



4160-01-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. 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 (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. 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance recommendations.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:

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SUPPLEMENTARY INFORMATION:

I. Background

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 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 of March 28, 2012 (77 FR 18827). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA's Web site concurrently with publication of this notice.

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

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

A

Aliskiren hemifumarate; amlodipine besylate

Alvimopan

Azilsartan medoxomil

B

Bacitracin

Boceprevir

C

Cefpodoxime proxetil (multiple reference listed drugs (RLDs))

Cefprozil (multiple RLDs)

Cetirizine HCl

Ciprofloxacin HCl; hydrocortisone

Clomiphene citrate

D

Dabigatran etexilate mesylate

Dexamethasone; tobramycin

Dinoprostone

Diphenhydramine; ibuprofen

E

Erythromycin

F

Famotidine; ibuprofen

G

Gabapentin enacarbil

I

Itraconazole

K

Ketoconazole

L

Lacosamide

M

Malathion

Morphine sulfate; naltrexone HCl

P

Podofilox

R

Rotigotine

Rufinamide

T

Tapentadol HCl

Tetrabenazine

Z

Zolpidem tartrate

III. Drug Products for Which Revised Draft Product-Specific

BE Recommendations Are Available

FDA is announcing revised draft product-specific BE recommendations for drug products containing the following active ingredients:

D

Dexamethasone; tobramycin (multiple RLDs)

E

Everolimus

L

Loteprednol etabonate

Loteprednol etabonate; tobramycin

S

Sorafenib tosylate

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 number 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 to the Division of Dockets Management (see ADDRESSES) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site. 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.

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: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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