

**US ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD  
January 12-13, 2016 PUBLIC MEETING AGENDA**

**Internet Virtual Meeting**

The meeting will be conducted at the following website:

<https://epa.connectsolutions.com/hsrb>

And on the phone: 866-299-3188 (access code: 2025647189)

Tuesday, January 12, 2016

**HSRB WEB SITE** <http://www.epa.gov/osa/human-studies-review-board>

**Docket Telephone: (202) 566 1752**

**Docket Number: EPA-HQ-ORD-2015-0588**

**12:50 PM HSRB members login online**

**1:00 PM\* Convene Public Meeting** – Jim Downing, Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor  
**Virtual Meeting operations** – Liza Dawson, Ph.D., HSRB Chair  
**Introduction of Board Members** – Liza Dawson, Ph.D., HSRB Chair  
**Opening Remarks** – Toby Schonfeld, Ph.D., Human Subjects Research Review Official, OSA, EPA

**1:15 PM Finalize the Draft Final Report from the HSRB October 2015 Meeting**

**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**

**1:30 PM EPA Science Review Highlights** –Wade Britton (Health Effects Division, OPP, EPA)

**1:50 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**2:10 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)

**2:30 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**2:50 PM Public Comments**

**2:55 PM Board Discussion**

\*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

Charge to the Board - Science:

- Is this research scientifically sound, providing reliable pet fur transferable residue data for use in evaluating potential exposures of adults and children from contact with pets treated with tetrachlorvinphos containing pet collars?

**Discussants:** Randy Maddalena, Ph.D. (George Fernandez, statistics)

Charge to the Board - Ethics:

1. Does the HSRB have any comments on EPA's determination that the samplers were not human subjects?
2. Does the HSRB have any comments on the ethical conduct of the research?

**Discussant:** Susanne M. Rivera, Ph.D., M.S.W.

**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)**

**3:25 PM EPA Science Review Highlights** –Eric Bohnenblust, Ph.D. (Registration Division, OPP, EPA)  
**3:55 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff  
**4:10 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)  
**4:40 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff  
**4:55 PM Public Comments**  
**5:10 PM Board Discussion**

Charge to the Board - Science:

- Is the study sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellent?

**Discussants:** Kenneth Ramos, Ph.D. (Jun Zhu, Ph.D., statistics)

Charge to the Board - Ethics:

- Does the available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

**Discussant:** Jewel H. Halanych, M.D., M.Sc.

**5:45 PM\* Adjourn**

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**US ENVIRONMENTAL PROTECTION AGENCY  
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JANUARY 12-13, 2016 PUBLIC MEETING AGENDA**

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                  **Opening Remarks** – Toby Schonfeld, Ph.D., Human Subjects Research Review Official, Office of the Science Advisor, EPA

**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)**

**1:15 PM EPA Science Review Highlights** –Eric Bohnenblust, Ph.D. (Registration Division, OPP, EPA)

**1:25 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**1:35 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)

**1:45 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff

**1:55 PM Public Comments**

**2:00 PM Board Discussion**

Charge to the Board - Science:

- Is the study sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellent?

**Discussants:** Helen Suh, Sc.D. (Ed Gbur, statistics)

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Charge to the Board - Ethics:

- Does the available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

**Discussant:** Susanne M. Rivera, Ph.D., M.S.W.

**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)**

- 2:15 PM EPA Science Review Highlights** – Mr. Kevin Sweeney (Registration Division, OPP, EPA)
- 2:25 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
- 2:35 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)
- 2:45 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
- 2:55 PM Public Comments**
- 3:00 PM Board Discussion**

Charge to the Board - Science:

- Is the study sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellent?

**Discussants:** Helen Suh, Sc.D. (Ed Gbur, statistics)

Charge to the Board - Ethics:

- Does the available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

**Discussant:** Kyle Galbraith, Ph.D.

**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)**

- 3:20 PM EPA Science Review Highlights** – Mr. Kevin Sweeney (Registration Division, OPP, EPA)
- 3:30 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
- 3:40 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)
- 3:50 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff
- 4:00 PM Public Comments**
- 4:05 PM Board Discussion**

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Charge to the Board - Science:

- Is the study sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellent?

**Discussants:** Kenneth Ramos, Ph.D. (Jun Zhu, Ph.D., statistics)

Charge to the Board - Ethics:

- Does the available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

**Discussant:** Jewel H. Halanych, M.D., M.Sc.

**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)**

**4:25 PM EPA Science Review Highlights** – Mr. Kevin Sweeney (Registration Division, OPP, EPA)  
**4:35 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff  
**4:45 PM EPA Ethics Review Highlights** - Maureen Lydon (OPP, EPA)  
**4:55 PM Board Questions of Clarification** – Liza Dawson, Ph.D., HSRB Chair, EPA staff  
**5:05 PM Public Comments**  
**5:10 PM Board Discussion**

Charge to the Board - Science:

- Is the study sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellent?

**Discussants:** Randy Maddalena, Ph.D. (George Fernandez, statistics)

Charge to the Board - Ethics:

- Does the available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

**Discussant:** Gary L. Chadwick, Pharm.D., M.P.H., C.I.P.

**5:30 PM\* Adjourn**

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