

and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on May 17, 2017 (82 FR 22668). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's Web site.

## II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of a new draft product-specific guidance for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Aspirin.  
Aspirin; omeprazole.  
Brexiprazole.  
Brivaracetam.  
Cefdinir.  
Clotolone pivalate.  
Cyanocobalamin.  
Dasabuvir sodium; Ombitasvir; Paritaprevir; Ritonavir.  
Dextroamphetamine sulfate.  
Diclofenac sodium.  
Fluphenazine hydrochloride.  
Gentamicin sulfate.  
Glycopyrrolate.  
Obeticholic acid.  
Silver sulfadiazine.  
Tenofovir alafenamide fumarate.  
Tiopronin.  
Tipiracil hydrochloride; Trifluridine.  
Triamcinolone acetonide (multiple reference listed drugs).  
Uridine triacetate.

## III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of a revised draft product-specific guidance for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Brimonidine tartrate.  
Dabigatran etexilate mesylate.  
Dorzolamide hydrochloride.  
Gefitinib.  
Latanoprost.  
Methoxsalen.

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Metoprolol tartrate.  
Minocycline HCl (multiple reference listed drugs).  
Minoxidil.  
Pimozide.  
Propafenone hydrochloride.  
Tetrabenazine.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidances at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: July 10, 2017.

**Anna K. Abram**,  
Deputy Commissioner for Policy, Planning,  
Legislation, and Analysis.

[FR Doc. 2017-14781 Filed 7-13-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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; Spinal Cord Injury, Epilepsy, and Other Neurological Disorders.

*Date:* August 3-4, 2017.

*Time:* 9:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Glioblastoma, Multiple Sclerosis.

*Date:* August 4, 2017.

*Time:* 11:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 10, 2017.

**Sylvia L. Neal**,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-14751 Filed 7-13-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Mental Health Council.

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:* August 2, 2017.

*Time:* 2:00 p.m. to 4:00 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 (Telephone Conference Call).

*Contact Person:* Jean G. Noronha, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892-9609, 301-443-3367, [jnoronha@mail.nih.gov](mailto:jnoronha@mail.nih.gov).

Information is also available on the Institute's/Center's home page: [www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml](http://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: July 10, 2017.

**Melanie A. Pantoja,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102-3.65(a), notice is hereby given that the Charter for the Sickle Cell Disease Advisory Council (SCDAC) was renewed for an additional two-year period on June 30, 2017.

It is determined that the SCDAC is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquires may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892

(Mail Code 4875), Telephone (301) 496-2123, or [spaethj@od.nih.gov](mailto:spaethj@od.nih.gov).

Dated: July 10, 2017.

**Michelle Trout,**

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

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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) 276-1243.

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.

#### Proposed Project: Biannual Infrastructure Development Measures for State Adolescent and Transitional Aged Youth Treatment Enhancement and Dissemination Implementation (SYT-I) and Adolescent and Transitional Aged Youth Treatment Implementation (YT-I) Programs—(OMB No. 0930-0344)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment has developed a set of infrastructure development measures in which recipients of cooperative agreements will report on various benchmarks on a semi-annual basis. The infrastructure development measures

are designed to collect information at the state-level and site-level.

The projects were previously named State Adolescent Treatment Enhancement and Dissemination (SAT-ED) and State Youth Treatment Enhancement and Dissemination (SYT-ED) Programs and are now called State Adolescent And Transitional Aged Youth Treatment Enhancement and Dissemination Implementation (SYT-I) and Adolescent and Transitional Aged Youth Treatment Implementation (YT-I) Programs.

No changes have been made to the Biannual Infrastructure Development Measures Report. The only revision to the biannual progress report is due to the decrease in the number of respondents.

The infrastructure development measures are based on the programmatic requirements conveyed in TI-15-004, Cooperative Agreements for SYT-I and TI-17-002, Cooperative Agreements for YT-I.

The purpose of this program is to provide funding to States/Territories/Tribes to improve treatment for adolescents and transitional age youth through the development of a learning laboratory with collaborating local community-based treatment provider sites. Through the shared experience between the State/Territory/Tribe and the local community-based treatment provider sites, an evidence-based practice (EBP) will be implemented, youth and families will be provided services, and a feedback loop will be developed to enable the State/Territory/Tribe and the sites to identify barriers and test solutions through a services component operating in real time. The expected outcomes of these cooperative agreements will include needed changes to State/Territorial/Tribal policies and procedures; development of financing structures that work in the current environment; and a blueprint for States/Territories/Tribes and providers that can be used throughout the State/Territory/Tribe to widen the use of effective substance use treatment EBPs. Additionally, adolescents (ages 12 to 18), transitional age youth (ages 18 to 24), and their families/primary caregivers who are provided services through grant funds will inform the process to improve systems issues.

Estimates for response burden were calculated based on the methodology (survey data collection) being used and are based on previous experience collecting similar data and results of the pilot study. For emailed biannual surveys, burden estimates of 12.0 hours were used for Project Directors and/or Program Managers and burden estimates