public will have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, 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 those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://fda.zoomgov.com/j/1604157441?pwd=YkVzZ28vNHQrVXh3ZlhrTmlHaFVzZz09.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, 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*, 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 June 26, 2024, the Center for Tobacco Product's TPSAC will convene for one open session, during which the committee will discuss the renewal of a risk modification order, submitted by Swedish Match USA, Inc. for the following loose snus and portioned snus products:

- MR0000020: General Loose
- MR0000021: General Dry Mint Portion Original Mini
- MR0000022: General Portion Original Large
- MR0000024: General Classic Blend Portion White Large—12 ct
- MR0000025: General Mint Portion White Large
- MR0000027: General Nordic Mint Portion White Large—12 ct
- MR0000028: General Portion White Large
- MR0000029: General Wintergreen Portion White Large

Additional discussion about broader Modified Risk Tobacco Products program developments related to the conceptualization and measurement of consumer understanding will also occur.

The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

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. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

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 June 20, 2024. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. EST on June 26, 2024. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement describing the general nature of the evidence or arguments they wish to present and the names and email addresses of proposed participants, whether they would like to present online or in person, on or before June 11, 2024, by 5 p.m. Eastern Time. 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. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in person. The contact person will notify interested persons regarding their request to speak by June 12, 2024.

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 Serina Hunter-Thomas 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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: May 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09786 Filed 5–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5365]

Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.'' This draft guidance, when finalized, will describe the factors FDA intends to assess when deciding to issue an enforcement policy regarding test manufacturers' offering of certain unapproved tests and unapproved uses of approved tests during a declared emergency. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–5365 for ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

During an emergency, appropriately safe and effective diagnostic tests are critical to the diagnosis, treatment, tracking, and interruption of transmission of infectious diseases during outbreaks, as well as for diagnosing and treating diseases or conditions caused by chemical, biological, radiological, and nuclear threat agents. FDA is issuing this draft guidance that, when finalized, will describe the factors FDA plans to assess in deciding whether to issue an enforcement policy regarding test manufacturers' offering of certain unapproved tests and unapproved uses of approved tests for the diagnosis of a disease or other condition to help quickly increase test availability when appropriate during a declared emergency under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This draft guidance describes the factors FDA intends to assess when issuing an enforcement policy including: (1) the need for accelerated availability of tests; (2) the known or potential risks of such tests; (3) the availability of appropriate alternative tests that are authorized or approved; and (4) the availability of sufficient mitigations to address risks of false results. When issuing an enforcement policy, FDA generally intends to describe the circumstances in which the Agency intends to exercise enforcement discretion, including, for example, when the test has been validated. FDA may also identify the initial duration in which an enforcement policy is intended to be in effect.

This draft guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov and https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007009 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595
803	Medical Device Reporting	0910–0437
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988'' (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08933 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, May 7, 2024, 10:00 a.m. to May 8, 2024, 3:30 p.m., National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Rooms A, B, & C, Bethesda, MD 20817 which was published in the **Federal Register** on April 9, 2024, FR Doc. 2024–07500, 89 FR 24846.

This notice is being amended to replace the Contact Person from Ranga V. Srinivas, Ph.D. to Philippe Marmillot, Ph.D. Director, Office of Extramural Activities, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Room 2118, Bethesda, MD 20892, (301) 443–2861, *marmillotp@mail.nih.gov.* Additionally, the meeting end time on May 8, 2024, has changed from 3:30 p.m. to 3:45 p.m. The meeting on May 7, 2024, is partially closed to the public in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended, and the meeting on May 8, 2024, is open to the public.

Dated: April 30, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09727 Filed 5–3–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: Center for Scientific Review Special Emphasis Panel; RFA–NS–24–021: HEAL Initiative: Individual Differences in Human Pain Conditions.

Date: June 3–4, 2024.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Mark Allen Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, Bethesda, MD 20892, 301–402–4128, *mark.vosvick@nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Motor Function, Speech and Rehabilitation Study Section.

Date: June 3–4, 2024.

Time: 9:00 a.m. to 7:00 p.m.