

**Jeffery M. Zirger,**  
*Lead, Information Collection Review Office,  
 Office of Scientific Integrity, Office of Science,  
 Centers for Disease Control and Prevention.*  
 [FR Doc. 2020-21621 Filed 9-29-20; 8:45 am]  
**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92-463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—DD21-001, Study to Explore Early Development (SEED) Follow up Studies.*

*Date: January 12-13, 2021.*

*Time: 10:00 a.m.–6:00 p.m., EST.*

*Place: Teleconference.*

*Agenda: To review and evaluate grant applications.*

*For Further Information Contact: Jaya Raman Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway, Mailstop S107-8, Atlanta, Georgia 30341,*

Telephone: (770) 488-6511, *JRaman@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2020-21604 Filed 9-29-20; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; National Advisory Committee on the Sex Trafficking of Children and Youth in the United States (NAC) Recommendations and State Self-Assessment Survey (NEW)**

**AGENCY:** Office on Trafficking in Persons, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new survey, the National Advisory Committee on the Sex Trafficking of Children and Youth in the United States (NAC) Recommendations and State Self-Assessment Survey.

**DATES:** *Comments due within 30 days of publication.* OMB is required to make a

decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**SUPPLEMENTARY INFORMATION:**

*Description:* The Preventing Sex Trafficking and Strengthening Families Act of 2014 mandated the NAC to develop a report describing how each state and territory has implemented its recommendations to address sex trafficking in children and youth. The NAC proposes to administer a survey allowing states to assess their progress in implementing NAC recommendations. Submissions will allow states to document their efforts in the following sections: Multidisciplinary Response, Screening and Identification, Child Welfare, Service Provision, Housing, Law Enforcement and Prosecution, Judiciary, Demand Reduction, Prevention, Legislation and Regulation, Research and Data, and Funding. Each state will have the opportunity to provide a self-assessed tier ranking for each recommendation, a justification of their assessment, sources for their assessment, and the public or private nature of those sources.

*Respondents:* State Governors, Child Welfare Agencies, Local Law Enforcement, and Other Local Agencies.

*Annual Burden Estimates:*

**ESTIMATED OPPORTUNITY COSTS FOR RESPONDENTS**

Instrument	Total number of respondents contributing for 50 states	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
NAC Recommendations and State Self-Assessment Survey .....	250	1	6.85	1,713

*Estimated Total Annual Burden Hours: 1,713.*

## ESTIMATED RECORDKEEPING COSTS

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
NAC Recommendations and State Self-Assessment Survey .....	50	1	40	2,000.

*Estimated Total Annual Burden Hours: 2,000*

(Authority: 42 U.S.C. 1314b)

**John M. Sweet Jr.,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020-21617 Filed 9-29-20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-D-1791]

#### **E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential—Questions and Answers; International Council for Harmonisation; Draft Guidance for Industry; 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 a draft guidance for industry entitled “E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential—Questions and Answers.” The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The draft guidance contains revised questions and answers (Q&As) for the ICH guidance for industry “E14 Clinical Evaluation of the QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs” and new Q&As for the ICH guidance for industry “S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals” that provide recommendations on considerations for an integrated risk assessment combining nonclinical and clinical data—in particular, at later stages of drug

development when clinical data are available. The draft guidance is intended to provide a harmonized approach to integrate nonclinical and clinical information for proarrhythmia risk assessment to streamline drug development and provide clarity on regulatory decision making.

**DATES:** Submit either electronic or written comments on the draft guidance by November 30, 2020 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-2020-D-1791 for “E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential—Questions and Answers” 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