investigational new drug review costs are included in this amount.) Twenty-nine of these applications (20 NDAs and 9 BLAs) received priority review, which would mean that the remaining 19 received standard reviews. Because a priority review compresses a review that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject. In the article ''Developing Drugs for Developing Countries,'' published in ''Health Affairs,'' Volume 25, Number 2, in 2006, the comparison of historical average review times by David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe, supports a priority review multiplier in the range of 1.48 to 2.35. The multiplier derived by FDA falls well below the midpoint of this range. Using FY 2014 figures, the costs of a priority and standard review are estimated using the following formula:

$$(29\ \alpha \times 1.67) + (19\ \alpha) = \$268{,}974{,}000$$

where ''α'' is the cost of a standard review and ''$\alpha \times 1.67$'' is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be $3,989,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $6,662,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or $2,673,000, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2016 fee, FDA will need to adjust the FY 2014 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2015, to adjust the FY 2014 amount for cost increases in FY 2015. That adjustment, published in the **Federal Register** on August 3, 2015 (see 80 FR 46028 at 46029), setting FY 2016 PDUFA fees, is 2.0266 percent for the most recent year, not compounded. Increasing the FY 2014 incremental priority review cost of $2,673,000 by 2.0266 percent results in an estimated cost of $2,727,000 (rounded to the nearest thousand dollars). This is the priority review user fee amount for FY 2016 that must be submitted with a priority review voucher in FY 2016, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2016

The fee rate for FY 2016 is set out in table 1:

TABLE 1—TROPICAL DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2016

Fee category	Fee rate for FY 2016
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee	$2,727,000

IV. Implementation of Tropical Disease Priority Review User Fee

Under section 524(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of a human drug application for which the priority review voucher is used. Section 524(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act and FDA may not collect priority review voucher fees prior to a relevant appropriation for fees for that fiscal year. Beginning with FDA's appropriation for FY 2009, the annual appropriation language states specifically that ''priority review user fees authorized by 21 U.S.C. 360n (section 524 of the FD&C Act) may be credited to this account, to remain available until expended.'' (Pub. L. 111–8, Section 5, Division A, Title VI).

The tropical disease priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2015, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. The user fee identification (ID) number should be included on the check, followed by the words ''Tropical Disease Priority Review.'' Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only.) The FDA post office box number (P.O. Box 979107) must be written on the check. The tax identification number of FDA is 53–0196965.

Wire transfer payments may also be used. 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: New York Federal Reserve Bank, U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002.

Dated: September 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23006 Filed 9–11–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Anesthetic and Analgesic Drug Products 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: Anesthetic and Analgesic Drug Products 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 November 6, 2015, from 8 a.m. to 5 p.m.

Location: 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.

Contact Person: Stephanie L. Begansky, 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, *AADPAC@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.

Agenda: The committee will discuss new drug application (NDA) 022225, sugammadex sodium injection, submitted by Organon USA Inc., a subsidiary of Merck & Co., Inc., for the proposed indication of reversal of moderate or deep neuromuscular blockade (NMB) induced by rocuronium or vecuronium.

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 October 23, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 October 15, 2015. 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 October 16, 2015.

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 accommodations due to a disability, please contact Stephanie L. Begansky 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: September 8, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–22984 Filed 9–11–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1600]

Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent; Guidance for Industry and Tobacco Retailers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent.'' This guidance provides information to tobacco retailers on FDA's enforcement policy regarding certain so-called provisional tobacco products that become subject to not substantially equivalent (NSE) orders issued under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–2000. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–2000, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent.'' This guidance provides information to tobacco retailers on FDA's enforcement policy regarding certain so-called provisional tobacco products that become subject to NSE orders issued under the FD&C Act. We received several comments to the draft guidance (79 FR 10534, February 25, 2014), and those comments were considered as the guidance was finalized.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent.'' It does not