

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").

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-1396 for “Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs.” 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 heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Susan Storey, Center for Veterinary Medicine (HFV-131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0578, Susan.Storey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 15, 2020 (85 FR 42867), FDA published the notice of availability for a draft guidance entitled “Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs,” giving interested persons until October 13, 2020, to comment on the draft guidance. This final guidance describes principles for designing, conducting, and reporting the results for investigations or studies, including data from foreign countries, in submissions to FDA of investigational new animal drug files, new animal drug applications (NADAs), and applications for conditional approval of a new animal drug (CNADAs) to demonstrate substantial evidence of effectiveness for NADAs or a reasonable expectation of effectiveness for CNADAs. It also describes how sponsors may obtain feedback from the Center for Veterinary Medicine regarding the incorporation of data from foreign countries into investigations and study protocols before the submission of an application.

FDA received comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to this final guidance to improve clarity. For example, we revised the language of the draft guidance to provide greater clarity regarding the level of evidence that may be required under certain circumstances to support effectiveness in clinical investigation protocols and

applications. The guidance announced in this notice finalizes the draft guidance dated July 2020.

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in FDA’s guidance entitled “Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs” have been approved under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 29, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1401]

Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs; Guidance for Industry; Availability

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

ACTION: Notice of availability.