

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 disabilities. If you require accommodations due to a disability, please contact Kalyani Bhatt 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: July 25, 2016.

**Janice M. Soreth,**

*Acting Associate Commissioner, Special Medical Programs.*

[FR Doc. 2016-17864 Filed 7-27-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Oncologic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on September 14, 2016, from 8 a.m. to 1 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

#### FOR FURTHER INFORMATION CONTACT:

Lauren D. Tesh, 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, [ODAC@fda.hhs.gov](mailto:ODAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

#### SUPPLEMENTARY INFORMATION:

**Agenda:** The committee will discuss new drug application 208714, apaziquone for intravesical instillation, application submitted by Spectrum Pharmaceuticals, Inc. The proposed indication (use) for this product is for immediate intravesical instillation post-transurethral resection of bladder tumors in patients with non-muscle invasive bladder cancer.

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 meeting 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 30, 2016. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Those individuals interested in making 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 22, 2016. 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 23, 2016.

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 disabilities. If you require special accommodations due to a disability, please contact Lauren D. Tesh 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: July 25, 2016.

**Janice M. Soreth,**

*Acting Associate Commissioner, Special Medical Programs.*

[FR Doc. 2016-17865 Filed 7-27-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0007]

#### Biosimilar User Fee Rates for Fiscal Year 2017

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2017. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development, certain applications and supplements for

approval of biosimilar biological products, establishments where approved biosimilar biological products are made, and a biosimilar biological product fee for each biosimilar biological product approved in a biosimilar biological product application.

BsUFA directs FDA to establish, before the beginning of each fiscal year, the initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application, establishment, and product fees. These fees are effective on October 1, 2016, and will remain in effect through September 30, 2017.

**FOR FURTHER INFORMATION CONTACT:**

David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202I, Silver Spring, MD 20993-0002, 240-402-9845.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j-51, 379j-52, and 379j-53), as added by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144), establish fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD program.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the

date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA also establishes fees for certain applications and supplements, establishments where approved biosimilar biological products are made in final dosage form, and for each biosimilar biological product approved in a biosimilar biological product application (section 744H(a)(2), 744H(a)(3), and 744H(a)(4), respectively, of the FD&C Act). Under certain conditions, FDA may grant a small business a waiver from its first biosimilar biological product application fee (section 744H(c)(1) of the FD&C Act).

Under BsUFA, the initial and annual BPD fee rates for a fiscal year are equal to 10 percent of the fee rate established under the Prescription Drug User Fee Act (PDUFA) for an application requiring clinical data for that fiscal year. The reactivation fee is equal to 20 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year. Finally, the application, establishment, and product fee rates under BsUFA are equal to the application, establishment, and product fee rates under PDUFA, respectively (section 744H(b)(1) of the FD&C Act).

**II. Fee Amounts for FY 2017**

BsUFA directs FDA to establish the biosimilar biological product fee rates in each fiscal year by reference to the user fees established under PDUFA for that fiscal year. For more information about BsUFA, please refer to the FDA Web site at <http://www.fda.gov/bsufa>. The BsUFA fee calculations for FY 2017 are described in this document.

*A. Initial and Annual BPD Fees, Reactivation Fees*

Under BsUFA, the initial and annual BPD fees equal 10 percent of the PDUFA fee for an application requiring clinical data, and the reactivation fee equals 20 percent of the PDUFA fee for an application requiring clinical data. The FY 2017 fee for an application requiring clinical data under PDUFA is \$2,038,100. Multiplying the PDUFA application fee, \$2,038,100, by 0.1 results in FY 2017 initial and annual BPD fees of \$203,810. Multiplying the PDUFA application fee, \$2,038,100, by 0.2 results in a FY 2017 reactivation fee of \$407,620.

*B. Application and Supplement Fees*

The FY 2017 fee for a biosimilar biological product application requiring clinical data equals the PDUFA fee for an application requiring clinical data, \$2,038,100. The FY 2017 fee for a biosimilar biological product application not requiring clinical data equals half this amount, \$1,019,050. However, under section 744H(a)(2)(A) of the FD&C Act, if a sponsor submitting a biosimilar biological product application has previously paid an initial BPD fee, annual BPD fee(s), and/or reactivation fee(s) for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees. The FY 2017 fee for a biosimilar biological product supplement with clinical data is \$1,019,050, which is half the fee for a biosimilar biological product application requiring clinical data.

*C. Establishment Fee*

The FY 2017 biosimilar biological product establishment fee for establishments where approved biosimilar biological products are made is equal to the FY 2017 PDUFA establishment fee of \$512,200.

*D. Product Fee*

The FY 2017 biosimilar biological product fee for each biosimilar biological product approved in a biosimilar biological product application is equal to the FY 2017 PDUFA product fee of \$97,750.

**III. Fee Schedule for FY 2017**

The fee rates for FY 2017 are provided in table 1.

**TABLE 1—FEE SCHEDULE FOR FY 2017**

Fee category	Fee rates for FY 2017 (\$)
Initial BPD .....	203,810
Annual BPD .....	203,810
Reactivation .....	407,620
Applications <sup>1</sup> .....	.....
Requiring clinical data .....	2,038,100
Not requiring clinical data ....	1,019,050
Supplement requiring clinical data .....	1,019,050
Establishment .....	512,200
Product .....	97,750

<sup>1</sup> Under section 744H(a)(2)(A) of the FD&C Act, if a sponsor that submits a biosimilar biological product application has previously paid an initial BPD fee, annual BPD fees, and/or reactivation fees for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees.

#### IV. Fee Payment Options and Procedures

##### A. Initial BPD, Reactivation, Application, and Supplement Fees

The fees established in the new fee schedule are effective October 1, 2016. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application.

The application or supplement fee for a biosimilar biological product is due upon submission of the application or supplement.

To make a payment of the initial BPD, reactivation, supplement, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (<http://www.fda.gov/bsufa>) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. Once you search for your invoice, click "Pay Now" to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use <http://www.pay.gov>, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after completing the Biosimilar User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order, and make it payable to the

Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. If you prefer to send a check by a courier such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, ATTN: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact U.S. Bank at 314-418-4013 if you have any questions concerning courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002.

The tax identification number of FDA is 53-0196965.

##### B. Annual BPD, Establishment, and Product Fees

FDA will issue invoices for annual BPD, biosimilar biological product establishment, and biosimilar biological product fees under the new fee schedule in August 2016. Payment instructions will be included in the invoices. Payment will be due on October 1, 2016. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2016, FDA will issue invoices in November 2016 to firms subject to fees for FY 2017 that qualify for the annual BPD fee after the August 2016 billing. FDA will issue invoices in November 2017 for any annual products and establishments subject to fees for FY 2017 that qualify for fee assessments after the August 2016 billing.

Dated: July 22, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-17800 Filed 7-27-16; 8:45 am]

**BILLING CODE 4164-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

##### National Cancer 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 Cancer Institute Special Emphasis Panel; NCI SPORE Review Meeting.

*Date:* October 7, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20892.

*Contact Person:* Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W120, Rockville, MD 20892-9750, 240-276-6457, [mh101v@nih.gov](mailto:mh101v@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Program Project Review III (P01).

*Date:* October 13-14, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

*Contact Person:* Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W612, Rockville, MD 20892-9750, 240-276-5413, [klaus.piontek@nih.gov](mailto:klaus.piontek@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Questions in Cancer Systems Biology.

*Date:* October 13, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

*Contact Person:* Caterina Bianco, MD, Ph.D., Scientific Review Officer, Research Programs Review, Branch Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room