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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4140–01–P

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.