

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

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

**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 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 In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, "Bioequivalence Recommendations for Specific Products," explaining the process that would be used to make product-specific BE recommendations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 notice were developed using the process described in that guidance.

DATES: Submit written or electronic comments on the draft product-specific BE recommendations listed in this notice by [*insert date 90 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. 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 <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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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, 7519 Standish Pl., Rockville, MD 20855, 240-276-9314.

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In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, "Bioequivalence Recommendations for Specific Products," that explained the process that would be used to make product-specific BE recommendations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. Since that notice was published we have published a correction notice concerning Bioequivalence Recommendations for Specific Products on October 25, 2007 (72 FR 60683). This notice includes draft product-specific recommendations either newly posted or updated since the **Federal Register** notice dated October 25, 2007, through April 30, 2008.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

The following draft BE product-specific recommendations have been newly posted since the FR notice dated October 25, 2007:

- (1) Abacavir Sulfate; Lamivudine
- (2) Alendronate Sodium
- (3) Alfuzosin HCl
- (4) Alprazolam
- (5) Amoxicillin; Clavulanate Potassium (multiple RLDs)
- (6) Amprenavir
- (7) Aripiprazole
- (8) Armodafinil
- (9) Atovaquone
- (10) Azithromycin
- (11) Balsalazide Disodium
- (12) Bupropion HCl (updated)
- (13) Carbamazepine (multiple dosage forms)
- (14) Cefdinir
- (15) Cefixime
- (16) Cetirizine HCl; Pseudoephedrine HCl
- (17) Ciprofloxacin; Ciprofloxacin HCl
- (18) Ciprofloxacin HCl
- (19) Clarithromycin
- (20) Darunavir Ethanolate
- (21) Delavirdine Mesylate
- (22) Dexmethylphenidate
- (23) Diltiazem HCl (multiple dosage forms; multiple RLDs)

- (24) Divalproex Sodium
- (25) Doxycycline (multiple dosage forms)
- (26) Eprosartan Mesylate; Hydrochlorothiazide
- (27) Esterified Estrogens
- (28) Eszopiclone
- (29) Ethambutol HCl
- (30) Ethinyl Estradiol; Levonorgestrel (multiple RLDs)
- (31) Fenofibrate
- (32) Fluvastatin Sodium (multiple dosage forms)
- (33) Fosamprenavir Calcium
- (34) Glimepiride; Rosiglitazone Maleate
- (35) Lamivudine
- (36) Linezolid
- (37) Lisinopril
- (38) Lopinavir; Ritonavir
- (39) Memantine HCl
- (40) Mesalamine
- (41) Metoprolol Succinate (updated)
- (42) Minocycline HCl
- (43) Nelfinavir Mesylate
- (44) Nevirapine
- (45) Omeprazole; Sodium Bicarbonate; Magnesium Hydroxide
- (46) Oxymorphone HCl (multiple dosage forms)
- (47) Paliperidone
- (48) Paricalcitol
- (49) Phenytoin
- (50) Pimozide

- (51) Posaconazole
- (52) Quinine Sulfate
- (53) Saquinavir Mesylate (multiple dosage forms)
- (54) Solifenacin Succinate
- (55) Tenofovir Disoproxil Fumarate
- (56) Tinidazole
- (57) Tipranavir
- (58) Tolterodine Tartrate
- (59) Tramadol HCl
- (60) Trospium Chloride
- (61) Varenicline Tartrate
- (62) Zafirlukast
- (63) Zalcitabine
- (64) Zileuton
- (65) Zolmitriptan
- (66) Zonisamide

III. Drug Products for Which Updated Draft Product-Specific BE Recommendations Are Available

The following five product-specific recommendations previously made available on FDA's Web site have been updated:

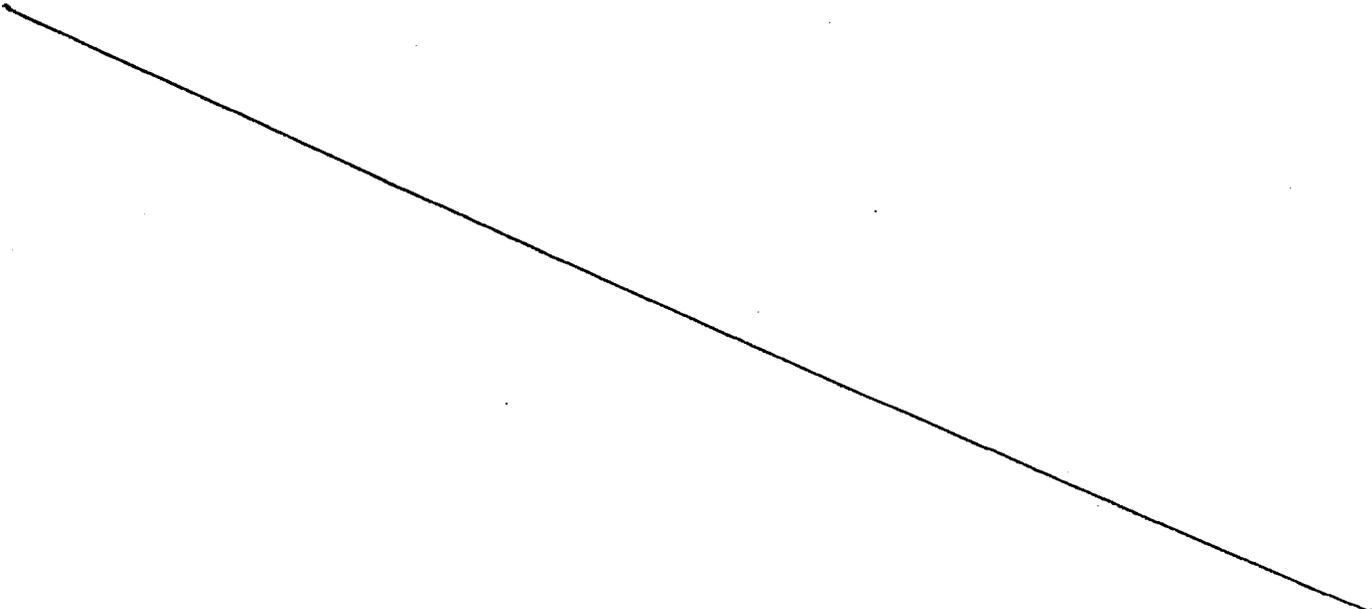
1. Risedronate Sodium
2. Fosinopril Sodium; Hydrochlorothiazide
3. Fluoxetine HCl; Olanzapine
4. Erlotinib HCl
5. Morphine Sulfate

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

IV. 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.

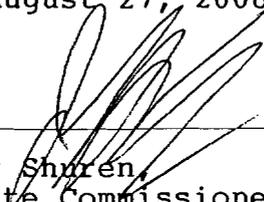
Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only at <http://www.regulations.gov>.



V. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.

Dated: 8/27/08
August 27, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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