

U. S. ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD—2015 - 0588; FRL]

Human Studies Review Board; Notification of a Public Meetings

AGENCY: U. S. Environmental Protection Agency

ACTION: Notice.

SUMMARY: The EPA Office of the Science Advisor announces two separate public meetings of the Human Studies Review Board to advise the Agency on the ethical and scientific reviews of EPA research with human subjects.

DATES: A public virtual meeting will be held on January 12-13, 2016, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time each day. A separate teleconference meeting is planned for Wednesday, March 30, 2016, from 1:00 p.m. to approximately 2:30 p.m. for the HSRB to finalize its Final Report of the January 12-13, 2016 meeting.

ADDRESSES: Both of these meetings will be conducted entirely on the Internet using Adobe Connect. For detailed access information visit the HSRB Website: <http://www2.epa.gov/osa/human-studies-review-board>

Comments: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2015-0588, by one of the following methods:

Internet: <http://www.regulations.gov>: Follow the online instructions for submitting comments.

Email: ORD.Docket@epa.gov.

Mail: The EPA Docket Center EPA/DC, ORD Docket, Mail code: 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

Hand Delivery: The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA WJC West, at 1301 Constitution Avenue NW, Washington, DC 20460. The hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays. Please call (202) 566-1744 or email the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available on the website at: <http://www.epa.gov/epahome/dockets.htm>.

Instructions: The Agency's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. The <http://www.regulations.gov> website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any electronic storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to receive further information should contact Jim Downing on telephone number (202) 564-2468; fax number:

(202) 564-2070; email address: downing.jim@epa.gov; or mailing address Environmental Protection Agency, Office of the Science Advisor, Mail code 8105R, 1200 Pennsylvania Avenue NW, Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA website at:

<http://www2.epa.gov/osa/human-studies-review-board>.

SUPPLEMENTARY INFORMATION:

Meeting access: Access to these Internet meetings are open to all by following the information provided above.

Procedures for providing public input: Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in Section I, **“Public Meeting”** under subsection D. **“How May I Participate in this Meeting?”** of this notice.

I. Public Meeting

A. Does this Action Apply to Me?

This action is directed to the public in general. This Notice may, however, be of particular interest to persons who conduct or assess human studies, especially studies on substances regulated by the EPA, or to persons who are, or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act. This notice might also be of special interest to participants of studies involving human subjects, or representatives of study participants or experts on community engagement. The Agency has not attempted to describe all the specific entities that may have interest in human subjects research. If you have any questions regarding this notice, consult with Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using regulations.gov, you may access this *Federal Register* document electronically through the EPA Internet under the “Federal Register” listings at <http://www.epa.gov/fedrgstr/>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although all documents are listed in the index, certain documents are not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the ORD Docket, EPA Docket Center, in the Public Reading Room. The Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA WJC West, at 1301 Constitution Avenue NW, Washington, DC 20460. The hours of operation are 8:30 am to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays. Please call (202) 566-1744 or email the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available on the website (<http://www.epa.gov/epahome/dockets.htm>).

The Agency’s position paper(s), charge/questions to the HSRB, and the meeting agenda will be available by late December 2015. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and other related documents that are available electronically, from the regulations.gov website and the EPA HSRB website at <http://www2.epa.gov/osa/human-studies-review-board>. For questions on document availability, or if you do not have access to the Internet, consult with Jim Downing listed under **FOR FURTHER INFORMATION**.

C. What Should I Consider as I Prepare My Comments for the EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data that you used to support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by the EPA, be sure to identify the Docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and *Federal Register* citation.

D. How May I Participate in this Meeting?

You may participate in these meetings by following the instructions in this section. To ensure proper receipt by the EPA, it is imperative that you identify Docket ID number EPA-HQ-ORD-2015-0588 in the subject line on the first page of your request.

1. Oral comments. Requests to present oral comments during either conference call will be accepted up to Noon Eastern Time on Wednesday, January 6, 2016, for the January 12-13, 2016 meeting and up to Noon Eastern Time on Wednesday, March 23, 2016 for the March 30, 2016 conference call. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments during either call. Individuals or groups wishing to make brief oral comments to the HSRB on January 12-13, 2016 are strongly advised to submit their request (preferably via email) to Jim Downing, listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, Wednesday, January 6, 2016 in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official to review the meeting agenda to provide an appropriate public comment period. Individuals or groups wishing to make brief oral comments to the HSRB during the March 30, 2016 teleconference should submit their request by Noon Eastern Time on Wednesday, March 23, 2016. The request should identify

the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are generally limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, further public comments may be possible.

