

US EPA ARCHIVE DOCUMENT

9/23/09 DRAFT

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
OCTOBER 20-21, 2009*
PUBLIC MEETING**

**OCTOBER 20, 2009
Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive
Arlington, VA 22202**

**HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2009-0658**

- **10:30 AM Convene Meeting and Administrative Procedures** – Paul Lewis, Ph.D.
(Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor)
- **10:35 AM Introduction and Identification of Board Members** – Sean Philpott, Ph.D.
(HSRB Chair)
- **10:45 AM Welcome** – Kevin Teichman, Ph.D. (Acting Science Advisor, Office of the Science Advisor)
- **10:50 AM Opening Remarks** – Mr. Steve Owens (Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, EPA)
- **10:55 AM Opening Remarks** – Debbie Edwards, Ph.D. (Director, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, EPA)
- **11:00 AM EPA Follow-up on Pesticide Specific HSRB Recommendations** – Mr. William Jordan (OPP, EPA)

Published reports of pyrethrins/pyrethroids research completed before enactment of EPA's expanded human studies rule (40 CFR part 26: Protection of Human Subjects)

- **11:05 AM EPA Science and Ethics Reviews**
- **12:00 PM Lunch**
- **1:00 PM EPA Science and Ethics Reviews (continued)**
 - Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair)
 - EPA -
 - Principal investigator/sponsor –
- **1:30 PM Public Comments**
- **1:45 PM Board Discussion**

Newton & Breslin study (1983)

Is the Newton & Breslin study scientifically sound, providing reliable data?

If so, is the Newton & Breslin study relevant to an assessment of the proposition that exposures to pyrethrins/pyrethroids may be associated with asthmatic or allergic respiratory responses?

If so, what limitations of the Newton & Breslin study should be taken into account by EPA in assessing the proposition that exposures to pyrethrins/ pyrethroids may be associated with asthmatic or allergic respiratory responses?

Is there clear and convincing evidence that the conduct of the Newton & Breslin study was fundamentally unethical, or that its conduct was significantly deficient relative to standards prevailing when it was conducted?

Lisi study (1992)

Is the Lisi study scientifically sound, providing reliable data?

If so, is the Lisi study relevant to an assessment of the proposition that exposures to pyrethrins/pyrethroids may be associated with allergic contact dermatitis or sensitization responses?

If so, what limitations of the Lisi study should be taken into account by EPA in assessing the proposition that exposures to pyrethrins/pyrethroids may be associated with allergic contact dermatitis or sensitization responses?

Is there clear and convincing evidence that the conduct of the Lisi study was fundamentally unethical, or significantly deficient relative to the standards of ethical research conduct prevailing when it was conducted?

- **3:00 PM** **Break**
- **3:15 PM** **Draft Summary of Board Conclusions - Sean Philpott, Ph.D. (HSRB Chair)**

Proposed AEATF-II research on exposure of janitorial workers applying antimicrobial pesticides formulated as aerosol sprays (Protocol AEA04)

- **3:30 PM** **EPA Science and Ethics Reviews**
 Board Questions of Clarification – Sean Philpott, Ph.D. (HSRB Chair)
 EPA -
 Principal investigator/sponsor –

- **4:45 PM** **Public Comments**

- **5:00 PM** **Board Discussion**

If the proposed AEATF-II aerosol application scenario and field study protocol AEA04 is revised as suggested in EPA's review and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who apply antimicrobial pesticides formulated as aerosol sprays?

2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

- **6:00 PM** **Adjournment** – Sean Philpott, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (HSRB DFO)

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- **8:30 AM** **Opening of Meeting** – Paul Lewis, Ph.D. (HSRB DFO)
- **8:35 AM** **Introduction** – Sean Philpott, Ph.D. (HSRB Chair)
- **8:40 AM** **Follow-up From Previous Day** – Mr. William Jordan (OPP, EPA)

Proposed AEATF-II research on exposure of janitorial workers applying antimicrobial pesticides formulated as aerosol sprays (Protocol AEA04)

- **8:45 AM** **Draft summary of Board conclusions** - Sean Philpott, Ph.D. (HSRB Chair)

Review of June 24-25, 2009 HSRB Meeting Report

- **9:00 AM** **Review Process** - Sean Philpott, Ph.D. (HSRB Chair)
- **9:05 AM** **Public Comments**
- **9:15 AM** **Board Discussion and Decision on Report** - Sean Philpott, Ph.D. (HSRB Chair)
- **10:00 AM** **Break**

Proposed Carroll-Loye Biological Research, Inc. Study (LNX-003): Efficacy of Two Picaridin-Based Personal Insect Repellent Formulations against Ticks

- **10:15 AM** **EPA Science and Ethics Reviews**
 Board Questions of Clarification – Sean Philpott, Ph.D. (HSRB Chair)
 EPA -
 Principal investigator/sponsor –
- **11:15 AM** **Public Comments**
- **11:30 PM** **Board Discussion**

If the proposed laboratory tick repellency study protocol LNX-003 is revised as suggested in EPA's review and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the efficacy of the tested materials in repelling ticks?
2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

- **12:30 PM** **Break**
- **12:45 PM** **Draft Summary of Board Conclusions** - Sean Philpott, Ph.D. (HSRB Chair)
- **1:00 PM** **Adjournment** – Sean Philpott, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (HSRB DFO)

*Please be advised that agenda times are approximate and subject to change. For further information, please contact the Designated Federal Officer for this meeting, Paul Lewis, via telephone: (202) 564-8381 or email: lewis.paul@epa.gov