

the CD-ROM and the attachments according to current managed review procedures. Only new IND applications and their amendments will be eligible for participation in the pilot program.

During the IND application process, CBER staff will be available to answer any questions or concerns that may arise. As each application is completed, the users will be asked to comment on the eSubmitter program. These comments and discussions will assist CBER in the final development and release of this electronic program for use by industry.

III. Requests for Participation

Requests to participate in the eSubmitter Pilot Evaluation Program should be sent electronically to *CBER eSubmitter program* @*fda.hhs.gov*. You should include the following information in your request: Contact name, contact phone number, email address, name of the facility, address, and registration number (if applicable). Once requests for participation are received, FDA will contact interested sponsors to discuss the pilot program.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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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 June 7, 2013.

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: Kris André, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9326.

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 December 17, 2012 (77 FR 74669). 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
Albuterol sulfate (multiple RLDs)
Amoxicillin

C
Cefixime

D
Desipramine hydrochloride
Desvenlafaxine
Dutasteride; tamsulosin hydrochloride

E
Estramustine phosphate sodium
Ethinyl estradiol, etonogestrel
Ethionamide
Ezogabine

F
Flutamide

H
Hydrocortisone

I
Icosapent ethyl

K
Ketorolac tromethamine

L
Loratadine

M
Miconazole
Minocycline hydrochloride
Mitotane

N
Nevirapine

P
Phentermine hydrochloride; topiramate

R
Rimexolone
Rizatriptan benzoate

S

Silodosin

T

Testosterone (multiple reference listed drugs and dosage forms)

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:

C

Cefixime

D

Darunavir ethanolate
Dextromethorphan hydrobromide;
quinidine sulfate

I

Imatinib mesylate

L

Loteprednol etabonate

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 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: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0349]

Draft Guidance for Industry on Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)." This guidance is intended to inform applicants of the conditions under which FDA will exercise its waiver authority to permit applicants to submit an International Conference on Harmonisation (ICH) E2C(R2) Periodic Benefit-Risk Evaluation Report (PBRER) in place of the ICH E2C(R1) Periodic Safety Update Report (PSUR), U.S. periodic adverse drug experience report (PADER), or U.S. periodic adverse experience report (PAER), to satisfy the periodic safety reporting requirements in FDA regulations. The guidance describes the steps applicants can take to submit the PBRER, and discusses the format, content, submission deadline, and frequency of reporting for the PBRER.

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 May 8, 2013.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993-0002, 301-796-2380; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)." We are issuing the draft guidance to describe the conditions under which FDA will exercise its waiver authority to permit the holders of approved new drug applications, abbreviated new drug applications, and biologics license applications (applicants) to use the reporting format of the PBRER to submit periodic safety reports for their marketed products. The harmonized PBRER is intended to promote a consistent approach to periodic postmarket safety reporting among the ICH regions (the European Union, Japan, and the United States) and to enhance efficiency by reducing the number of reports generated for submissions to the regulatory authorities.

FDA's postmarket safety reporting regulations require applicants to submit periodic safety reports in the form of a