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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Monograph on the Systematic Review of Evidence of Long-Term Neurological Effects Following Acute Exposure to the Organophosphorus Nerve Agent Sarin; Availability of Document; Request for Comments; Notice of Peer-Review Meeting; Amended Notice

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice amends **Federal Register** notice 83 FR 63662, published December 11, 2018, announcing the availability of the Draft National Toxicology Program (NTP) Monograph on the Systematic Review of Evidence of Long-Term Neurological Effects Following Acute Exposure to the Organophosphorus Nerve Agent Sarin for public comment prior to peer review. In partnership with the National Institutes of Health (NIH) Countermeasures Against Chemical Threats (CounterACT) Program, the Office of Health Assessment and Translation (OHAT), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), conducted a systematic review to evaluate the evidence of long-term neurological damage in humans after acute, sub-lethal exposure to sarin. The peer-

review meeting will be held by webcast only and open to the public; registration will be required for attendance by webcast and to present oral comments. Information about the meeting and registration is available at <https://ntp.niehs.nih.gov/go/36051>.

DATES:

Meeting: Scheduled for February 4, 2019, 9:00 a.m. Eastern Standard Time (EST) to adjournment. The preliminary agenda is available at <https://ntp.niehs.nih.gov/go/36051> and will be updated one week before the meeting.

Document Availability: The draft NTP monograph is available at <https://ntp.niehs.nih.gov/go/36051>.

Written Public Comment Submissions: Deadline was January 17, 2019.

Registration for Oral Comments: Deadline is January 28, 2019.

Registration to View Webcast: Deadline is February 4, 2019.

ADDRESSES:

Meeting Location: Webcast.

Meeting Webpage: The draft NTP monograph, preliminary agenda, registration, and other meeting materials are available at <https://ntp.niehs.nih.gov/go/36051>.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

This meeting notice is being published less than 15 days in advance of the meeting due to the partial Government shutdown of December 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Camden Byrd, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293-1660, Fax: (919) 293-1645, Email: NTP-Meetings@icf.com. Dr. Elizabeth Maull, NIEHS/DNTP, Designated Federal Official. Phone: (984) 287-3157, Email: maull@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background: OHAT serves as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels.

Sarin is a highly toxic organophosphorus nerve agent that was developed for chemical warfare during World War II and continues to be used as a weapon. The draft NTP monograph presents the results of the systematic review to evaluate the evidence for long-term neurological effects in humans following acute, sub-lethal exposure to sarin with consideration of human, experimental animal, and mechanistic data.

Long-term neurological effects of acute exposure to sarin are not well characterized. Previous reviews of potential health effects of sarin have generally not assessed individual study quality or considered multiple evidence streams (human, animal, and mechanistic data). In addition, the interpretation of effects of sarin in some

previous reviews was compounded by concurrent exposure to multiple chemicals, such as assessments of health effects in military personnel during the Gulf War or other conflicts.

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment. Registration to view the webcast is open through February 4, 2019, and is found at <https://ntp.niehs.nih.gov/go/36051>. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals with disabilities who need accommodation to view the webcast should contact Camden Byrd by phone: (919) 293-1660 or email: NTP-Meetings@icf.com. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Public Comment Registration: NTP invites public comments on the draft NTP monograph that address scientific or technical issues. Guidelines for public comments are at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf. The deadline for submission of written comments has passed.

The agenda will allow for one oral public comment period (up to 12 commenters, up to 5 minutes per speaker). Registration to provide oral comments is January 28, 2019, at <https://ntp.niehs.nih.gov/go/36051>. Registration will be on a first-come, first-served basis. Each organization will be allowed one time slot. Oral comments will be presented by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified approximately one week before the peer-review meeting about the actual time allotted per speaker.

If possible, oral public commenters will be asked to send a copy of their slides and/or statement or talking points to Camden Byrd by email: NTP-Meetings@icf.com by the registration deadline.

Meeting Materials: The draft NTP monograph and preliminary agenda are available on the NTP website at <https://ntp.niehs.nih.gov/go/36051>. Additional information will be posted when available or may be requested in hardcopy from Camden Byrd by phone: (919) 293-1660 or email: NTP-Meetings@icf.com. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Camden Byrd by

email: NTP-Meetings@icf.com. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended.

The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: January 17, 2019.

Brian R. Berridge,
Associate Director,
National Toxicology Program.

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