

If you need special accommodations due to a disability, please contact Lynn Colegrove by phone 847-434-7820 at least 7 days in advance.

Registration and seating will be on a first-come, first-served basis. A discussion preference will be afforded to clinical research investigators involved in pediatric clinical device trials, health care givers, and patient advocates. There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited. There will be no onsite registration.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: In the medical device industry, rarely have devices been developed, evaluated, and approved specifically for treatment of children with congenital heart disease. The small, heterogeneous population, need for long-term followup, lack of market incentive, and misperceptions of regulatory requirements and costs are a few of the issues that make a standard randomized control trial difficult to conduct in pediatric cardiology. The goal of the workshop is to educate the medical device industry and pediatric clinical community about device development and regulatory approval processes, and to identify clinical trial designs that lend themselves to overcoming the challenges in pediatric cardiovascular device development. Subsequently making this information available to industry, the clinical community, and the public is imperative to furthering the development of pediatric cardiovascular devices and alleviating this critical unmet need. The marketing approval of more cardiovascular devices specifically designed and/or labeled for pediatric patients would have a significant impact on public health. Invited experts will address types of clinical trials with a particular focus on trial designs and statistical analysis methods, as well as alternative sources of clinical data, that can help to address the challenges in this particular patient population. After

each section there will be an audience question and answer session and panel discussion allowing workshop participants to interact with the speakers and panelists. A concluding session will allow for additional interactions.

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>.

Dated: August 4, 2010.

Nancy Stade,

Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0381]

Generic Drug User Fee; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to gather stakeholder input on the development of a generic drug user fee program. The number of human generic drug applications awaiting FDA action and the median review times for generic drug applications have increased in recent years. A user fee program could provide necessary supplemental funding, in addition to current Congressional appropriations, to allow for the timely review of such applications. Although the President's Fiscal Year (FY) 2011 budget includes generic drug user fees, new legislation would be required for FDA to establish and collect user fees under such a program. As FDA begins negotiations with the regulated industry about generic drug user fees, FDA will hold a public meeting to gather the public's input on such a program.

Date and Time: The public meeting will be held on September 17, 2010, from 9 a.m. to 5 p.m.

Location: The meeting will be held at the Hilton Washington DC/Rockville and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Persons: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6178, Silver Spring, MD 20993, 301-796-3519, FAX: 301-847-8753, e-mail:

mary.gross@fda.hhs.gov, or Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993, 301-796-4830, FAX: 301-847-3541, e-mail: peter.beckerman@fda.hhs.gov.

Registration and Requests for Oral Presentations: If you wish to attend and/or present at the meeting, please register by September 9, 2010. Please e-mail your registration information to GDUFA_Meeting@fda.hhs.gov. Those without e-mail access may register by contacting one of the persons listed in the *Contact Persons* section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail address, and phone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants, based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak, and if the entire meeting time is not needed for presentations, FDA reserves the right to terminate the meeting early.

If you need special accommodations due to a disability, please contact Mary Gross or Peter Beckerman (see *Contact Persons*) at least 7 days before the meeting.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments by October 17, 2010. Submit electronic comments 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m.,

Monday through Friday. Submission of comments prior to the meeting is strongly encouraged.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing its intention to hold a public meeting related to generic drug user fees. The number of generic drug applications awaiting FDA action and the median review time for such applications have increased. The Agency is soliciting comment on whether to seek a user fee program that would provide additional resources for the review of human generic drug applications, as well as what such a program should look like. New legislation would be required for FDA to establish and collect user fees for generic drugs, and FDA is initiating the process for defining the scope and structure of a generic drug user fee program. As part of this process, FDA will hold a public meeting to seek input from stakeholders and the public on generic drug user fees. In addition, members of the public are encouraged to submit written comments. FDA is particularly interested in responses to the following questions and welcomes other pertinent information stakeholders would like to share regarding the application process for generic drugs:

1. How, if at all, should a generic drug user fee program differ from FDA's existing user fee programs, including the Prescription Drug User Fee Act (PDUFA), the Animal Drug User Fee Act (ADUFA), the Medical Device User Fee and Modernization Act (MDUFMA) and Tobacco Product User Fees? (Information on these programs can be found at <http://www.fda.gov>).

2. What should a generic drug user fee program look like or how should a generic user fee be structured? (User fees for brand name drugs include a one-time fee for a new drug application and annual fees for marketed products and facilities at which these products are produced. Should the generic drug fees follow the same structure? If not, what are the unique aspects of the generic drug industry or market that should be considered and how might these impact a proposed user fee plan?)

3. Are performance goals recommended for FDA. If so, what performance goals would you recommend for FDA? If not, why not?

4. Should all applications pay the same fees and be subject to the same goals? (For example, should applications for more complex products pay a higher application fee to reflect the additional regulatory efforts they entail? Should such differences be captured through differential goals?)

5. Including applications for which exclusivities would prevent current marketing, and applications that are awaiting responses from sponsors for noted deficiencies, there is a current queue of over 2,000 applications under review, and approximately 800 new applications submitted each year. How should a generic drug user fee program address applications currently awaiting FDA review?

6. PDUFA currently supports oversight of post-marketing safety of drugs. What kind of support, if any, should a generic user fee provide for post-marketing safety?

II. Why Is FDA Undertaking This Process?

An important responsibility of FDA is to assess generic drug applications. Generic drugs currently are used to fill more than two-thirds of all prescriptions dispensed in the United States and they provide important cost-effective alternatives to the American public. Nonetheless, despite increasing productivity on the part of FDA's Office of Generic Drugs, the number of applications awaiting FDA action has been steadily increasing, and the median time for review of such applications has grown.

Similar to user fees for brand name human drugs, animal drugs, generic animal drugs, and medical devices, the intent of a generic drug user fee program would be to provide additional revenues so that FDA can hire more staff and improve systems to support the generic drug review process. FDA believes the supplementary revenues from generic drug user fees would allow the Agency to review generic drug applications in a timely manner and will provide flexibility, adequacy, and predictability in the funding of FDA's review of generic drug applications.

Although the President's FY 2011 budget contains a generic drug user fee program, new legislation would be needed to put such fees into place. At this time, generic drugs for humans are the largest category of preapproval products regulated by FDA and generic drug applicants do not currently pay any type of user fee. FDA believes that the predictability, flexibility, and adequacy of a funding stream from user fees and the accompanying ability to more efficiently review generic drug applications would benefit the public health, FDA, and the generic drug industry.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will FDA Use?

Through this notice, we are announcing a public meeting to hear stakeholder views on what features FDA should propose for a generic drug user fee program. We will conduct the meeting on September 17, 2010, at the Hilton Washington DC/Rockville and Executive Meeting Center, see *Location*).

In general, the meeting format will include presentations by FDA and presentations by stakeholders and members of the public who have registered in advance to present at the meeting. The amount of time available for presentations will be determined by the number of people who register to make a presentation. We will also provide an opportunity for organizations and individuals to submit written comments to the docket after the meeting. FDA policy issues are beyond the scope of this initiative. Accordingly, the presentations should focus on process and funding issues, and not focus on policy issues.

B. Will Meeting Transcripts Be Available?

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: August 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee