

US EPA ARCHIVE DOCUMENT

2/12/2009

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
FEBRUARY 17, 2009
PUBLIC TELECONFERENCE MEETING**

**HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2009-0030**

**Meeting by Teleconference
Call 202 564 7189 for the teleconference number**

- **12:30 AM Convene Meeting and Identification of Board Members** – Celia Fisher, Ph.D. (HSRB Chair)
- **12:40 AM Meeting Administrative Procedures** - Paul Lewis, Ph.D. (Designated Federal Officer [DFO], HSRB, OSA, EPA)
- **12:45 AM Welcome** –Pai-Yei Whung, Ph.D. (Chief Scientist, OSA)
- **12:55 AM EPA Follow-up on Pesticide Specific HSRB Recommendations** – Mr. William Jordan (OPP, EPA)

Carroll-Loye Biological Research Tick Repellent Efficacy Study (SPC-002)

- **1:05 PM Carroll-Loye Biological Research Tick Repellent Efficacy Study (SPC-002)** - Mr. Kevin Sweeney (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **1:25 PM Public Comments**
- **1:35 PM Board Discussion**

Is study SPC-002 sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy against ticks of the three formulations tested?

Does available information support a determination that study SPC-002 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

Carroll-Loye Biological Research Mosquito Repellent Efficacy Study (SPC-001)

- **1:55 PM EPA Science and Ethics Assessment of Carroll-Loye Biological Research Mosquito Repellent Efficacy Study (SPC-001)** - Mr. Kevin Sweeney (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **2:15 PM Public Comments**
- **2:25 PM Board Discussion**

Is study SPC-001 sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy against mosquitoes of the three formulations tested?

Does available information support a determination that study SPC-001 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

- **2:45 PM Break**

Spatial/area Insect Repellent Testing

- **2:50 PM Introduction - Celia Fisher, Ph.D. (HSRB Chair)**
- **2:55 PM Technical aspects of spatial/area repellent testing – HSRB Consultant**
- **3:15 PM Board Discussion**

Environmental Aspects

1. What are the environmental (temperature, wind, time of day, humidity, proximity to water/plants, size and type of space) and human factors (height/weight; gender, age, ethnicity, density of humans in space) that can affect insect behavior and repellent efficacy relevant to space treatment studies?
2. What factors need to be considered for test spaces with respect to size of area in which the test is conducted? How is the most appropriate test area determined?
3. Does the number of human subjects within testing environments of different sizes affect insect activity? Does the number of subjects in a given area affect product efficacy or the measurement of product efficacy?
4. Are there any other special considerations regarding insect behavior in such studies that require inclusion in protocols?

Study Design

1. How is the location of open spaces typically selected? How many different or similar types of sites are appropriate to assess generalizability?
2. What are common spatial dispensing devices? How are they related to the nature of the product dispensed (e.g., gas, suspended liquid, smoke)? What are design or measurement challenges for different dispensing devices and products?
3. What type of dosimetry data is required to determine amount of product application used in testing? How is discharge time determined? What are the relative design merits of the experimenter or subject discharging the repellent?
4. How are outcomes measured in these studies? How are insect knockdown and mortality effects measured? Are both knockdown and landings/bites usually measured in the same study? What is the difference in knockdowns vs bites in terms of information regarding product efficacy/effectiveness?

5. What is the difference with respect to measurement in assessing efficacy of the active ingredient and effectiveness of the formulation?

Sample Size and Statistics

1. Depending on the outcome measure, what are best practices with respect to human sample size? What is the sample size norm in the field? How is determination of sample size related to square feet of test area? What is the best way to determine power for these studies?
2. What are best practices with respect to statistical analysis? How is censored data handled?
3. What are the pros and cons of various endpoints (e.g. ending the study after a set number of hours, waiting until the first landing/bite, other) to assess product efficacy (e.g. to meet assumptions for appropriate statistical analyses)?

Human Subjects

1. Why are human subjects necessary for such studies if the outcome measures are knockdowns or mortality?
2. What are the potential risks to treated subjects (e.g. inhalation, dermal effects)? What are exclusion criteria in subject selection to avoid such risks? How is the degree of risk related to dosage, ingredient, formulations, aerosol pressure?
3. What is the methodological rationale for continuous versus intermittent exposure? How do human risk differ for these types of exposures? Will exposure start at the beginning of the test period immediately after release of the product?
4. If the test agent has properties to repel or destroy an insect, what is the relationship (if any) to a related mechanism of action to humans?

- **4:45 PM** **Concluding Remarks** - Mr. William Jordan (OPP, EPA)
- **4:50 PM** **Adjournment** - Celia Fisher, 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 including the teleconference phone number please contact Lu-Ann Kleibacker via telephone at 202 564 7189 or email: kleibacker.lu-ann@epa.gov