Notice requests comment on whether and how studies should also be rated on the number of null effects on 'target outcomes', and on whether and how ratings should consider the number or magnitude of unfavorable effects.

2.5.3 Sustained Favorable Effect. HHS intends for studies with at least one favorable effect on a 'target outcome', as determined by the criteria in *2.5.1 Favorable Effects,* to be rated on whether or not they demonstrate a sustained favorable effect. As noted in section 471(e)(4)(C), a 'supported practice' must have at least one study that demonstrates ''a sustained effect (when compared to a control group) for at least 6 months beyond the end of treatment'' and a 'well-supported practice' must have at least one study that demonstrates ''a sustained effect (when compared to a control group) for at least 1 year beyond the end of treatment.'' HHS intends to classify studies as not demonstrating a sustained favorable effect (*i.e.,* effects are demonstrated for less than 6 months), demonstrating a sustained favorable effect of 6 months or more (but less than 12 months), or demonstrating a sustained favorable effect of 12 months or more.

2.5.4 Rigorous Study Design. HHS intends to rate studies as either high, moderate, or low on the rigor and appropriateness of their study design. Study designs that receive the highest rating will be either Randomized Controlled Trials (RCTs) or rigorous quasi-experimental designs. HHS defines randomized controlled trials as a study design in which sample members are assigned to the program or service and comparison groups by chance. Randomized control designs are often considered the ''gold standard'' of research design because personal characteristics (before the program or service begins) do not affect whether someone is assigned to the program or service or control group. HHS defines a quasi-experimental design as a study design in which sample members are selected for the program or service and comparison groups in a nonrandom way. Similar to criteria considered in other federal evidence clearinghouses, rigorous study designs will be those that are appropriately powered, include an appropriate control group, maintain original assignment to study arms, and are appropriate to combat threats to internal validity. This Notice requests comment on threats to internal validity that should be considered. This Notice requests comment on appropriate thresholds for evaluating and assigning a rating to a study design.

2.5.5 Rigorous Study Analysis. HHS intends to rate studies as either high, moderate, or low on the rigor and appropriateness of their analysis. Study analyses that receive the highest rating may be those that tested and established baseline equivalence, appropriately accounted for overall and differential sample attrition, appropriately accounted for multiple comparisons, and when necessary accounted for clustering. This Notice requests comment on appropriate thresholds for evaluating and assigning a rating to a study analysis.

2.5.6 Reliability, Validity, and Systematic Administration of Outcome Measures. HHS intends to rate studies as either high, moderate, or low on the extent to which 'target outcome' measures are reliable (*i.e.,* the extent to which a measure produces the same results when used repeatedly), valid (*i.e.,* the extent to which a measure captures what it is intended to measure), and were administered consistently and accurately across all those receiving the practice in accordance with FFPSA statutory language [section 471(e)(4)(C)] or receiving the appropriate comparison practice. This Notice requests comment on appropriate thresholds for evaluating and assigning a rating to the reliability, validity, and administration of 'target outcome' measures.

2.6 *Program or Service Rating Criteria.* HHS intends for programs or services to be rated as promising, supported, or well-supported practices if they meet the below criteria that collectively assess the strength of evidence for a practice and build from the individual study criteria described in section *2.5 Study Rating Criteria.* These criteria were developed in accordance with FFPSA statutory language [section 471(e)(4)(C)].

