4164-01-P

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.

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 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, 10001 New Hampshire Ave., Hillandale Bldg., 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance recommendations.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: 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 June 30, 2015 (80 FR 37273). 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

Aclidinium bromide
Acyclovir
Aminocaproic acid
Apremilast
Benazepril hydrochloride; Hydrochlorothiazide
Brimonidine tartrate
Carbidopa; Levodopa
Ceritinib
Clobetasol propionate
Clomipramine hydrochloride
Clonidine hydrochloride
Cobicistat
Cysteamine bitartrate
Dapagliflozin propanediol; Metformin hydrochloride
Dasabuvir sodium; Ombitasvir; Paritaprevir; Ritonavir
Desvenlafaxine fumarate
Eslicarbazepine acetate
Ferric citrate
Fluticasone propionate (multiple reference listed drugs)
Formoterol fumarate
Idelalisib
Ledipasvir; Sofosbuvir
Levocarnitine
Loperamide hydrochloride; Simethicone
Mometasone furoate monohydrate

Naltrexone HCL; Bupropion HCL
Netupitant; Palonosetron hydrochloride
Nintedanib esylate
Nortriptyline hydrochloride
Pirfenidone
Pomalidomide
Ponatinib hydrochloride
Rivaroxaban
Ruxolitinib phosphate
Suvorexant
Tasimelteon
Tedizolid phosphate
Tramadol hydrochloride
Trimipramine maleate

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

Acitretin
Amantadine hydrochloride
Benzonatate
Carbamazepine
Colesevelam hydrochloride
Cyclophosphamide
Dabigatran etexilate mesylate
Dasatinib
Desvenlafaxine succinate
Esomeprazole magnesium
Estradiol
Ethinyl estradiol; Norethindrone
Gabapentin
Isotretinoin
Minocycline hydrochloride
Naltrexone
Sevelamer carbonate
Sirolimus

For a complete history of previously published Federal Register notices related to product-specific BE recommendations, 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 establish any rights for anyone and are not binding on FDA or the public. You may use an alternative approach if it 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: September 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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