U.S. ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD
OCTOBER 2011 PUBLIC MEETING AGENDA

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

Wednesday, October 19, 2011

10:30 AM* **Convene Public Meeting and Review Administrative Procedures –** Jim Downing , Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor
Introduction and Identification of Board Members – Sean Philpott, Ph.D., HSRB Chair
Welcome – Mary Greene, Ph.D., Deputy Director, Office of the Science Advisor
Opening Remarks – Steven Bradbury, Ph.D., Director, Office of Pesticide Programs (OPP), Office of Chemical Safety and Pollution Prevention, EPA
OPP Follow-up on Previous HSRB Recommendations – Mr. William Jordan, OPP, EPA

Session 1: **A completed Carroll-Loye Biological Research, Inc. (CLBR) study (No Mas 003) to evaluate the field repellent efficacy against mosquitoes of a product containing 16% para-methane-3,8-diol and 2% lemongrass oil.**

10:50 AM **EPA Science and Ethics Reviews –** Clara Fuentes, Ph.D. (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
11:20 AM **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor
11:40 AM **Public Comments**
11:50 AM **Board Discussion**

Charge to the Board:

- Is the CLBR completed study No Mas 003 sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellent?

- Does available information support a determination that the study No Mas 003 was conducted in substantial compliance with 40 CFR Part 26, subparts K and L?

12:45 PM **Lunch**

*Agenda times are approximate and subject to change. 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

Session 2: A new scenario design and associated protocol from the Antimicrobial Exposure Assessment Task Force II (AEATF-II), describing proposed research to monitor the dermal and inhalation exposure of workers while pouring liquid antimicrobial pesticide products from both conventional and reduced-splash containers

1:30 PM **EPA Science and Ethics Reviews** – Mr. Tim Leighton (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
2:30 PM **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor
3:00 PM **Public Comments**
3:15 PM **Break**
3:30 PM **Board Discussion**

Charge to the Board:

If the AEATF liquid pour study proposal is revised as suggested in EPA's review and if the research is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of individuals who manually pour liquid antimicrobial products?

- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

5:00 PM **Adjournment**

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Thursday, October 20, 2011

9:00 AM* **Convene Public Meeting and Review Administrative Procedures –** Jim Downing (Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor)
Introduction and Identification of Board Members – Sean Philpott, Ph.D. (HSRB Chair)
Follow-up from Previous Day – Mr. William Jordan (OPP, EPA)

Session 1: **A new scenario design and associated protocols from the Agricultural Handler Exposure Task Force (AHETF) describing proposed research to measure dermal and inhalation exposure to workers who use closed system equipment to load liquid pesticide products from returnable and non-returnable containers**

9:15 AM **EPA Science and Ethics Reviews** – Mr. Jeff Evans (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
10:00 AM **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair), EPA, Principal Investigator/Sponsor
10:30 AM **Public Comments**
10:45 AM **Break**
11:00 AM **Board Discussion**

Charge to the Board:

If the AHETF closed system liquid loading study proposal is revised as suggested in EPA's review and if the research is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of workers using closed systems to load liquid pesticide products from returnable or non-returnable containers?

- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

12:30 PM **Lunch**

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Session 2: A published report by *Moiemen et al* (2011) of an intentional exposure human study measuring dermal absorption of silver from the use of nanosilver-containing wound dressings to treat major burns

1:30 PM **EPA Science and Ethics Reviews –** Jessica Ryman, Ph.D. (OPP, EPA) and Ms. Kelly Sherman (OPP, EPA)
2:15 PM **Board Questions of Clarification** – Sean Philpott, Ph.D. (HSRB Chair), EPA
2:40 PM **Public Comments**
2:50 PM **Break**
3:05 PM **Board Discussion**

Charge to the Board:

- Is the Moiemen (2011) study scientifically sound, providing reliable data?
- If so, can the Moiemen (2011) study be used to support the Agency's conclusion that the dermal absorption factor for silver from nanosilver on human skin is less than 0.1%?
- Is there adequate information to support a determination that the study was conducted in substantial compliance procedures at least as protective as those at subparts A-L of 40 CFR Part 26?

4:30 PM **Adjournment**

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