

PDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0168]

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Certifier A. Corbin

Publication of Guidances for Industry Describing Product-Specific Bioequivalence Recommendations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of 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 In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, "Bioequivalence Recommendations for Specific Products," explaining the process that would be used to make product-specific BE recommendations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: Submit written or electronic comments on the draft product-specific BE recommendations by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft product-specific BE recommendations to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0495.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, “Bioequivalence Recommendations for Specific Products,” that explained the “process” that would be used to make product-specific BE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/CDER/GUIDANCE/bioequivalence/default.htm*. As described in that draft 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.

In that same issue of the **Federal Register** (72 FR 30386), FDA also announced that 200 product-specific BE recommendations were being made available on FDA’s Web site at *http://www.fda.gov/CDER/GUIDANCE/bioequivalence/default.htm*. However, a number of the recommendations listed

in that notice were not posted on the Web site. In addition, some of the recommendations posted on the Web site were omitted from the **Federal Register** notice. Finally, four recommendations announced in the May 31, 2007, notice and posted on the Web site were incorrect and have now been corrected. This document clarifies the notice of May 31, 2007 (72 FR 30386), as follows:

A. Recommendations Listed in the May 31, 2007, Federal Register Notice That Were Not Posted on the Web Site

- (1) Ganciclovir
- (2) Ibuprofen; Pseudoephedrine HCl
- (3) Felbamate (multiple dosage forms)
- (4) Leflunomide

These drugs are now available on the Web site.

B. Recommendations Posted on the Web Site That Were Not Listed in the May 31, 2007, Federal Register Notice

- (1) Fosinopril Sodium
- (2) Hydrochlorothiazide and Irbesartan
- (3) Levonorgestrel
- (4) Lidocaine
- (5) Loratadine
- (6) Phenytoin Sodium (multiple RLDs)
- (7) Phenytoin
- (8) Terazosin HCl

C. Recommendations Listed in the May 31, 2007, Federal Register Notice and Posted on the Web Site That Were Incorrect

- (1) Mycophenolate mofetil tablet 50723, corrected the analytes to measure

(2) Mycophenolate mofetil capsule 50722, corrected the analytes to measure

(3) Erlotinib HCl tablet, deleted the IND requirement

(4) Hydrochlorothiazide and losartan potassium tablets, added waiver strength 12.5 mg/100mg

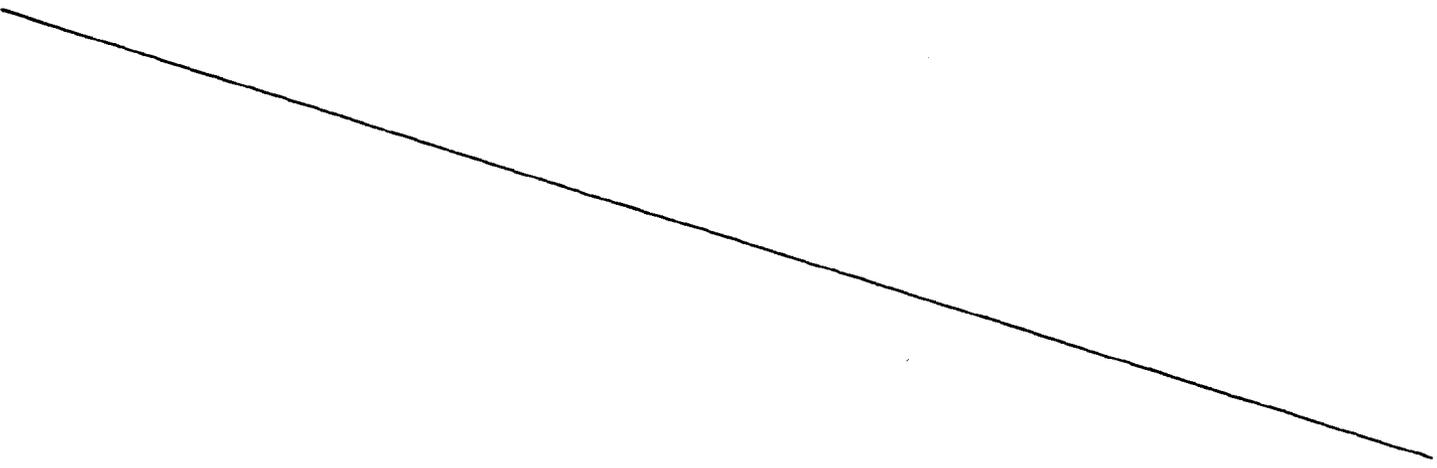
The recommendations listed in sections I.A, B, and C of this document are available for comment by (see **DATES**).

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on any of the specific BE recommendations posted on FDA's Web site. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified 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.

III. Electronic Access

Persons with access to the Internet may obtain these BE recommendations at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.



Dated: OCT 19, 2007

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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