12/21/06 DRAFT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY HUMAN STUDIES REVIEW BOARD (HSRB) JANUARY 24, 2007 * PUBLIC MEETING

Sheraton Crystal City Hotel 1800 Jefferson Davis Highway Arlington, VA 22202 703 486 1111

HSRB WEB SITE http://www.epa.gov/osa/hsrb/ Docket Telephone: (202) 566 1752 Docket Number: EPA-HQ-ORD-2006-0998

• 8:30 AM	Introduction and Identification of Board Members – Celia Fisher, Ph.D. (HSRB Chair)
• 8:45 AM	Welcome – George Gray, Ph.D. (EPA Science Advisor)
• 8:55 AM	Opening Remarks – Mr. Jim Jones (Director, Office of Pesticide Programs, OPPTS) EPA)
• 9:05 AM	Meeting Administrative Procedures - Paul Lewis, Ph.D. (Designated Federal Officer [DFO], HSRB, OSA, EPA)
• 9:10 AM	Meeting Process – Celia Fisher, Ph.D. (HSRB Chair)
• 9:25 AM	Update on EPA Follow-up of HSRB Recommendations – Mr. William Jordan (EPA, OPP)

Insect Repellent Completed Efficacy Studies EMD-003 and EMD-004

- 9:35 PM Science and Ethics of Insect Repellent Completed Efficacy Studies EMD-003 and EMD-004 Clara Fuentes, Ph.D. (OPP, EPA) and Mr. John Carley (OPP, EPA)
- 10:15 AM Break
- 10:30 AM Public Comments
- 11:00 AM Board Discussion

EMD-003.1 and EMD-003.2: Tick Repellency with Lotion and Pump Spray Formulations

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

EMD-004.1 and EMD-004.2: Mosquito Repellency with Lotion and Pump Spray Formulations

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

• 12:30 PM Lunch

Insect Repellent Efficacy Protocol SCI-001

- 1:30 PM Science and Ethics of Insect Repellent Efficacy Protocol SCI-001– Mr. Kevin Sweeney (OPP, EPA) and Mr. John Carley (OPP, EPA)
- 2:30 PM Public Comments
- 3:00 PM Break
- 3:15 PM Board Discussion
 - a. If the proposed research described in Protocol SCI-001 from Carroll-Loye Biological Research is revised as suggested by EPA, 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 SCI-001 from Carroll-Loye Biological Research is revised as suggested by EPA, does the research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

• 4:30 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