US ENVIRONMENTAL PROTECTION AGENCY HUMAN STUDIES REVIEW BOARD July 21-22, 2020 PUBLIC MEETING AGENDA

Internet Virtual Meeting

The meeting will be conducted at the following website: https://epawebconferencing.acms.com/hsrb1
Meeting password: 7549

And on the phone: 866-299-3188 (access code: 2025648451)

Tuesday, July 21, 2020

HSRB WEB SITE http://www.epa.gov/osa/human-studies-review-board

12:50 PM	HSRB members login	(webinar and	teleconference line)
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1:00 PM* Convene Public Meeting – Tom O'Farrell, Ph.D., Designated Federal Officer, EPA Human Studies Review Board (HSRB), Office of the Science Advisor, Policy and Engagement (OSAPE)

Welcome and Virtual Meeting Operations – Jennifer Cavallari, Sc.D., HSRB Chair

1:20 PM Brief Update on Research Discussed at Last HSRB Meeting – Michelle Arling, Office of Pesticide Programs (OPP)

Topic: A Single Group Trial to Determine the Complete Protection Time of an Insect Repellent Formulation Containing 30% Citridiol ® (Oil of Lemon Eucalyptus) against three species of ticks.

1:25 PM EPA Science Review Highlights – Helen Hull-Sanders, Ph.D. & Clara Fuentes, Ph.D., OPP
 2:10 PM Board Questions of Clarification – Jennifer Cavallari, HSRB Chair
 2:20 PM EPA Ethics Review Highlights – Michelle Arling, OPP
 2:50 PM Board Questions of Clarification – Jennifer Cavallari, HSRB Chair
 3:00 PM Public Comments
 3:10 PM Break

Charge to the Board - Science:

Board Discussion

3:25 PM

Did the research summarized in "Single group trial to determine the complete protection time of an insect repellent formulation containing 30% Citriodiol ® (Oil of Lemon Eucalyptus) against three species of ticks" generate scientifically reliable data, useful for deriving a typical consumer dose and estimating the amount of time the product tested repels ticks?

^{*}Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

Discussants – Lisa Corey, Ph.D., Thomas Lewandowski, Ph.D., and consultant Kendra Lawrence, Ph.D., scientific review Julia Sharp, Ph.D., statistical review

Charge to the Board - Ethics:

Does the available information support a determination that the research was conducted in substantial compliance with procedures at least as protective as those in the applicable requirements of 40 CFR part 26, subparts K-L?

Discussant – AJ Allen, M.D., Ph.D., ethics review

5:15 PM* Adjourn

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Wednesday, July 22, 2020

HSRB WEB SITE http://www.epa.gov/osa/human-studies-review-board

12:50 PM **HSRB** members login (webinar and teleconference line)

1:00 PM* Convene Public Meeting – Tom O'Farrell, Ph.D., Designated Federal Officer, EPA

HSRB, OSA

Welcome and Virtual Meeting Operations – Jennifer Cavallari, Sc.D., HSRB Chair

Topic: A Study for Measurement of Potential Dermal and Inhalation Exposure

During Pressurized Hand-Wand Spraying of Antimicrobial Products along with

Study Addendum: Addition of Electrostatic Sprayers (AEA14)

1:20 PM **EPA Science Review Highlights** – Tim Leighton & Tim Dole, OPP 2:20 PM Board Questions of Clarification – Jennifer Cavallari, HSRB Chair **EPA Ethics Review Highlights** – Michelle Arling, OPP 2:35 PM Board Questions of Clarification – Jennifer Cavallari, HSRB Chair 3:05 PM 3:20 PM **Break**

3:35 PM **Public Comments** 3:45 PM **Board Discussion**

Charge to the Board - Science:

Is the protocol "A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products" and the "Study Addendum: Addition of Electrostatic Sprayers" likely to generate scientifically reliable data, useful for assessing the exposure of those who apply products containing antimicrobial pesticides using hand wand or electrostatic sprayers?

Discussants – Lisa Corey, Ph.D., and Janice Britt, Ph.D., scientific review Ann Um, Ed.D., statistical review

Charge to the Board - Ethics:

Is the research proposed in the protocol "A Study for Measurement of Potential

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Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products", the "Study Addendum: Addition of Electrostatic Sprayers" and related documents likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Discussant – Mark Aulisio, Ph.D., ethics review

5:15 PM* Adjourn

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