

interested in any other pertinent information stakeholders would like to share on this topic. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

Questions

1. Given the legal requirements in place for applications submitted under section 505(b) and approved under section 505(c) of the FD&C Act, are there regulatory or policy rationales for treating PANDAs differently from other 505(b) applications in certain respects, in particular with respect to the following:

1.1. Labeling requirements, including requirements related to updating product labeling to reflect certain types of newly acquired safety-related information by submitting a “changes being effected” (CBE-0) supplement to FDA?

1.2. Patent listing requirements?

1.3. Eligibility for exclusivity?

1.4. Certain safety-related requirements, such as the postmarket studies and clinical trials or safety-labeling change requirements in section 505(o) of the FD&C Act or the risk evaluation and mitigation strategies requirements in section 505-1 of the FD&C Act?

In responding to the questions above, please provide a specific rationale for treating these applications differently.

2. To the extent that PANDA holders are expected to make changes to their current practices, what factors should FDA consider in determining a reasonable amount of time for PANDA holders to make such changes to their practices?

3. Are there additional steps FDA should take to highlight for PANDA holders that their “abbreviated new drug application” is a PANDA, *i.e.*, that it is a 505(b) application?

4. Are there additional steps FDA should take beyond posting the list on the Orange Book website to aid other interested persons in identifying PANDAs?

5. Are modifications needed to the list of PANDAs posted on the Orange Book website for accuracy? For example, are some PANDAs missing from the list?

6. Are there other issues FDA should consider in assessing the regulatory framework for PANDAs under the FD&C Act? Please provide specific examples and explain FDA’s authority to address these issues.

Dated: August 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-17378 Filed 8-12-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

The meeting 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: September 9, 2021.

Open: 10:00 a.m. to 2:30 p.m.

Agenda: Report of the Director, NICDR and concept clearances.

Place: National Institutes of Health, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Closed: 2:45 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892, 301-594-4805, adombroski@nidcr.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute’s/Center’s home page: <http://www.nidcr.nih.gov/about>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: August 9, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-17302 Filed 8-12-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

The meeting 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 14–15, 2021.

Open: September 14, 2021, 12:00 p.m. to 4:30 p.m.

Agenda: Presentation of the NIMH Director’s Report and discussion of NIMH program.

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

Closed: September 15, 2021, 11:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

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

Contact Person: Tracy Lynn Waldeck, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, Neuroscience Center, 6001 Executive Boulevard, Room 4133, Rockville, MD 20892, (301) 480-6833, waldeckt@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 9, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-17323 Filed 8-12-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 Alcohol Abuse and Alcoholism Special Emphasis Panel; Integrative Neuroscience

Initiative on Alcoholism (INIA) Consortia (RFA AA 21-011,012,013) Review Panel B.

Date: October 19, 2021.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20817, (301) 443-0800, bbuzas@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: August 9, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-17301 Filed 8-12-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276-0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology.

Project: Minority AIDS Initiative-Management Reporting Tools (MAI-MRTs)—(OMB No. 0930-0357)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) is requesting from the Office of Management and Budget (OMB) approval for the revised Minority AIDS Initiative (MAI) monitoring tools, which includes both youth and adult questionnaires, as well as the quarterly progress report. This revision includes the inclusion of new cohorts, substantial revisions to the youth and adult questionnaires, updates to the data used to estimate response rates and expected numbers of participants by service duration (see Table 1 below).

The cohorts of grantees funded by the MAI and included in this clearance request are:

- Capacity Building Initiative 2017
- Capacity Building Initiative 2018
- Prevention Navigators 2017
- Prevention Navigators 2019
- Prevention Navigators 2020
- Prevention Navigators 2021

The target population for the grantees will be at-risk minority adolescents and young adults. All MAI grantees are expected to report their monitoring data using SAMHSA's Strategic Prevention Framework (SPF) and to target minority populations, as well as other high-risk groups residing in communities of color with high prevalence of Substance Abuse and HIV/AIDS. The primary objectives of the monitoring tools include:

- Assess the success of the MAI in reducing risk factors and increasing protective factors associated with the transmission of the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and other sexually transmitted diseases (STD).
- Measure the effectiveness of evidence-based programs and infrastructure development activities such as: Outreach and training, mobilization of key stakeholders, substance abuse and HIV/AIDS counseling and education, testing, referrals to appropriate medical treatment and/or other intervention strategies (*i.e.*, cultural enrichment activities, educational and vocational resources, social marketing campaigns, and computer-based curricula).
- Investigate intervention types and features that yield the best outcomes for specific population groups.