postmenopausal women have symptoms of VVA that require treatment, but some women (particularly those 5 to10 years postmenopausal), when asked, will report one or more of the above symptoms, which they deem to be bothersome and self-categorize as moderate to severe in intensity. To date, the Agency has approved estrogen products (both estrogen-alone and estrogen plus progestin) for the indications of ''treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy due to menopause'' and ''treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause.''

Estrogen-alone products have Boxed Warnings stating:

(1) There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogen;

(2) estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia;

(3) an increased risk of stroke and deep vein thrombosis was reported in the Women's Health Initiative (WHI) estrogen-alone substudy; and

(4) an increased risk of probable dementia in postmenopausal women 65 years of age and older was reported in WHI Memory Study (WHIMS) estrogen-alone ancillary study.

The WHI estrogen-alone studies evaluated only a single estrogen dose consisting of 0.625 mg of conjugated estrogen. As lower-dose estrogen products are now approved for the treatment of moderate to severe symptoms of VVA due to menopause, some in the scientific/medical community have questioned whether these statements in the Boxed Warning section are applicable in whole or in part to the lower-dose estrogen products.

II. Discussion Topics

The scientific workshop on November 10th will include discussions of scientific challenges related to the following topics:

- The relevance to lower-dose estrogen products of the Boxed Warnings related to the WHI findings that: (1) Estrogens should not be used for the prevention of cardiovascular disease or dementia, (2) there is an increased risk of stroke and deep vein thrombosis in women treated with estrogen-alone, and (3) there is an increased risk of probable dementia in postmenopausal women 65 years of age and older treated with estrogen-alone.
- How to educate prescribers on the interpretation of estrogen exposure data across various estrogen dosage forms indicated for treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause. Presentation of basic PK and clinical pharmacology data concepts and an informed framework for comparing various estrogen products for prescribing purposes.
- Discuss the level of available data supporting that a given estrogen serum concentration is or is not related to adverse outcomes (for example, pulmonary emboli, deep venous thrombosis, and myocardial infarction).
- Presentation and discussion of PD biomarkers for thrombosis. Presentation of a comparison of metabolic profiles from various products, key clotting factors responsible for thrombosis, and PK/PD relationships.

III. Meeting Attendance and Participation

If you wish to attend this meeting, email *FDAVVAworkshop@fda.hhs.gov.* Please register by October 16, 2015. Those who are unable to attend the meeting in person can register to view a live Webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the Webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and telephone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization 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. If you need special accommodations because of disability, please contact Kimberly Shiley (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

FDA will hold an open public comment session during the November 10th public meeting to give the public an opportunity to comment. Register for this session at *FDAVVAworkshop@fda.hhs.gov* by October 16, 2015. Additional registration will occur at the registration desk on the day of the meeting on a first-come, first-served basis if there is still time available during this session.

Docket Comments: Regardless of attendance at the meeting, you can submit electronic or written comments, including responses to the public docket (see **ADDRESSES**), by October 16, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Transcripts: Transcripts for the November 10th meeting will be posted, when available, at *http://www.fda.gov/Drugs/NewsEvents/ucm401167.htm*.

Dated: September 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24509 Filed 9–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3326]

Biosimilar User Fee Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting on the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2018 through 2022. BsUFA authorizes FDA to collect user fees for the process for the review of biosimilar biological products. The current legislative authority for BsUFA expires in September 2017. At that time, new legislation will be required for FDA to continue collecting user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA begin the BsUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input and holding a public meeting where the public may present its views on the reauthorization. FDA invites public comment on the BsUFA performance goals as the Agency begins the process to reauthorize the program in FYs 2018–2022.

DATES: The public meeting will be held on December 18, 2015, from 9 a.m. to 2 p.m. Registration to attend the meeting must be received by November 18, 2015. See section III of this document for information on how to register for the meeting. Submit written or electronic comments by January 19, 2016.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, in section B and C of the Great Room (Rm. 1503), Silver Spring, MD 20993. Participants must

enter through Building 1 and undergo security screening. For more information on parking and security procedures, please visit *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit written comments 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.* All comments should be identified with the docket number found in brackets in the heading of this document.

Transcripts of the meeting will be available on the FDA Web site approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993, 301–796–1042, FAX: 301–847–3529, *sandra.benton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, which included BsUFA (Pub. L. 112–144, title IV), was signed into law by the President. BsUFA authorizes FDA to collect fees for certain activities relating to biosimilar biological product development, for certain types of applications and supplements for approval of biosimilar biological products, on establishments where approved biosimilar biological products are made, and on biosimilar biological products after approval.

BsUFA's intent is to provide additional revenues so that FDA can hire more staff, improve systems, and establish a better managed biosimilar biological product review process to make biosimilar biological product therapies available to patients sooner without compromising review quality. As part of FDA's agreement with industry during the first BsUFA authorization, the Agency agreed to certain performance goals. These goals, which are captured in a Commitment Letter, apply to the process for the review of biosimilar biological product applications, including biosimilar biological product development meetings, review of applications and supplements, and other review activities.

Although BsUFA is similar to the Prescription Drug User Fee Act (PDUFA) program in that it includes fees for marketing applications, manufacturing establishments, and products, there are some differences because of the relatively nascent state of the biosimilar industry in the United States. For example, at the time BsUFA was signed into law, there were no currently marketed biosimilar biological products. Accordingly, BsUFA includes fees for products in the development phase in order to generate fee revenue to support FDA's review work during this phase and enable sponsors to have meetings with FDA early in the development of biosimilar biological product candidates. Additional information concerning BsUFA, including the text of the law, the ''Biosimilar Biological Product Authorization Performance Goals And Procedures—Fiscal Years 2013 Through 2017'' (the Commitment Letter), key **Federal Register** documents, BsUFA-related guidances, performance reports, and financial reports may be found on the FDA Web site at *http://www.fda.gov/forindustry/userfees/biosimilaruserfeeactbsufa/default.htm.*

II. Purpose of Public Meeting

FDA is announcing a public meeting on BsUFA. The authority for BsUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees to fund the biosimilar biological product review process. Before FDA begins negotiations with the regulated industry on BsUFA reauthorization, the Agency is holding the public meeting announced in this notice, at which members of the public may present their views on reauthorization, including any suggestions for changes to the performance goals referred to in the Commitment Letter. In addition, FDA will provide a period of 30 days after the public meeting to obtain written comments from the public. The purpose of this public meeting is to hear stakeholder views as we consider whether to retain, change, or discontinue the current BsUFA performance goals in the next BsUFA. In addition to any other relevant information the public would like to share, the FDA is interested in responses to the following two general questions:

- What is your assessment of the overall performance of the BsUFA program to date?
- What aspects of BsUFA performance goals should be retained, changed, or discontinued to further strengthen and improve the program?

The meeting will likely include presentations by FDA and a series of panels representing different stakeholder groups. We will also provide an opportunity for other stakeholders to provide public comment at the meeting. FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the comments should focus on process enhancements and funding issues, and not on policy issues.

III. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://fdapublicmeeting-bsufa.eventbrite.com.* Please register by November 18, 2015. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration must also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once their registrations have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Sandra Benton (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

In addition, any person may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Comments are to be identified 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, and will be posted to the docket at *http://www.regulations.gov.* To ensure consideration, all comments must be received by January 19, 2016.

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM461774.htm.*

Dated: September 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24524 Filed 9–25–15; 8:45 am]

BILLING CODE 4164–01–P