

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.*

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## 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](mailto: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

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:** On April 9, 2015, from 8:30 a.m. to 4 p.m. and on April 10, 2015, from 8 a.m. to 5 p.m., the meeting is open to the public. 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 March 20, 2015. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. on April 10, 2015. 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 March 12, 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 March 13, 2015.

**Closed Committee Deliberations:** On April 9, 2015, between 4 p.m. and 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (see 5 U.S.C. 552b(c)(3) and (c)(4)). This portion of the meeting will be closed because the Committee will be discussing trade secret and/or confidential data provided by Swedish Match North America Inc.

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 Caryn Cohen 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: February 9, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Bethesda Campus Master Plan Record of Decision

**SUMMARY:** The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (FEIS) and a thorough consideration of the public comments on the Draft EIS, to implement the Proposed Action, referred to as the Proposed Action in the Final EIS. This action is for a long-range physical Master Plan for National Institutes of Health Bethesda Campus (NIH) located in Bethesda, Maryland. This alternative accounts for potential growth in NIH personnel, new construction, additions, renovations, demolitions, and upgrades in site utilities.

**Responsible Official:** Daniel G. Wheeland, Director, Office of Research Facilities (ORF) Development and Operations, NIH.

**FOR FURTHER INFORMATION CONTACT:** Valerie Nottingham, Deputy Director, DEP, ORF, NIH, Building 13, Room 2S11, 9000 Rockville Pike, Bethesda, MD 20892, Phone 301-496-7775, [nihnepa@mail.nih.gov](mailto:nihnepa@mail.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement for the Master Plan, National Institutes of Health Bethesda Campus, and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

##### Selected Alternative

The Selected Alternative is intended to be a strategic tool for the efficient allocation of campus resources, the orderly accommodation of future growth, and the creation of an environment that is both functionally and aesthetically conducive to

accomplishing the NIH mission. The Selected Alternative will provide a guide for the reasoned and orderly development of the NIH campus, one that values and builds on existing resources, corrects current deficiencies and meets changing needs through new construction or renovation. The plan sets forth implementation priorities and a logical sequencing of planned development.

The Selected Alternative is for a long-range physical Master Plan for NIH. This alternative covers a 20-year planning period, with reviews every 5 years to ensure that the plan continues to address issues affecting the campus. The alternative addresses the future development of the NIH site, including placement of future construction; vehicular and pedestrian circulation on and off-campus; parking within the property boundaries; open space in and around the campus; required setbacks; historic properties; natural and scenic resources; noise; and lighting. This alternative accounts for potential growth in NIH personnel, and consequent construction of space over the planning period. Future construction on the site could include such facilities as new animal holding, research laboratories, and support facilities.

NIH will continue to develop the Bethesda campus to accommodate NIH's research needs and required programmatic needs consistent with the commitment to maintain the "campus" character of the site. The Selected Alternative advances this objective by programming and locating future NIH growth so that new development would tie into the existing utility services and utilities are available to support growth, and establishing development guidelines for future changes to the site that ensure that as the campus grows new development would be responsive to the context of adjacent neighborhoods or developments. Under the Selected Alternative, the total NIH population on the campus is anticipated to grow in the next twenty years to a total of approximately 23,594, which is an increase of approximately 3,000 employees. The primary growth at the campus would be in intramural research personnel and the administrative and facility staff to support them. The majority, if not all, of the employees would be coming from off-site facilities and are already employees, or contractors, of NIH.

##### Alternatives Considered

The Proposed Action Alternative, the Redevelopment Alternative and No Action Alternative were the three alternatives analyzed in the Final EIS.