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.

[FR Doc. 2010–19537 Filed 8–6–10; 8:45 am]

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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

of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 15 and 16, 2010, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College (UMUC), 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301–985–7300.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 15, 2010, the committee will discuss the results of the Sibutramine Cardiovascular Outcomes Trial (SCOUT) (M01–392), for new drug application (NDA) 20–632, MERIDIA (sibutramine hydrochloride monohydrate) Capsules, sponsored by Abbott Laboratories, for treatment of obesity. The SCOUT study was a randomized, double-blind, placebo-controlled trial, which is a kind of clinical trial designed to provide data with strong measures of accuracy and reliability. The SCOUT trial evaluated the potential benefits of weight loss with MERIDIA on major cardiovascular (heart and blood circulation) adverse events. The preliminary results of the SCOUT trial indicated that clinical trial participants who received MERIDIA instead of placebo (no active drug) had a higher incidence of major cardiovascular adverse events that was statistically significant.

On September 16, 2010, the committee will discuss the safety and efficacy of new drug application (NDA) 22–529, with the proposed trade name LORQESS (lorcaserin hydrochloride) Tablets, sponsored by Arena Pharmaceuticals, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) of equal to or greater than 30 kilograms (kg) per square meter, or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related co-morbidities (which include, for example: High blood pressure, heart disease, or diabetes). The BMI is a measure of body weight (mass) based on a person's weight and height, and is a widely-used tool for doctors in assessing optimum weights for a patient.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 31, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 23, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 24, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 3, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–19484 Filed 8–6–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form G–639, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form G–639, Freedom of Information/Privacy Act Request; OMB Control No. 1615–0102.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on May 4, 2010, at 75 FR 23785, allowing for a 60-day public comment period. USCIS did not receive any comments for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until September 8, 2010. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS,