4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369 (formerly Docket 2007D-0168)]

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, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance recommendations.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 (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 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 June 14, 2012 (77 FR 35688). 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

Amoxicillin

Amoxicillin; clavulanate potassium

Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate

B

Budesonide

Bupropion hydrochloride (multiple reference listed drugs (RLDs))

C

Calcitonin salmon

Carbidopa; levodopa

Carglumic acid

Ciclesonide

Ciprofloxacin; dexamethasone

Cyclophosphamide

D

Dalteparin sodium

E

Estramustine phosphate sodium

F

Fentanyl citrate

K

Ketoconazole

L

Linagliptin

M

Mesalamine (multiple RLDs and dosage forms)

Methylphenidate hydrochloride (multiple RLDs)

N

Nifedipine

O

Omega-3-acid ethyl esters

Omeprazole

P

Paclitaxel

Pazopanib hydrochloride

Progesterone

R

Rilpivirine hydrochloride

Roflumilast

S

Saxagliptin hydrochloride

T

Telaprevir

Tenofovir disoproxil fumarate

Thioguanine

Thalidomide

Tretinoin (multiple RLDs and dosage forms)

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:

A

Azacitidine

Azelaic acid

C

Capecitabine

E

Estrogen, esterified

Etravirine

H

Hydrochlorothiazide; losartan potassium

L

Lopinavir; ritonavir

P

Phytonadione (multiple RLDs and dosage forms)

Propranolol hydrochloride

S

Sapropterin dihydrochloride

Sumatriptan

T

Tadalafil

Theophylline (multiple RLDs)

Tolterodine tartrate

Topiramate

Trazodone 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 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. 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.

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: September 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-22658 Filed 09/13/2012 at 8:45 am; Publication Date: 09/14/2012]