document at *http://www.regulations.gov* into the ''Search'' box, clear filter under Document Type (left side of screen), and check ''Supporting and Related Material,'' then Sort By Best Match (from the drop-down menu; top right side of screen), ''ID Number (Z–A)'' or Sort By Best Match (from the drop-down menu) ''Title (A–Z),'' also found in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Committee Management Officer, Advisory Committee and Oversight Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8220.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2013, through September 30, 2014:

Center for Biologics Evaluation and Research:

Blood Products Advisory Committee
Cellular, Tissue, and Gene Therapies Advisory Committee
Vaccines and Related Biological Products Advisory Committee

National Center for Toxicological Research:

Science Board to the National Center for Toxicological Research

Annual Reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

(1) The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., Rm. 133, Washington, DC; and

(2) The Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30460 Filed 12–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2065]

Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Radiation Biodosimetry Devices.'' This draft guidance provides recommendations to assist industry in designing studies to establish the analytical and clinical performance characteristics of radiation biodosimetry medical countermeasure devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 30, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Radiation Biodosimetry Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices