

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Final 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 final 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, "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: Submit written or electronic comments on Agency guidances at any time.

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 recommendations.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments on product-specific BE recommendations to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-8608.

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/CDER/GUIDANCE/bioequivalence/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, 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. Once finalized, the recommendations are posted on FDA's Web site and announced in the **Federal Register**. This notice announces final product-specific recommendations that were posted on FDA's Web site in October 2011.

For a complete history of previous **Federal Register** notices relating to product-specific BE recommendations, please go to <http://www.regulations.gov> and enter docket number FDA-2007-D-0369.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The 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.

II. Drug Products for Which Final Product-Specific BE Recommendations are Available

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

A
Acetaminophen; Caffeine; Dihydrocodeine Bitartrate
C
Cephalexin
Ciprofloxacin
D
Desmopressin Acetate

E
Eletriptan HBr
F
Fenoprofen Calcium
Fludrocortisone Acetate
G
Glimepiride; Pioglitazone
H
Hydroxyzine Pamoate (multiple RLDs)
I
Imatinib Mesylate
L
Lansoprazole
Levetiracetam
Linezolid
M
Meprobamate
Methotrexate Sodium (multiple RLDs)
Methylprednisolone Acetate
Metoclopramide HCl
N
Nadolol
Nifedipine
Nilutamide
Nisoldipine
Nitazoxanide
Nitrofurantoin
Nitrofurantoin Macrocrystalline
O
Oxybutynin Chloride
P
Phendimetrazine Tartrate (multiple RLDs)
Phentermine HCl (multiple RLDs)
Phytonadione
Pregabalin
Propafenone HCl
Pyridostigmine Bromide
R
Raltegravir Potassium
Ramelteon
S
Scopolamine
Selegiline
Sorafenib Tosylate
T
Tamoxifen Citrate
Telbivudine
Temazepam
Terbinafine HCl
Toremifene Citrate
V
Voriconazole
Z
Zolpidem
III. 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

guidance, notices, and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/CDER/GUIDANCE/bioequivalence/default.htm> or <http://www.regulations.gov>.

Dated: February 14, 2012.

Leslie Kux,

Acting 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 document 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 April 23, 2012.

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:

Doan T. Nguyen, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-8608.

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 the 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 January 25, 2012 (77 FR 3777). This notice announces draft product-specific recommendations, either new or revised, that have been posted on the FDA's Web site in the period from July 1, 2011, through November 30, 2011.

For a complete history of previously published **Federal Register** notices relating 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). The 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.

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:

C
Carbamazepine
Cholestyramine
Clindamycin HCl
D
Dinoprostone (multiple RLDs)
E
Enoxaparin
Ethinyl Estradiol Norethindrone
Etravirine
F
Fingolimod
I
Ibuprofen; Phenylephrine HCl
Imiquimod
L
Lanthanum Carbonate
Loteprednol; Tobramycin
M
Methylphenidate HCl
P
Paliperidone Palmitate
Podofilox
Potassium Chloride (multiple RLDs)
Pyridostigmine Bromide
T
Testosterone