



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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: Xiaoqiu 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. Cephalexin
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
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.

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