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.*

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record and will be accessible to the public at *http://www.regulations.gov.* The transcript of the proceedings from the public meeting will become part of the administrative record. Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov,* Docket No. FDA–2014–N–1049, and at FDA's CVM Web site at: *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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 the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be recording the meeting via Adobe Connect on March 16, 2015. Once the recording has been made 508 compliant, it will be accessible at FDA's CVM Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm.*

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03004 Filed 2–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1050]

Regulation of Combination Drug Medicated Feeds; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting to explore the feasibility of pursuing statutory revisions that may modify the current requirement that the use of multiple new animal drugs in the same medicated feed be subject to an approved application. This policy exploration is consistent with a stated performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter. FDA is requesting that you submit any comments related to this issue by March 31, 2016.

Date and Time: The public meeting will be held on March 16, 2015, from 9 a.m. until 12 p.m.

Location: The public meeting will be held at the Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., 3rd Floor, Rockville, MD 20855. Parking is free.

Contact Person: Laura Bradbard, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rm. 159, Rockville, MD 20855, 240–276–9109, FAX: 240–276–9020, email: *Laura.Bradbard@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this meeting must register by March 10, 2015. For general questions about the meeting, for assistance to register for the meeting, to request an opportunity to make an oral presentation, or to request special accommodations due to a disability, contact Laura Bradbard (see *Contact Person*). Please include your name, organization, and contact information. If you are requesting an opportunity to speak, please send a brief summary of your comments. Early registration for the meeting is encouraged due to limited time and space.

SUPPLEMENTARY INFORMATION:

I. Background

FDA considers the timely review of the safety and effectiveness of new animal drugs to be central to the Agency's mission to protect and promote the public health. Before 2004, the timeliness and predictability of the new animal drug review program was a concern. The Animal Drug User Fee Act enacted in 2003 (Pub. L. 108–130; hereinafter referred to as ''ADUFA I''), authorized FDA to collect user fees for 5 years—fiscal year (FY) 2004 to FY 2008—that were to be dedicated to expediting the review of new animal drug applications (NADAs) according to certain performance goals and to expand and modernize the new animal drug review program. The Agency agreed to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new animal drug application review process.

In 2008, before ADUFA I expired, Congress passed the Animal Drug User Fee Amendments of 2008 (Pub. L. 110–316; hereinafter referred to as ''ADUFA II''), which included an extension of ADUFA for an additional 5 years—FY 2009 to FY 2013. ADUFA II performance goals were established based on ADUFA I FY 2008 review timeframes. In addition, FDA provided program enhancements to reduce review cycles and improve communications during reviews.

In 2013, before ADUFA II expired, Congress passed ADUFA III (Pub. L. 113–14), which was signed by the President on June 13, 2013. Like its predecessors, ADUFA III includes its own comprehensive set of performance goals. One such goal, as stated in the ADUFA III goals letter, is: Beginning in early FY 2014, the Agency agrees to explore, in concert with affected parties, the feasibility of pursuing statutory revisions, consistent with the Agency's mission to protect and promote the public health, that may modify the current requirement that the use of multiple new animal drugs in the same medicated feed be subject to an approved application and develop recommendations by September 30, 2016.

Currently, the use of multiple new animal drugs in the same medicated feed (*i.e.,* a combination drug medicated feed) requires an approved NADA for each new animal drug in the combination and a separate approved NADA for the combination new animal drug itself (21 U.S.C. 360b(d)(4); 21 CFR 514.4(c)). FDA and members of regulated industry jointly agreed to explore, as part of the performance goals outlined in the ADUFA III goals letter, potential changes to the approval process for the use of a combination drug medicated feed. The intent of this exploration is to consider changes intended to allow combination drug medicated feeds to be made available to the end user in the most efficient manner possible while protecting and promoting the public health.

This public meeting is intended to provide an additional opportunity for public comment. Although in the ADUFA III performance goals letter FDA only agreed to explore the feasibility of pursuing statutory changes, the Agency also invites comment on potential changes to procedures and requirements

related to the approval process for these products that can be accomplished under the Agency's existing statutory authority. FDA will consider comments received at this meeting as it moves forward with this process.

FDA has already opened public docket FDA Docket No. FDA–2014–N–1050 to receive comments on the issue (79 FR 53431, September 9, 2014). Although you can comment on this document at any time, to ensure that the Agency considers your comment before finalizing work on the exploration process described in this document, submit either electronic or written comments by March 31, 2016.

II. Participation in a Public Meeting

While oral presentations from specific individuals and organizations may be limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administration record (the docket). All relevant data and documentation should be submitted with the comments to Docket No. FDA–2014–N–1050. 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. Identify comments with the docket number FDA–2014–N–1050. 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.*

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record and will be accessible to the public at *http://www.regulations.gov.* The transcript of the proceedings from the public meeting will become part of the administrative record. Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov,* Docket No. FDA–2014–N–1050, and at FDA's CVM Web site at: *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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 the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be recording the meeting via Adobe Connect on March 16, 2015. Once the recording has been made 508 compliant, it will be accessible at FDA's CVM Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm.*

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03002 Filed 2–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

The Tobacco Products Scientific 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). At least one portion of the meeting will be closed to the public.

Name of Committee: The Tobacco Products Scientific 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 April 9, 2015, from 8:30 a.m. to 5 p.m. and April 10, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak, 10903 New Hampshire Ave., Building 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: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *TPSAC@fda.hhs.gov.* 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: On April 9 and 10, 2015, the Committee will discuss modified risk tobacco product applications submitted by Swedish Match North America Inc. for 10 tobacco products:

- MR0000020: General Loose, smokeless tobacco, loose snus, 1.59 oz (45g), cardboard can (SKU 4852);
- MR0000021: General Dry Mint Portion Original Mini, smokeless tobacco, snus portions, 0.21 oz (6g), 20 0.3g portions, plastic can (SKU 4800);
- MR0000022: General Portion Original Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4880);
- MR0000023: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15 0.9g portions, plastic can (SKU 4877);
- MR0000024: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12 0.9g portions, plastic can (SKU 4878);
- MR0000025: General Mint Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4352);
- MR0000026: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15 0.9g portions, plastic can (SKU 4876);
- MR0000027: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12 0.9g portions, plastic can (SKU 4875);
- MR0000028: General Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4881); and
- MR0000029: General Wintergreen Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4882).

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