

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD (HSRB)  
PUBLIC TELECONFERENCE MEETING  
Thursday, September 9, 2010  
1:30 pm -3:00 pm (Eastern Time)\*

HSRB MEETING FOR REVIEW AND APPROVAL OF  
DRAFT JUNE 23, 2010 HSRB MEETING REPORT

HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>  
Docket Telephone: (202) 566 1752  
Docket Number: EPA-HQ-ORD-2010-0617

Meeting location via telephone only  
Dial in number 866-299-3188; conference code 2025647189

- 1:30 PM** Convene Meeting and Identification of Board Members – Jim Downing (Designated Federal Officer, HSRB, OSA, EPA)  
**1:40 PM** Meeting Administrative Procedures – Jim Downing, DFO  
**1:45 PM** Meeting Process –Sean Philpott, Ph.D. (HSRB Chair)  
**1:50 PM** Public Comments  
**2:00 PM** Board Discussion and Decision on Final Report – Sean Philpott, Ph.D. (HSRB Chair)

The Board's response to EPA charge questions presented at the June 23, 2010 meeting.

**Completed Carroll-Loye Biological Research, Inc. Study LNX-002: Field Repellency of Two Picaridin-Based Personal Insect Repellents to Black Flies**

Charge to the Board:

1. Is the CLBR study LNX-002 sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against black flies provided by the tested repellents?
2. Does available information support a determination that study LNX-002 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

**Completed Carroll-Loye Biological Research, Inc. Study LNX-003: Laboratory Repellency of Two Picaridin-Based Personal Insect Repellents to Two Species of Ticks**

Charge to the Board:

1. Is the CLBR study LNX-003 sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against ticks provided by the tested repellents?
2. Does available information support a determination that study LNX-003 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

## **Revised Product Performance Test Guidelines for Insect Repellents to be Applied to Human Skin**

The Board recommended several changes or clarifications, including:

- Removal of the maximum-likelihood method requirement in the data analysis section;
- Clarification of recommendations regarding the use of positive controls, particularly with respect to the number of controls and the rationale for including them in the study;
- Careful consideration of recommendations regarding the recruitment and inclusion of so-called ‘vulnerable’ populations, including racial and ethnic minorities; and
- Encouraging the use of study designs that will enable investigators to collect data that will allow quantitative measurement of the repellent efficacy during the complete protection period.

**2:55 PM**      **Summary and Next Steps** – Sean Philpott, Ph.D. (HSRB Chair) and Jim Downing (DFO)

**3:00 PM**      **Adjournment**

\* Please be advised that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Jim Downing via telephone: (202) 564-2468 or email: [downing.jim@epa.gov](mailto:downing.jim@epa.gov)