6. User and nonuser perception data summary; and

7. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):

a. Study objective(s);

b. Study hypotheses;

c. Study design;

d. Study population (inclusion/exclusion criteria, comparison group(s));

e. Human subject protection information, including Institutional Review Board information;

f. Primary and secondary endpoints (definition and success criteria);

g. Sample size calculation;

h. Data collection procedures;

i. Duration of follow up and baseline and follow up assessments, and

j. Data analysis plan(s).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the Agency's experience, reviewing such information is critical to achieving a productive meeting. If the information package was previously submitted in the meeting request, it should be revised, as applicable, so that the information reflects the most current and accurate information available.

In the **Federal Register** of September 12, 2018 (83 FR 46174), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received; however, none were PRA related.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| **Meeting Requests** | | | | | |
| Combining and Sending Meeting Request Letters for Manufacturers, Importers, and Researchers | 83 | 1 | 83 | 10 | 830 |
| **Meeting Information Packages** | | | | | |
| Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers | 83 | 1 | 83 | 18 | 1,494 |
| Total | | | | | 2,324 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents for meeting requests in table 1 is based on the number of meeting requests received and projected over the next 3 years. FDA estimates that 83 preapplication meetings will be requested.

The hours per response for combining and sending meeting request letters are estimated at 10 hours each, and the total burden hours for meeting requests are expected to be 830 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA estimates that 83 respondents will compile meeting information packages and submit to FDA at 18 hours per response. Based on FDA's experience, the Agency expects that it will take respondents, collectively, 1,494 hours (83 respondents × 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is estimated to be 2,324 hours (830 hours to prepare and submit meeting requests and 1,494 hours to prepare and submit information packages).

Our estimated burden for the information collection reflects an overall increase of 16 respondents and 448 hours. We attribute this adjustment to an increase in the number of industry meetings as the premarket tobacco application compliance deadlines will come due in the next 3 years.

Dated: May 23, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–11225 Filed 5–29–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee, June 18, 2019 to June 19, 2019, which was published in the **Federal Register** on May 20, 2019, 84 FR 22866.

This notice is being amended to update location information to Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814. The date and time will remain the same. This meeting is closed to the public.

Dated: May 23, 2019.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019–11206 Filed 5–29–19; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, which was published in the **Federal Register** on May 20, 2019, 84 FR 22870.

The meeting date, time and place remain the same. This notice is amended to update contact information—Dr. Kathy Salaita, Chief,

Scientific Review Branch, NIAMS/NIH/DHHS, 6701 Democracy Blvd., Rm. 818, Bethesda, MD 20892, *Kathy.Salaita@nih.gov*. The meeting is closed to the public.

Dated: May 23, 2019.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019–11201 Filed 5–29–19; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Center for Advancing Translational Sciences; 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 cooperative agreement applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Advancing Translational Sciences Special Emphasis Panel CTSA.

*Date:* June 20, 2019.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate cooperative agreement applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892–4878, 301–435–0813, *henriquv@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: May 23, 2019.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019–11202 Filed 5–29–19; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Notice of Subcommittee Meetings for the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC)

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of subcommittee meetings (virtual).

**SUMMARY:** The Secretary of Health and Human Services (Secretary) announces subcommittee meetings of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC).

The meetings are open to the public and can be accessed via telephone only. Agenda with call-in information will be posted on the SAMHSA website prior to the meetings at: *https://www.samhsa.gov/about-us/advisory-councils/meetings*

The meetings will include information on the following focus areas: Data, Access, Treatment and Recovery, Justice, and Finance.

*Committee Name:* Interdepartmental Serious Mental Illness Coordinating Committee (subcommittee meetings)

*Date/Time/Type:* June 20, 2019/1:00 p.m.–2:30 p.m. (EDT)/OPEN/Focus Area 1: Data, June 26, 2019/9:00 a.m.–10:30 a.m. (EDT)/OPEN/Focus Area 2: Access, June 26, 2019/9:00 a.m.–10:30 a.m. (EDT)/OPEN/Focus Area 3: Treatment and Recovery, June 26, 2019/10:45 a.m.–12:15 p.m. (EDT)/OPEN/Focus Area 4: Justice, June 26, 2019/10:45 a.m.–12:15 p.m. (EDT)/OPEN/Focus Area 5: Finance.

**ADDRESSES:** The meetings will be held (virtually) at SAMHSA Headquarters, 5600 Fishers Lane, Rockville, Maryland 20857.

Substantive meeting information and a roster of Committee members is available at the Committee's website *https://www.samhsa.gov/about-us/advisory-councils/smi-committee*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background and Authority

The ISMICC was established on March 15, 2017, in accordance with section 6031 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to report to the Secretary, Congress, and any other relevant federal department or agency on advances in serious mental illness (SMI) and serious emotional disturbance (SED), research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of SMIs, SEDs, and advances in access to services and support for adults with SMI or children with SED. In addition, the ISMICC will evaluate the effect federal programs related to serious mental illness have on public health, including public health outcomes such as (A) rates of suicide, suicide attempts, incidence and prevalence of SMIs, SEDs, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment; (B) increased rates of employment and enrollment in educational and vocational programs; (C) quality of mental and substance use disorders treatment services; or (D) any other criteria as may be determined by the Secretary. Finally, the ISMICC will make specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with SMI or children with SED. Not later than 1 (one) year after the date of enactment of the 21st Century Cures Act, and 5 (five) years after such date of enactment, the ISMICC shall submit a report to Congress and any other relevant federal department or agency.

#### II. Membership

This ISMICC consists of federal members listed below or their designees, and non-federal public members.

*Federal Membership:* Members include, The Secretary of Health and Human Services; The Assistant Secretary for Mental Health and Substance Use; The Attorney General; The Secretary of the Department of Veterans Affairs; The Secretary of the Department of Defense; The Secretary of the Department of Housing and Urban Development; The Secretary of the Department of Education; The Secretary of the Department of Labor; The Administrator of the Centers for Medicare and Medicaid Services; and The Commissioner of the Social Security Administration.

*Non-Federal Membership:* Members include, 14 non-federal public members appointed by the Secretary, representing psychologists, psychiatrists, social workers, peer support specialists, and other providers, patients, family of patients, law enforcement, the judiciary, and leading research, advocacy, or service organizations. The ISMICC is required to meet at least twice per year.

**FOR FURTHER INFORMATION CONTACT:** Pamela Foote, Substance Abuse and