2.6.1 *Promising Practice:* HHS intends to designate a program or service as a 'promising practice' if the program or service has at least one study that demonstrates a favorable effect on a target outcome as described by criterion *2.5.1 Favorable Effects* and achieves, at a minimum, moderate ratings on criteria *2.5.4* through *2.5.6.*

2.6.2 *Supported Practice:* HHS intends to designate a program or service as a 'supported practice' if the program or service has at least one study that demonstrates a favorable effect on a target outcome as described by *2.5.1 Favorable Effects,* demonstrates a sustained favorable effect on a target outcome of at least 6 months beyond the end of treatment as described in *Section 2.5.3 Sustained Favorable Effect,* and achieves the high rating on criteria *2.5.4* through *2.5.6.*

2.6.3 *Well-Supported Practice:* HHS intends to designate a program or service as a 'well-supported practice' if the practice has at least two studies with non-overlapping analytic samples and distinct implementations that demonstrate favorable effects as described by *2.5.1 Favorable Effects,* demonstrate sustained favorable effects of at least 12 months beyond the end of treatment as described in *Section 2.5.3 Sustained Favorable Effect,* and achieve the high rating on criteria *2.5.4* through *2.5.6.*

HHS does not intend to rate a program or service as a 'promising', 'supported', or 'well-supported practice' if there is an empirical basis, as evidenced by multiple unfavorable effects on target or non-target outcomes across reviewed studies, as described in *2.5.2 Unfavorable Effects,* that suggest the overall weight of evidence does not support the benefits of the program or service. This Notice requests comment on approaches for determining that promising, supported, and well-supported practices do not constitute a risk of harm. As described in FFPSA [section 471(e)(4)(C)], ''There is no empirical basis suggesting that, compared to its likely benefits, the practice constitutes a risk of harm to those receiving it'', ''If multiple outcome studies are conducted, the overall weight of evidences supports the benefits of the practice'', and ''There is no case data suggesting a risk of harm that was probably caused by the treatment and that was severe or frequent''.

3.0 Recommendations of Potential Candidate Programs and Services for Review

This Notice requests comment on potential candidate programs and services to consider for the systematic evidence review. Comments should identify how recommended programs and services meet the criteria described in section *2.1 Program or Service Eligibility Criteria.* These criteria include: Types of Programs and Services and Book/Manual/Writings Available. Comments should also identify how recommended programs and services meet the criteria described in section *2.2 Program or Service Prioritization Criteria.* These criteria include: Types of Programs and Services, Target Population of Interest, Target Outcomes, Number of Impact Studies, In Use/Active, Implementation and Fidelity Support, Trauma-Informed, and Delivery Setting for In-Home Parent Skill-Based Programs and Services. In order to leverage new insights from the field, HHS may put forth additional future Notices requesting recommendations of potential candidate programs and services for review.

4.0 Submission of Comments

Comments may be submitted until July 22, 2018 by email to *ffclearinghouse@acf.hhs.gov.*

Naomi Goldstein,

Deputy Assistant Secretary for Planning, Research, and Evaluation.

[FR Doc. 2018–13420 Filed 6–21–18; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2066]

Tobacco Products Scientific 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 Tobacco Products Scientific 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 13, 2018, from 8:30 a.m. to 5 p.m. and on September 14, 2018, from 8 a.m. to 3 p.m.

ADDRESSES: FDA White Oak Conference Center, 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: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *TPSAC@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 website at *https://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: On September 13 and 14, 2018, the Committee will discuss modified risk tobacco product applications, submitted by R.J. Reynolds Tobacco Company for six products:

- MR0000068: Camel Snus Frost
- MR0000069: Camel Snus Frost Large
- MR0000070: Camel Snus Mellow
- MR0000071: Camel Snus Mint
- MR0000072: Camel Snus Robust
- MR0000073: Camel Snus Winterchill

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 website 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 website after the meeting. Background material is available at *https://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 29, 2018. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. on September 14, 2018. 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 16, 2018. 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 17, 2018.

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 Caryn Cohen at least 7 days in advance of the meeting (see, **FOR FURTHER INFORMATION CONTACT**).

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: June 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–13405 Filed 6–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Institute on Drug Abuse Special Emphasis Panel; Mechanism for Time-Sensitive Drug Abuse Research (R21 Clinical Trial Optional).

Date: June 29, 2018.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301–827–5820, *hiromi.ono@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Multi-site Clinical Trials.

Date: July 26–27, 2018.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, (301) 827–5817, *mcguireso@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)