

4/12/07

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
APRIL 18-20, 2007 *
PUBLIC MEETING**

**Wednesday, April 18, 2007
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-2007-0216**

- **10:00 AM Convene Meeting and Identification of Board Members** – Celia Fisher, Ph.D. (HSRB Chair)
- **10:15 AM Welcome** – Warren Lux, MD (Human Subjects Research Review Official, Office of the Science Advisor, EPA)
- **10:25 AM Opening Remarks** – Mr. Jim Jones (Principal Deputy Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, EPA) and Debbie Edwards, Ph.D. (Director, Office of Pesticide Programs)
- **10:40 AM Meeting Administrative Procedures** - Paul Lewis, Ph.D. (Designated Federal Officer [DFO], HSRB, OSA, EPA)
- **10:45 AM Meeting Process** – Celia Fisher, Ph.D. (HSRB Chair)
- **10:55 AM EPA Follow-up on HSRB Recommendations** – Mr. William Jordan (EPA, OPP)

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

- **11:10 AM Science and Ethics of Repellent Efficacy Studies** – Clara Fuentes, Ph.D. (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **11:50 AM Public Comments**
- **12:15 PM Lunch**
- **1:15 PM Board Discussion**

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

- **2:15 PM** **Science and Ethics of Protocol WPC-001**– Clara Fuentes, Ph.D. (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **3:00 PM** **Break**
- **3:15 PM** **Public Comments**
- **3:40 PM** **Board Discussion**

- 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

- **4:40 PM** **Meaning of “Substantial Compliance”** – Mr. William Jordan (OPP, EPA) and Mr. Keith Matthews (OGC, EPA)
- **5:00 PM** **Public Comment**
- **5:20 PM** **Board Discussion**
- **6:00 PM** **Adjournment**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
APRIL 18-20, 2007 *
PUBLIC MEETING**

**Thursday, April 19, 2007
Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive
Arlington, VA 22202**

- **8:30 AM** **Convene Meeting** – Celia Fisher, Ph.D. (HSRB Chair)
- **8:40 AM** **Follow-up From Previous Day's Discussion** – Mr. William Jordan (OPP, EPA)

Completed Patch Test Studies

- **8:50 AM** **HSRB Workgroup and EPA Process on CBI Redacted Submissions** - Celia Fisher, Ph.D. (HSRB Chair) and Mr. William Jordan (OPP, EPA)

Part I. 48-Hour Dermal Irritation Patch Test

- **9:00 AM** **Science and Ethics of 48 Hour Dermal Irritation Patch Test** –Roger Gardner, Ph.D. (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **10:00 AM** **Public Comments**
- **10:30 AM** **Break**
- **10:45 AM** **Board Discussion**

- 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?

- **12:15 PM** **Lunch**

Part II. Repeated Insult Patch Test

- **1:30 PM** **Science and Ethics of Repeated Insult Patch Test** –Roger Gardner, Ph.D. (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **2:15 PM** **Public Comments**
- **2:45 PM** **Board Discussion**

- 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?

• **3:45 PM Break**

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

- **4:00 PM Framework for Developing Best Practices for Subject Recruitment for Handler Exposure Research - Mr. John Carley (OPP, EPA)**
- **4:30 PM Public Comments**
- **4:45 PM Board Discussion**

- 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.

• **5:45 PM Adjournment**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
APRIL 18-20, 2007 *
PUBLIC MEETING**

**Friday, April 20, 2007
Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive
Arlington, VA 22202**

- **8:30 AM** **Convene Meeting** – Celia Fisher, Ph.D. (HSRB Chair)
- **8:40 AM** **Follow-up From Previous Day's Discussion** – Mr. William Jordan (OPP, EPA)

Follow-up on AHETF and AEATF Protocols

- **8:50 AM** **EPA's Need for New Research on Occupational Handler Exposure** - Mr. William Jordan (OPP, EPA), Mr. Jeff Evans (OPP, EPA), Mr. Jeff Dawson (OPP, EPA), and Mr. Matthew Crowley (OPP, EPA)
- **10:00 AM** **Break**
- **10:15 AM** **EPA's Need for New Research on Occupational Handler Exposure (continued)** - Mr. William Jordan (OPP, EPA), Mr. Jeff Evans (OPP, EPA), Mr. Jeff Dawson (OPP, EPA), and Mr. Matthew Crowley (OPP, EPA)
- **11:15 AM** **Summary of EPA FIFRA SAP January 2007 Report "Worker Exposure Methods"** – FIFRA SAP Chair and/or Designee
- **11:45 AM** **Public Comments**
- **12:15 PM** **Lunch**
- **1:15 PM** **Board Discussion**

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?

• **2:15 PM Adjournment**

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