

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

### 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:

A

Alendronate Sodium  
Alendronate Sodium; Cholecalciferol

B

Benzoyl Peroxide; Erythromycin (multiple RLDs)

M

Milnacipran HCl  
Mupirocin Calcium

N

Niacin; Simvastatin

S

Sevelamer HCl

### IV. Drug Products for Which Draft Product-Specific BE Recommendations Have Been Withdrawn

FDA is announcing the withdrawal of the product-specific BE recommendations for drug products containing the following ingredients: Acetaminophen; Propoxyphene Napsylate. FDA has requested that products containing propoxyphene be withdrawn from sale for reasons of safety or efficacy. The product-specific BE recommendations for Acetaminophen; Propoxyphene Napsylate that previously were published on the "Bioequivalence Recommendations for Specific Products" Web page have been deleted.

### V. 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 may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### VI. 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: 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-2012-N-0001]

### Food and Drug Administration/Xavier University Global Medical Device Conference

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University Global Medical Device Conference." This 3-day public conference includes presentations from key FDA officials and industry experts, and has two separate tracks of interest. The conference is intended for companies of all sizes and employees at all levels.

**Dates and Times:** The public conference will be held on May 2, 2012, from 8:30 a.m. to 5 p.m.; May 3, 2012, from 8:30 a.m. to 5 p.m.; and May 4, 2012, from 8:30 a.m. to 1 p.m.

**Location:** The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

**Contact Persons:** Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700, ext. 2167, FAX: 513-679-2771, email: [gina.brackett@fda.hhs.gov](mailto:gina.brackett@fda.hhs.gov).

**For information regarding the conference and registration:** Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, email: [phillipsm4@xavier.edu](mailto:phillipsm4@xavier.edu).

**Registration:** There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 3 days of the conference. Early registration ends March 6, 2012. Standard registration ends March 27, 2012. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES<sup>1</sup>

| Attendee                         | Fee by March 6th | Fee by March 27th |
|----------------------------------|------------------|-------------------|
| Industry .....                   | \$995 .....      | \$1,295           |
| Small Business (<100 employees). | 800 .....        | 900               |
| Consultant .....                 | 500 .....        | 600               |
| Academic .....                   | 200 .....        | 250               |
| FDA/Government Employee.         | Free .....       | Free              |

<sup>1</sup> The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the "Registration" link on the conference Web site at <http://www.XavierMedCon.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Sue Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th St., Cincinnati, OH, 45202, 513-421-9100. Special conference block rates are available through April 11, 2012. To make reservations online, please visit the "Venue & Logistics" link at <http://www.XavierMedCon.com>.

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

**SUPPLEMENTARY INFORMATION:** The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- CDRH Medical Device Innovation Initiative Keynote Address;
- 510(k)—Office of Device Evaluation Perspective;
- The Purchasing Control Subsystem—Requirements and Implementation;
- Draft 510(k) Guidance—Deciding When to Submit a 510(k) for a Change or Modification;
- Challenges of Design Controls;
- FDA 483s and Regulatory Action—Response Workshop;