2. Written comments. Submit your written comments prior to the meetings. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments by Noon Eastern Time on Wednesday, January 6, 2016 for the January 12-13, 2016 meeting, and by noon Eastern Time on Wednesday, March 23, 2016 for the March 30, 2016 teleconference. If you submit comments after these dates, those comments will be provided to the HSRB members, but you should recognize that the HSRB members may not have adequate time to consider your comments prior to their discussion. You should submit your comments using the instructions in Section I., under subsection C., **“What Should I Consider as I Prepare My Comments for the EPA?”** In addition, the agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

E. Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 § 9. The HSRB provides advice, information, and recommendations to the EPA on issues related to scientific and ethical aspects of human subjects research. The major

objectives of the HSRB are to provide advice and recommendations on: (1) research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through the Agency's Science Advisor.

1. Topics for discussion. On Tuesday, January 12-13, 2016, EPA's Human Studies Review Board will consider seven scientific and ethical topics: 1.) Assessing intermittent pesticide exposure from flea control collars containing the organophosphorus insecticide tetrachlorvinphos, authored by M. Keith Davis, J. Scott Boone, John E. Moran, John W. Tyler, and Janice E. Chambers. *Journal of Exposure Science and Environmental Epidemiology* (2008) 18, 564-570; 2.) Field Testing of SC Johnson Personal Mosquito Repellent Products to Support their Use of the EPA Repellency Awareness Graphic, GLP Study Number 865E1, J. Palm, September 24, 2015. Test Substance: MARK-3 OFF! Deep Woods Sportsmen Insect Repellent I (Maximum Strength Pump Spray Deep Woods OFF! EPA Reg. No. 4822-276); 3.) Field Testing of SC Johnson Personal Mosquito Repellent Products to Support their Use of the EPA Repellency Awareness Graphic, GLP Study Number 864E1, J. Palm, September 24, 2015. Test Substance: MARK-2 OFF! Deep Woods Sportsmen Insect Repellent II (UNSCENTED DEEP WOODS OFF! EPA Reg. No. 4822-397); 4.) Field Testing of SC Johnson Personal Mosquito Repellent Products to Support their Use of the EPA Repellency Awareness Graphic, GLP Study Number 867E1, E. Laznicka, October 21, 2015. Test Substance: MARK-5 OFF! Family Care Insect Repellent IV (Unscented) (UNSCENTED OFF! SKINTASTIC SPRAY INSECT REPELLENT, EPA Reg. No. 4822-395); 5.) Field Testing of SC Johnson Personal Mosquito Repellent Products to Support their Use of the EPA Repellency Awareness Graphic, GLP Study Number 866E1, E. Laznicka, October 21, 2015. Test Substance: MARK-4 OFF! Active Insect Repellent I (Unscented OFF! Insect Repellent, EPA Reg. No. 4822-380); 6.) Field Testing of SC Johnson Personal Mosquito Repellent Products to Support their Use

of the EPA Repellency Awareness Graphic, GLP Study Number 873E1, C. Talbert, October 21, 2015. Test Substance: MARK-8 OFF! Deep Woods Insect Repellent V (OFF! Insect Repellent Formula, EPA Reg. No. 4822-167)

On Wednesday, March 30, 2016 the HSRB will approve its Final Report of the January 12-13, 2016 meeting.

2. Meeting minutes and reports. Minutes of these meetings, summarizing the matters discussed and recommendations, if any, made by the advisory committee regarding such matters, will be released within 90 calendar days of the meeting. Such minutes will be available at <http://www2.epa.gov/osa/human-studies-review-board> and <http://www.regulations.gov>. In addition, information regarding the HSRB's Final Report, will be found at <http://www2.epa.gov/osa/human-studies-review-board> or from the person listed under FOR FURTHER INFORMATION CONTACT.

Dated: _____

Thomas A. Burke, PhD, MPH
EPA Science Advisor