

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 Drug Products for Which Draft Product-Specific BE Recommendations Have Been Withdrawn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 FDA has requested that products containing propoxyphene be withdrawn from sale for reasons of safety or efficacy.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.

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, email: 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 ¹

| 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 |

¹ 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;

- Recalls—Globally;
 - GHTF Document on CAPA—Workshop;
 - 510(k)—An Industry Perspective;
 - Interdependency of Postmarket Surveillance, Risk, and CAPA;
 - Promotional Practices—Global;
 - Office of Compliance Initiatives;
 - U.S. Senate HELP Committee
- Keynote Dinner;
- Risk Management Across the Quality Systems—FDA Expectations and Implementation;
 - Global Regulatory Strategy; and
 - FDA Inspectional Approach—Panel With Current FDA Investigators.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 15, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4036 Filed 2–21–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0093]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the Agency by April 23, 2012.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4160, Silver Spring, MD 20993–0002, 301–796–0578, email: dan.brum@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the

regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms interested in offering a site tour or learning more about this training opportunity should respond by submitting a proposed agenda to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: February 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Cardiothoracic Surgery Program.

Date: March 12, 2012.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7179, Bethesda, MD 20892–7924, 301–435–0287, carolko@mail.nih.gov.