

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Lead Exposure and Prevention Advisory Committee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Lead Exposure and Prevention Advisory Committee (LEPAC). This meeting is open to the public by teleconference but advance registration by November 19, 2021 is needed to receive the information to join the meeting. The registration link is https://www.zoomgov.com/webinar/register/WN_qeMSB7npRJ23PTV6t1KMtQ.

DATES: The meeting will be held on December 3, 2021, from 9:00 a.m. to 4:15 p.m., EST.

ADDRESSES: Register in advance at https://www.zoomgov.com/webinar/register/WN_qeMSB7npRJ23PTV6t1KMtQ to receive the information to join the meeting.

FOR FURTHER INFORMATION CONTACT:

Alexis Pullia, M.P.H., C.P.H., Committee Management Specialist, National Center for Environmental Health, CDC, 4770 Buford Highway, Atlanta, GA, 30341, Telephone: (770) 488-3300; Email: lepac@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Lead Exposure and Prevention Advisory Committee was established under Section 2203 of Public Law 114-322, the Water Infrastructure Improvements for the Nation Act; 42 U.S.C. 300j-27, Registry for Lead Exposure and Advisory Committee. The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC and Administrator, NCEH/ATSDR, are authorized under Section 2203 of Public Law 114-322 (42 U.S.C. 300j-27) to review research and Federal programs and services related to lead poisoning and to identify effective services and best practices for addressing and preventing lead exposure in communities.

The LEPAC is charged with providing advice and guidance to the Secretary, HHS, and the Director, CDC and Administrator, ATSDR, on (1) reviewing Federal programs and services available to individual communities exposed to lead; (2) reviewing current research on lead exposure to identify additional

research needs; (3) reviewing and identifying best practices, or the need for best practices regarding lead screening and the prevention of lead poisoning; (4) identifying effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in Section 2203 (b) of Public Law 114-322; and (5) undertaking any other review or activities that the Secretary determines to be appropriate.

Matters To Be Considered: The agenda will include updates on the blood lead reference value, lead-related activities from Federal LEPAC Members, the 1988 CLIA Amendment, and from Federal environmental justice efforts focused on lead, a discussion of best practices for increasing and enhancing screening in underserved populations, and presentations on mapping efforts to identify populations at higher risk of lead exposure and Lead Safe Cleveland. Agenda items are subject to change as priorities dictate.

Public Participation

Procedure for Oral Public Comment: The public comment period is scheduled on December 3, 2021 from 11:05 a.m. until 11:20 a.m. Individuals wishing to make a comment during the public comment period, please email your name, organization, and telephone number by November 19, 2021, to LEPAC@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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1396]

Use of Data From Foreign Investigational Studies To Support Effectiveness of New Animal Drugs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry #265 entitled "Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs." The guidance describes FDA's current thinking with respect to assisting sponsors in incorporating data from foreign countries into proposed clinical investigational protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act.

DATES: The announcement of the guidance is published in the **Federal Register** on October 6, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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").