

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at FDA's Internet site at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. FDA will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to standards@cdrh.fda.gov. To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, <http://www.fda.gov/MedicalDevices>, includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice

announcing "Modification to the List of Recognized Standards, Recognition List Number: 046" will be available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-31008 Filed 12-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 June 11, 2010, FDA announced the availability of a guidance for industry entitled "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. 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 comment on 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 February 21, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2007-D-0369 for "Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance 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 document.

FOR FURTHER INFORMATION CONTACT:

Xiaoqi Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

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" 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that 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. 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 October 5, 2016 (81 FR 69064). This notice announces draft product-specific BE 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

1. Adapalene; benzoyl peroxide.
2. Amphetamine.
3. Betamethasone valerate.
4. Budesonide.
5. Cephalixin.
6. Cetirizine hydrochloride.
7. Clozapine.
8. Colchicine.
9. Doxycycline hyclate.
10. Emtricitabine; Rilpivirine hydrochloride; Tenofovir alafenamide fumarate.
11. Emtricitabine; Tenofovir alafenamide fumarate.
12. Epinephrine.
13. Esomeprazole Magnesium.
14. Ethiodized oil.
15. Fenofibrate.
16. Fluocinonide.
17. Fluoxetine hydrochloride.
18. Halcinonide.
19. Ibuprofen; pseudoephedrine hydrochloride.
20. Lidocaine.
21. Morphine sulfate.
22. Nicotine polacrilex.

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

23. Nitisinone.
24. Omega-3-acid ethyl esters type A.
25. Oxycodone.
26. Panobinostat lactate.
27. Perampanel.
28. Pimavanserin tartrate.
29. Prazosin hydrochloride.
30. Simvastatin.
31. Tofacitinib citrate.

II. 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

- Acyclovir.
Albuterol sulfate.
Buprenorphine hydrochloride; Naloxone hydrochloride (multiple reference listed drugs).
Cobicistat; Darunavir ethanolate.
Divalproex sodium (multiple reference listed drugs).
Levomilnacipran hydrochloride.
Medroxyprogesterone acetate.
Nepafenac (multiple reference listed drugs).
Omega-3-acid ethyl esters.
Omega-3-carboxylic acids.
Ruxolitinib phosphate.
Tedizolid phosphate.
Venlafaxine hydrochloride.

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: December 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-30984 Filed 12-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to CARB@hhs.gov. Registration information is available on the Web site <http://www.hhs.gov/ash/carb/> and must be completed by January 20, 2017; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/ash/carb/> on the Meetings page.

DATES: The meeting is scheduled to be held on January 25, 2017, from 9:30 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the Web site for the Advisory Council at <http://www.hhs.gov/ash/carb/> when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than January 20, 2017; public attendance at the meeting is limited to the available space.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201.

The meeting can also be accessed through a live webcast on the day of the meeting. For more information, visit <http://www.hhs.gov/ash/carb/>.

FOR FURTHER INFORMATION CONTACT:

Bruce Gellin, Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 260-6638; email: CARB@hhs.gov.

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council provides advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council functions solely for advisory purposes.

In carrying out its mission, the Advisory Council provides advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The January public meeting will be dedicated to presentations from federal and non-federal stakeholders surrounding the topic areas of infection prevention and control. The meeting agenda will be posted on the Advisory Council Web site at <http://www.hhs.gov/>

[ash/carb/](http://www.hhs.gov/ash/carb/) when it has been finalized. All agenda items are tentative and subject to change.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Advisory Council at the address/telephone number listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at <http://www.hhs.gov/ash/carb/>.

Members of the public will have the opportunity to provide comments prior to the Advisory Council meeting by emailing CARB@hhs.gov. Public comments should be sent in by midnight January 20, 2017, and should be limited to no more than one page. All public comments received prior to January 20, 2017, will be provided to Advisory Council members; comments are limited to two minutes per speaker.

Dated: December 16, 2016.

Bruce Gellin,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Deputy Assistant Secretary for Health.

[FR Doc. 2016-30904 Filed 12-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; PAR Panel: Global Infectious Diseases Research Training Program.

Date: January 5, 2017.

Time: 9:00 a.m. to 12:00 p.m.