## U.S. ENVIRONMENTAL PROTECTION AGENCY HUMAN STUDIES REVIEW BOARD APRIL 2014 PUBLIC MEETING AGENDA

### **Environmental Protection Agency Conference Center**

Lobby Level - One Potomac Yard (South Bldg.) 2777 S. Crystal Drive, Arlington, VA 22202

Tuesday, April 8, 2014

HSRB WEBSITE: http://www.epa.gov/osa/hsrb/ Docket Telephone: (202) 566-1752 Docket Number: EPA-HQ-ORD-2014-0189

10:00 AM\* Convene Public Meeting – Jim Downing, Designated Federal Officer, Human Studies Review Board (HSRB), Office of the Science Advisor, EPA Introduction of Board Members – Rebecca Parkin, Ph.D., MPH, HSRB Chair Opening Remarks – Glenn Paulson, Ph.D., Science Advisor, EPA Welcome – Mr. William Jordan, Deputy Director, Office of Pesticide Programs (OPP), Office of Chemical Safety and Pollution Prevention, EPA Estimating Pesticide Handler Exposure – Mr. William Jordan, Deputy Director, OPP, Office of Chemical Safety and Pollution Prevention, EPA

Session 1: A New Scenario Design and Associated Protocol from the Antimicrobial Exposure Assessment Task Force II (AEATF-II) Describing Proposed Research to Monitor Dermal and Inhalation Exposure During Manual Pouring of Solid Formulation Antimicrobial Products

(This topic was originally scheduled for review by the HSRB on October 1, 2013, but that meeting was cancelled as a result of the federal government shutdown that occurred from October 1-16, 2013.)

- **10:20 AM EPA Science Review –** Mr. Tim Leighton (OPP, EPA)
- **10:50 AM Board Questions of Clarification** Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA, Principal Investigator/Sponsor
- 11:00 AM EPA Ethics Review Ms. Kelly Sherman (OPP, EPA)
- **11:20 AM Board Questions of Clarification** Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA, Principal Investigator/Sponsor
- 11:30 AM Public Comments
- 11:40 AM Board Discussion

If the AEATF-II study proposal AEA07 is revised as suggested in EPA's science and ethics reviews and if the research is performed as described:

Charge to the Board - Science:

• Is this research likely to generate scientifically reliable data, useful for assessing the exposure of those who pour solid formulation antimicrobial pesticide products?

<sup>\*</sup>Agenda times are approximate and subject to change depending upon the discussion.

Charge to the Board - Ethics:

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

#### **12:30 PM** Lunch

Session 2: A New Scenario Design and Associated Protocol from the AEATF-II
Describing Proposed Research to Monitor Dermal and Inhalation Exposure
During Application of Latex Paint Containing an Antimicrobial Pesticide
Product Using Brush and Roller Equipment

1:30 PM	EPA Science Review – Mr. Tim Leighton (OPP, EPA)
2:00 PM	Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair),
	EPA, Principal Investigator/Sponsor
2:10 PM	EPA Ethics Review – Ms. Kelly Sherman (OPP, EPA)
2:30 PM	Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair),
	EPA, Principal Investigator/Sponsor
2:40 PM	<b>Public Comments</b>
2:50 PM	Board Discussion

If the AEATF-II study proposal AEA09 is revised as suggested in EPA's science and ethics reviews and if the research is performed as described:

Charge to the Board - Science:

• Is this research likely to generate scientifically reliable data, useful for assessing the exposure of those who apply latex paint containing an antimicrobial pesticide using a brush or roller?

Charge to the Board - Ethics:

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

#### 3:35 PM Break

<sup>\*</sup>Agenda times are approximate and subject to change depending upon the discussion.

BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash **Procedure** 3:45 PM **EPA Science Review –** Mr. Tim Leighton (OPP, EPA) Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), 4:10 PM EPA, Principal Investigator/Sponsor **EPA Ethics Review** – Ms. Kelly Sherman (OPP, EPA) 4:20 PM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), 4:40 PM EPA, Principal Investigator/Sponsor **Public Comments** 4:30 PM 4:40 PM **Board Discussion** 

A New Protocol from the AEATF-II Describing Proposed Research to

Measure the Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (Known as

If the AEATF-II study proposal AEA08 is revised as suggested in EPA's science and ethics reviews and if the research is performed as described:

Charge to the Board - Science:

• Is this research likely to generate scientifically reliable data, useful for determining the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint and non-paint liquid solutions containing containing BIT?

Charge to the Board - Ethics:

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

#### 5:30 PM\* Adjourn

**Session 3:** 

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# **Environmental Protection Agency Conference Center**

Lobby Level - One Potomac Yard (South Bldg.) 2777 S. Crystal Drive, Arlington, VA 22202

Wednesday, April 9, 2014

HSRB WEBSITE: http://www.epa.gov/osa/hsrb/ Docket Telephone: (202) 566-1752 Docket Number: EPA-HQ-ORD-2014-0189

9:30 AM\* Convene Public Meeting – Jim Downing, Designated Federal Officer, Human Studies Review Board, Office of the Science Advisor, EPA Introduction of Board Members – Rebecca Parkin, Ph.D., MPH, HSRB Chair Follow-up on Previous Day's Discussion – Mr. William Jordan, Deputy Director, OPP, Office of Chemical Safety and Pollution Prevention, EPA

Session 1: A New Protocol from the U.S. Department of Agriculture Describing Proposed Research to Determine the Bite Protection Level of Repellent Treated Clothing for the United States Military

9:40 AM EPA Science Review – Mr. Kevin Sweeney (OPP, EPA)
 10:25 AM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA, Principal Investigator/Sponsor
 10:40 AM EPA Ethics Review – Ms. Kelly Sherman (OPP, EPA)
 11:00 AM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA Principal Investigator/Sponsor

EPA, Principal Investigator/Sponsor

Public Comments

11:10 AM Public Comments 11:20 AM Board Discussion

If the study proposal is revised as suggested in EPA's science and ethics reviews and if the research is performed as described:

Charge to the Board - Science:

• Is the protocol "Laboratory Evaluation of Bite Protection From Repellent Impregnated Clothing for the United States Military" likely to generate scientifically reliable data, useful for estimating the level of mosquito bite protection provided by two different textiles treated with etofenprox?

Charge to the Board - Ethics:

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

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12:15 PM	Lunch
Session 2:	Background presentation on the Repellency Awareness Graphic and possible implications for the HSRB
1:15 PM 1:35 PM	Presentation – Ms. Rose Kyprianou and Ms. Kelly Sherman (OPP, EPA)  Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair)
Session 3:	Report from the HSRB Work Group of the Return of Individual Research Results
2:00 PM	HSRB Work Group on Return of Individual Research Results Report Presentation – Sean Philpott, Ph.D., Work Group Chair
2:20 PM	Board Discussion – Rebecca Parkin, Ph.D., MPH (HSRB Chair)
2:50 PM	<b>Topics for next HSRB Meeting (June 10-12, 2014)</b> – Ms. Kelly Sherman (OPP, EPA)
3:00 PM	Adjourn

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