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)—CE21–002; Research Grants to Develop or Identify Effective Strategies to Prevent Overdose Involving Illicit Stimulants and Polysubstance Use Involving Stimulants.


Times: 8:30 a.m.–5:00 p.m., EDT.

Place: Videoconference.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Mikel Walters, Ph.D., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone (404) 639–0913, MWalters@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.


By direction of the Commission.

Joel Christie,
Acting Secretary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–20–0051; Docket No. ATSDR–2020–0005]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled “Assessment of Chemical Exposures (ACE) Investigations.” The purpose of ACE Investigations is to focus on performing rapid epidemiological assessments to assist state, regional, local, or tribal health departments (the requesting agencies) to respond to or prepare for acute environmental incidents.

DATES: ATSDR must receive written comments on or before April 26, 2021.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2020–0005 by any of the following methods:

• Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

• Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7118; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Assessment of Chemical Exposures (ACE) Investigations (OMB Control No. 0923–0051)—Reinstatement with
Change—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for the Revision of "Assessment of Chemical Exposures (ACE) Investigations" information collection request (ICR) (OMB Control No. 0923–0051; Expiration Date 03/31/2021). ATSDR conducts ACE Investigations to assist state and local health departments after acute environmental incidents.

ATSDR has successfully completed five investigations to date using this valuable mechanism. ATSDR would like to continue these impactful information collections. A brief summary of recent information collections approved under this tool includes the following:

- During 2015, in U.S. Virgin Islands there was a methyl bromide exposure incident at a condominium resort severely injuring a family and causing symptoms in the first responders to the incident. ATSDR interviewed all potentially exposed persons who stayed or worked at the resort to look for signs of exposure. Under this ACE investigation, ATSDR raised awareness among pest control companies that methyl bromide is currently prohibited in homes and other residential settings. Additionally, ATSDR raised awareness among clinicians about the toxicologic syndrome caused by exposure to methyl bromide and the importance of notifying first responders immediately when they have encountered contaminated patients.

- During 2016, the ACE Team conducted a rash investigation in Flint, Michigan. Persons who were exposed to Flint municipal water and had current or worsening rashes were surveyed and referred to free dermatologist screening if desired. Findings revealed that when the city was using water from the Flint River, there were large swings in chlorine, pH, and hardness, which could be one possible explanation for the eczema-related rashes.

- During 2016, the ACE Team also conducted a follow-up investigation for people who were referred to a dermatologist in the first Flint investigation. The follow-up interviews resulted in improvements in medical exam and referral processes that were still on-going at the time.

The ACE Investigations have focused on performing rapid epidemiological assessments to assist state, regional, local, and tribal health departments (the requesting agencies) to respond to or prepare for acute chemical releases.

The main objectives for performing these rapid assessments are to:

- Characterize exposure and acute health effects of the affected community to inform health officials and the community;
- Identify needs (i.e., medical, mental health, and basic) of those exposed during the incidents to aid in planning interventions in the community;
- Determine the sequence of events responsible for the incident so that actions can be taken to prevent future incidents;
- Assess the impact of the incidents on the emergency response and health services use and share lessons learned for use in hospital, local, and state planning for environmental incidents; and
- Identify cohorts that may be followed and assessed for persistent health effects resulting from environmental releases.

Because each incident is different, it is not possible to predict in advance exactly what type of, and how many respondents will be consented and interviewed to effectively evaluate the incident. Respondents typically include, but are not limited to, emergency responders with police, fire, hazardous material technicians, emergency medical services, and personnel at hospitals where patients from the incident were treated.

Incidents may occur at businesses or in the community setting; therefore, respondents may also include business owners, managers, workers, customers, community residents, and those passing through the affected area.

The multidisciplinary ACE Team consisting of staff from ATSDR, the Centers for Disease Control and Prevention (CDC), and the requesting agencies will be collecting data. ATSDR has developed a quickly tailored series of draft survey forms used in the field to collect data that will meet the goals of the investigation. ATSDR collections will be administered based on time permitted and urgency. For example, it is preferable to administer the General Survey to as many respondents as possible. However, if there are time constraints, the shorter Household Survey or the former ACE Short Form, now modified as the Epidemiologic Contact Assessment Symptom Exposure (Epi CASE) Survey, may be administered instead. The individual surveys collect information about exposure, acute health effects, health services use, medical history, needs resulting from the incident, communication during the release, health impact on children, and demographic data. Hospital personnel are asked about the surge, response and communication, decontamination, and lessons learned.

Depending on the situation, data collected by face-to-face interviews, telephone interviews, written surveys, mailed surveys, or on-line surveys can be collected. Medical charts may also be considered for review. In rare situations, an investigation might involve collection of clinical specimens.

ATSDR is proposing to increase the utility of this Generic ICR in response to stakeholder requests. We would like to expand the ACE toolkit to be more inclusive of other types of environmental incidents affecting the community and which fall under ATSDR's mandate and, at times, the mandates of our partners in the CDC's National Center for Environmental Health (NCEH) and the National Center for Occupational Safety and Health (NIOSH). In addition to acute chemical releases, we propose to include radiological and nuclear incidents, explosions, natural disasters, and other environmental incidents.

We propose revisions to select information collection forms, which will be deployed using handheld devices whenever possible to reduce burden, and to adjust the number of responses and time per response for several forms. A new brief Eligibility Screener (900 responses per year; 30 hours) will be added prior to administering consent for our surveys. The Epi CASE Survey, formerly the ACE Short Form, has been modified for the expanded scope of eligible incidents requested (1,000 responses per year; 250 hours).

To reduce time burden, there will be new field data entry screens and deletion of unused questions for the General Survey (800 responses per year; 333 hours), the Household Survey (120 responses per year; 20 hours) and for the Hospital Survey (40 responses per year; 17 hours). We are retaining the Medical Chart Abstraction Form (250 responses per year; 125 hours) but are removing the Veterinary Chart Abstraction Form as it has not been used in the past.

ATSDR anticipates up to four ACE investigations per year. We are requesting approval for 3,110 annual responses (increase of 1,820 responses per year) and for 775 annual hours (increase of 184 hours per year). Participation in ACE investigations is voluntary and there are no anticipated costs to respondents other than their time.

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0672]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reprocessed, single-use device labeling.

DATES: Submit either electronic or written comments on the collection of information by April 26, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 26, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 26, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 publicly available, 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–2011–N–0672 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.” Received comments, those filed in a timely manner (see ADDRESSES), 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://