

SUPPLEMENTARY INFORMATION: The National Occupational Research Agenda (NORA) is a partnership program created to stimulate innovative research and improved workplace practices. The national agenda is developed and implemented through the NORA sector and cross-sector councils. Each council develops and maintains an agenda for its sector or cross-sector.

Background: The National Occupational Research Agenda for Wholesale and Retail Trade (WRT) is intended to identify the research, information, and actions most urgently needed to prevent occupational illnesses and injuries in the WRT sector. The National Occupational Research Agenda for WRT provides a vehicle for stakeholders to describe the most relevant issues, gaps, and safety and health needs for the sector. Each NORA research agenda is meant to guide or promote high priority research efforts on a national level, conducted by various entities, including: Government, higher education, and the private sector.

The first National Occupational Research Agenda for WRT was published in 2009 for the second decade of NORA (2006–2016). This draft is an updated agenda for the third decade of NORA (2016–2026). The revised agenda was developed considering new information about injuries and illnesses, the state of the science, and the probability that new information and approaches will make a difference. As the steward of the NORA process, NIOSH invites comments on the draft *National Occupational Research Agenda for Wholesale and Retail Trade*. Comments expressing support or with specific recommendations to improve the Agenda are requested. A copy of the draft Agenda is available at <https://www.regulations.gov> (see Docket Number CDC–2018–0028).

Dated: April 19, 2018.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2018–0038, NIOSH–312]

Research Plan, Continuing To Protect the Nanotechnology Workforce: NIOSH Nanotechnology Research Plan for 2018–2025

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention announces the availability of a draft research plan entitled *Continuing To Protect the Nanotechnology Workforce: NIOSH Nanotechnology Research Plan for 2018–2025* for public comment. To view the notice and related materials, visit <https://www.regulations.gov> and enter CDC–2018–0038 in the search field and click “Search.”

DATES: Electronic or written comments must be received by June 25, 2018.

ADDRESSES: You may submit comments, identified by CDC–2018–0038 and docket number NIOSH–312, by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All submissions received in response to this notice must include the agency name and docket number [CDC–2018–0038; NIOSH–312]. All relevant comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226–1998.

FOR FURTHER INFORMATION CONTACT:

Charles L. Geraci (CGeraci@cdc.gov), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum

Avenue, MS C–14, Cincinnati, OH 45226, phone (513) 533–8339 (not a toll free number).

SUPPLEMENTARY INFORMATION: NIOSH is seeking stakeholder input on the draft document *Continuing To Protect the Nanotechnology Workforce: NIOSH Nanotechnology Research Plan for 2018–2025*, to ensure that the program is meeting the needs of the stakeholders, and to identify ways in which the program can be improved to increase its impact on the safety and health of nanomaterial workers across the United States.

Background: Since 2004, NIOSH has pioneered research on the toxicological properties and characteristics of nanoparticles. This research has involved characterizing occupationally relevant nanoparticles for predicting whether these particles pose a risk of adverse health effects and for providing guidance on controlling workplace exposures. In September 2005, NIOSH developed its first nanotechnology strategic plan to further guide the Institute in identifying and prioritizing nanotechnology research. This strategic plan was updated in 2009 [<https://www.cdc.gov/niosh/docs/2010-105/pdfs/2010-105.pdf>] and again in 2013 [<https://www.cdc.gov/niosh/docs/2014-106/pdfs/2014-106.pdf>]. NIOSH would like to build on the accomplishments of ongoing research to develop the next strategic research goals and objectives for 2018–2025. NIOSH has identified 10 critical research areas for nanotechnology research and communication. These 10 critical research areas are: (1) Toxicity and internal dose, (2) measurement methods, (3) exposure assessment, (4) epidemiology and surveillance, (5) risk assessment, (6) engineering controls and personal protective equipment (PPE), (7) fire and explosion safety, (8) recommendations and guidance, (9) global collaborations, and (10) applications and informatics.

NIOSH is considering focusing the overarching strategic research goals for these critical areas on 5 key goals: (1) Increase understanding of new hazards and related health risks to nanomaterial workers, (2) expand understanding of the initial hazard findings of engineered nanomaterials, (3) support the creation of guidance materials to inform nanomaterial workers, employers, health professionals, regulatory agencies, and decision makers about hazards, risks and risk management approaches, (4) support epidemiologic studies for nanomaterial workers including medical and exposure studies, and (5) assess and promote national

adherence with risk management guidance.

Public comments are requested, including those expressing support or with specific suggestions to improve the Research plan. A copy of the draft Research plan is available at <https://www.regulations.gov> (see Docket Number CDC-2018-0038).

Dated: April 19, 2018.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1328]

Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals; 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 “Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals.” The purpose of this guidance is to provide information to assist sponsors in the design of an appropriate program of nonclinical studies for the development of pharmaceuticals used to treat patients with severely debilitating or life-threatening hematologic disorders (SDLTHDs). While FDA has guidance for oncology indications (most of which are considered severely debilitating or life-threatening diseases) and for rare diseases (which include some SDLTHD conditions), FDA has no guidance to facilitate nonclinical development specifically for pharmaceuticals used to treat nononcology patients with SDLTHDs. A streamlined approach to drug development is necessary to allow patients with SDLTHDs earlier and continued access to new and potentially effective therapies.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2018 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-2018-D-1328 for “Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals; Draft Guidance for Industry; Availability.” 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. 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: John Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2204, Silver Spring, MD 20993-0002, 301-796-0750; or Haleh Saber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2117, Silver Spring, MD 20993-0002, 301-796-0750.