

8/9/07

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE MEETING
AUGUST 14, 2007
3:00 pm -5:00 pm (Eastern Time)**

**HSRB MEETING FOR REVIEW AND APPROVAL OF
DRAFT APRIL 18-20, 2007 HSRB MEETING REPORT ***

**HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2007-0216**

**Meeting location via telephone only
Members of the public may obtain the call in number at 202-564-5275**

- **3:00 PM** **Introduction and Identification of Board Members** – Celia Fisher, Ph.D. (HSRB Chair)
- **3:10 PM** **Meeting Administrative Procedures** - Paul Lewis, Ph.D. (Designated Federal Officer, HSRB, OSA, EPA)
- **3:15 PM** **Meeting Process** – Celia Fisher, Ph.D. (HSRB Chair)
- **3:20 PM** **Public Comments**
- **3:30 PM** **Board Discussion and Decision on Report** - Celia Fisher, Ph.D. (HSRB Chair)

Completed Repellent Efficacy Studies: IR3535 Aerosol (EMD-003.3 and EMD-004.3)

EMD-003.3: Tick Repellency with Aerosol Spray Formulations

- a. Is this study sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy of the formulation tested against ticks?
- b. Does available information support a determination that this study was conducted in substantial compliance with subparts K and L of EPA regulations at 40 CFR part 26?

EMD-004.3: Mosquito Repellency with Aerosol Spray Formulations

- a. Is this study sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy of the formulation tested against mosquitoes?

- b. Does available information support a determination that this study was conducted in substantial compliance with subparts K and L of EPA regulations at 40 CFR part 26?

Carroll-Loye Mosquito Repellent Efficacy Protocol WPC-001

- a. If the proposed research described in Protocol WPC-001 from Carroll-Loye Biological Research is revised as suggested in EPA's review, does the research appear likely to generate scientifically reliable data, useful for assessing the efficacy of the test substances for repelling mosquitoes?
- b. If the proposed research described in Protocol WPC-001 from Carroll-Loye Biological Research is revised as suggested in EPA's review, does the research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Research Conducted After April 7, 2006: Meaning of "Substantial Compliance" with 40 CFR Part 26

(no charge question)

Completed Patch Test Studies

Part I. 48-Hour Dermal Irritation Patch Test

- a. Is this study sufficiently sound, from a scientific perspective, to be used as part of a weight-of-evidence assessment to evaluate the potential of the formulations tested to irritate human skin?
- b. Is there clear and convincing evidence that the conduct of this study was fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted?

Part II. Repeated Insult Patch Test

- a. Is this study sufficiently sound, from a scientific perspective, to be used to be used as part of a weight-of-evidence assessment to evaluate the potential of the formulations tested to cause sensitization of human skin?
- b. Is there clear and convincing evidence that the conduct of this study was fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted?

Framework for Developing Best Practices for Subject Recruitment for Handler Exposure Research

- a. What additional elements of the process of recruiting and enrolling subjects in handler exposure research should be addressed in a “Best Practices Framework”?
- b. For each of the elements in the “Best Practices Framework,” please identify any additional sources of guidance that could be useful for an investigator who is designing a process for recruiting and enrolling subjects in handler exposure research.

Follow-up on AHETF and AEATF Protocols

Recognizing that protocol-specific science and ethics issues will be addressed in later HSRB meetings, EPA has attempted to explain the basis for its conclusion that additional information on exposure for people who mix, load, and apply pesticides (handlers) would be useful in EPA's regulatory decision-making and therefore new research would be valuable. Do the materials provided by EPA regarding the quality of the scientific data currently available for assessing exposures for handlers contain useful information to establish the societal value of proposed new handler exposure research, assuming individual protocols would generate scientifically valid information?

What additional information, if any, would the Board want with respect either to handler research in general or to individual protocols?

- **4:45 PM** **Summary and Next Steps** - Celia Fisher, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (Designated Federal Officer, HSRB, EPA)
- **5:00 PM** **Adjournment**

* Please be advised that agenda times are approximate. 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