

- Committee comments
- Next steps

Biweekly Task Group Conference Calls

These meetings allow the Task Groups to develop consensus recommendations to the Committee, which will, in turn, decide whether to proceed with formal advice to GSA based upon these recommendations.

The *Building and Grid Integration Task Group*, Phase II continues to build on the recommendations of the first phase of this Task Group, posted at <https://www.gsa.gov/cdnstatic/Bldg%20Grid%20Integration%20Advice%20Letter%202-21-19%20-%20508.pdf>, to prioritize federal building and grid integration strategies and develop implementation plans and scenarios with future rate structures, including consideration of electronic vehicles (EVs) and energy storage.

The *Data-Integrated Building Systems Task Group* continues to document and recognize data-integrated building system (e.g., smart building system) use cases that demonstrate the business case and quantify the multiple benefits of integrating building technologies and systems.

In-Person Meeting

The Committee meeting will convene experts in buildings, including architects, material suppliers, construction contractors, environment, health, security and transportation to accelerate the successful transformation of the Federal building portfolio to sustainable technologies and practices. The Meeting provides the venue for the Building-grid integration and Data-integrated building systems Task Groups to present their findings and recommendations.

This full Committee meeting is being rescheduled from May 16, 2019 (**Federal Register**/Vol. 83, No. 65166).

In-Person Meeting Agenda

- Updates and introductions
- Building-grid integration task group findings & recommendations
- Lunchtime speaker (TBD)
- Data-integrated building systems task group findings & recommendations
- Additional topics proposed by Committee members
- Public comment
- Next steps and closing comments

Kevin Kampschroer,

Federal Director, Office of Federal High-Performance Buildings, General Services Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Docket No. ATSDR-2019-0005]

Proposed Substances To Be Evaluated for Toxicological Profile Development

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

ACTION: Request for comments on proposed substances to be evaluated for Toxicological Profile development.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR) within the Department of Health and Human Services is initiating the development of another set of Toxicological Profiles. This notice solicits public nominations of substances for ATSDR to evaluate for Toxicological Profile development. ATSDR will consider nominations from the Substance Priority List (available at <https://www.atsdr.cdc.gov/SPL/>). ATSDR also accepts nominations for non-Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) substances that may have public health implications, on the basis of ATSDR's authority to prepare Toxicological Profiles for substances not found at sites on the CERCLA National Priorities List. For more information on the CERCLA National Priorities List, visit <https://www.epa.gov/superfund/superfund-national-priorities-list-npl>. The agency will do so in order to establish and maintain an inventory of literature, research, and studies on the health effects of toxic substances, to respond to requests for consultation, and to support the site-specific response actions conducted by ATSDR, as otherwise necessary.

DATES: Nominations from the Substance Priority List and/or additional substances must be received by May 20, 2019.

ADDRESSES: You may submit nominations, identified by Docket No. ATSDR-2019-0005, by any of the following methods:

- **Internet:** Access the Federal eRulemaking portal at www.regulations.gov. Follow the instructions for submitting comments.
- **Mail:** Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd. NE, Mail Stop S102-1, Atlanta, GA, 30329-4027. Attn: Docket No. ATSDR-2019-xxxx.

Instructions: All submissions must include the agency name and docket number for this notice. All relevant comments will be posted without change. This means that no confidential business information or other confidential information should be submitted in response to this notice. Refer to the section *Submission of Nominations* (below) for the specific information required.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Susan Ingber, Agency for Toxic Substances and Disease Registry, Division of Toxicology and Human Health Sciences, 1600 Clifton Rd. NE, Mail Stop S102-1, Atlanta, GA, 30329-4027, Email: ATSDRToxProfileFRNs@cdc.gov; Phone: 1-800-232-4636.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*] amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) [42 U.S.C. 9601 *et seq.*] by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) with regard to hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL) (for more information, visit <https://www.epa.gov/superfund/superfund-national-priorities-list-npl>). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare Toxicological Profiles for each substance included on the Priority List of Hazardous Substances (also known as the Substance Priority list (SPL)). This list identifies 275 hazardous substances found at NPL sites that ATSDR and EPA have determined pose the most significant current potential threat to human health.

Substances To Be Evaluated for Toxicological Profile Development

Each year, ATSDR develops a list of substances to be considered for Toxicological Profile development. The nomination process includes consideration of all substances on ATSDR's SPL, as well as other substances nominated by the public. For more information on ATSDR's SPL, visit <https://www.atsdr.cdc.gov/SPL/>.

Submission of nominations for Toxicological Profile development: Today's notice invites voluntary public nominations for substances included on the SPL and for substances not listed on the SPL. All nominations should include the full name of the nominator, affiliation, and email address. When

nominating a non-SPL substance, please include the rationale for the nomination. Please note that email addresses will not be posted on [regulations.gov](https://www.regulations.gov). ATSDR will evaluate data and information associated with nominated substances and will determine the final list of substances to be chosen for Toxicological Profile development. Substances will be chosen according to ATSDR's specific guidelines for selection. These guidelines can be found in the *Selection Criteria*, which may be accessed at www.atsdr.cdc.gov/toxprofiles/guidance/ATSDR_TP_Selection%20Criteria.pdf.

Pamela I. Protzel Berman,

Director, Office of Policy, Partnerships and Planning, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-0621]

Bispecific Antibody Development Programs; 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 "Bispecific Antibody Development Programs." This draft guidance provides recommendations to assist industry and other parties involved in the bispecific antibody drug development process. The draft guidance focuses on general regulatory and scientific considerations for bispecific antibodies, but not on development of a particular bispecific antibody. Industry and other stakeholders are encouraged to engage FDA to discuss their individual bispecific antibody under development. **DATES:** Submit either electronic or written comments on the draft guidance by June 18, 2019 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-2019-D-0621 for "Bispecific Antibody Development Programs." 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.

- **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.gpo.gov/fdsys/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.

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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ebla Ali-Ibrahim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6302, Silver Spring, MD 20993, 301-796-3691; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: