Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
January 11, 2012 Public Teleconference Meeting
Docket Number: EPA-HQ-ORD-2011-0953
HSRB Website: http://www.epa.gov/osa/hsrb

Committee Members: (See EPA HSRB Members list – Attachment A)

Date and Time:	Wednesday, January 11, 2012, 1:00 p.m. – 4:00 p.m. (See *Federal Register* Notice – Attachment B)	
Location:	Via teleconference	
Purpose:	The EPA Human Studies Review Board provides advice, information and recommendations on issues related to the scientific and ethical aspects of human subjects research.	
Attendees:	Chair:	Sean Philpott, Ph.D., M.S., Bioethics
	Board Members:	Janice Chambers, Ph.D., D.A.B.T. George C.J. Fernandez, Ph.D. Jewell H. Halanych, M.D. Dallas E. Johnson, Ph.D. Michael D. Lebowitz, Ph.D., FCCP Jerry A. Menikoff, M.D. William J. Popendorf, Ph.D. Leonard Ritter, Ph.D. Virginia Ashby Sharpe, Ph.D. Linda J. Young, Ph.D.
Meeting Summary:	Meeting discussions generally followed the issues and general timing as presented in the meeting Agenda (Attachment C), unless noted otherwise in these minutes.	

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CONVENE MEETING AND IDENTIFICATION OF BOARD MEMBERS

Mr. Jim Downing (Designated Federal Officer [DFO], Human Studies Review Board [HSRB or Board], Office of the Science Advisor [OSA], U.S. Environmental Protection Agency [EPA or Agency]) opened the teleconference meeting and welcomed Board members on behalf of the EPA Science Advisor Dr. Paul Anastas and the Program in Human Research Ethics. He noted that the Agency appreciates the Board members' time in preparing for the meeting. He also welcomed EPA colleagues and members of the public. The purpose of this teleconference meeting was to review the decisions made by the Board at the October 19-20, 2011 HSRB meeting and to finalize the Board report from that meeting. The October 2011 meeting was the first HSRB meeting to be webcast, and this is an important tool for providing greater

transparency and open government. The Agency would like feedback from those who attended the webcast; feedback may be submitted via email to Mr. Downing at downing.jim@epa.gov.

MEETING ADMINISTRATIVE PROCEDURES

As DFO, Mr. Downing serves as the liaison between the HSRB and EPA and ensures that Federal Advisory Committee Act (FACA) requirements are met with regard to the operations of the HSRB. As DFO, he also works with the appropriate officials to ensure that all applicable ethics regulations are satisfied. Each Board member has been briefed on the provisions of the federal conflict of interest laws and has filed a standard government financial disclosure form that has been reviewed to ensure that all ethics disclosure requirements have been met. Mr. Downing reminded participants that meeting times listed on the agenda would be approximate, and that Board members should state their names before speaking. At the teleconference meeting, the Board will review the draft final report from the October 2011 meeting, and will finalize the report for submission to the Science Advisor and the Agency. At the appropriate time, members of the public may provide public comments; these must be limited to 5 minutes. No individuals pre-registered to provide public comments.

Copies of the meeting materials are available on regulations.gov under the docket number EPA-HQ-ORD-2011-0953. According to FACA requirements, meeting minutes including descriptions of the discussions and conclusions reached by the Board will be prepared. These minutes will be certified by the Chair within 90 days of the meeting and posted at www.regulations.gov and on the HSRB website.

MEETING PROCESS

Dr. Sean Philpott thanked the Board members for their diligent work at the October 2011 meeting and in completing their sections of the meeting report, and thanked the Agency staff for their help and comments. He explained that the Board would discuss the draft Board report, focusing on the charge questions presented to the Board and the HSRB's recommendations. Dr. Philpott requested that the HSRB focus on substantive changes to the report that directly affect the Board's recommendations. Board members should submit any typographical or grammatical corrections to Dr. Philpott and Mr. Downing via email. He requested that Board members identify the section of the report to which they were referring by line number, and to identify themselves before speaking. The report is intended to be a summary of the HSRB's consensus recommendations and not a detailed technical document. The Agency and study sponsors have access to detailed meeting minutes for additional information.

He noted that a number of members of the public were participating in the teleconference, and that the meeting was being recorded for purposes of drafting the meeting minutes.

PUBLIC COMMENTS

Dr. Philpott invited public comment on the draft October 2011 HSRB meeting report. No public comments were presented.

BOARD DISCUSSION AND DECISION ON FINAL REPORT

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.

Dr. Philpott stated that the science charge question was located at line 315 of the draft report, and asked whether the AEATF liquid pour study proposal, if revised as suggested in EPA's review and if the research is performed as described, would be likely to generate scientifically reliable data useful for assessing the exposure of individuals who manually pour liquid antimicrobial products. The Board concluded that the protocol, as submitted for review and if modified in accordance with EPA and HSRB recommendations, is likely to generate scientifically reliable data useful for accessing exposure of individuals who manually pour liquid antimicrobial products. In addition to providing several other comments and suggestions, the Board also pointed out two limitations not identified within the protocol or by the Agency: the wider range of exposures that could occur when pouring products outdoors instead of indoors, and the unknown impact of potential differences in exposures between consumers and professionals. He asked if any Board members had questions or concerns about this recommendation and its rationale that begins on line 343. Dr. Linda Young noted a typographical error on line 364 that created redundancy. Dr. Philpott agreed to correct it. There were no other comments.

Dr. Philpott stated the ethics charge question that begins on line 482 asked whether the AEATF liquid pour study proposal, if revised as suggested in EPA's review and if the research is performed as described, would be likely to meet the applicable requirements of 40 Code of Federal Regulations (CFR) part 26, subparts K and L. The Board concluded that the protocol, as submitted for review and if modified in accordance with EPA and HSRB recommendations, is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L. He asked if any Board members had questions or concerns on the recommendation and its rationale that begins on line 498. There were no Board comments or questions.

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.

Dr. Philpott noted that the discussion of the study begins on line 643. The science charge question begins on line 692 and asked the Board whether the AHETF closed system loading study proposal, if revised as suggested in the Agency's review and if research is performed as described, would be likely to generate scientifically reliable data, useful for assessing exposure

of workers to closed systems to load liquid pesticide products from returnable or non-returnable containers. The Board concurred with the Agency's assessment that the proposed AHETF scenario and field study proposal, if revised as suggested and performed as described, is 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. The Board raised a number of additional concerns for the Agency and study sponsors to consider when collecting and analyzing the exposure data. Those detailed recommendations and suggestions begin on line 712. He asked if there were any Board questions or concerns about the recommendations and their rationale. Dr. Young pointed out that the sentence that begins on line 743 should read "Exposure and normalized exposure are interpretable only when the proportionality constants are zero and one." The word "respectively" should be deleted. Dr. Philpott agreed to make the change. No other members offered comments.

Dr. Philpott noted that the ethics charge question was located at line 777, and asked the Board whether the proposed AHETF scenario and field study proposal, if revised as suggested in EPA's review and if the research is performed as described, is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L. The Board concluded that the protocol, as submitted for review and if modified in accordance with EPA and HSRB recommendations, is likely to meet applicable requirements of 40 CFR part 26, subparts K and L. The Board made a few additional recommendations that are detailed in lines 793 to 935. He asked if Board members had any questions or comments regarding the response to the Agency. No Board members offered comments.

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 (PMD) and 2% lemongrass oil.

Dr. Philpott mentioned that Dr. Sidney Green, who was unable to attend the teleconference meeting, had sent an email noting that on line 955, there was an error. The line reads "two untreated experienced volunteers from site 1 also participated as treated controls at site 2." The sentence should conclude "as treated subjects at site 2," and Dr. Philpott has made that change.

Dr. Philpott stated that the Board's response to the science charge question begins on line 997. The Agency asked the Board whether the CLBR completed study No Mas 003 was sufficiently sound from a scientific perspective to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellant. The Board concurred with the Agency's assessment that the study provided scientifically valid results to assess efficacy against mosquitoes for the formulation tested, and the detailed recommendations and rationale begin on line 1013. Dr. Philpott asked if any Board members had comments regarding the recommendations and rationale. No Board members offered comments.

Dr. Philpott stated that the ethics charge question, which begins on line 1041, asked the Board whether the available information supported a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR part 26. The Board concurred with the Agency's assessment that the study submitted for review was conducted in substantial

compliance with subparts K and L of 40 CFR part 26. The Board's detailed recommendations and rationale are located on lines 1056 to 1137. He asked if any Board members had comments or concerns about the recommendations or rationale. No Board members offered comments.

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.

Dr. Philpott noted that the Agency proposed to use the data reported in the study to make estimates of systemic absorption of silver as a nanoparticle through the skin. The Board's consideration of the study begins on line 1140. He also noted that this is a "post-rule" published study, so there are different considerations for the level of information that needs to be provided to the Board. EPA asked the Board to consider two science charge questions that begin on line 1180: Is the *Moiemen et al* study scientifically sound, providing reliable data? If so, can the *Moiemen et al* 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 percent? The Board concluded that despite several deficiencies identified in the study design, the small number of subjects and the interpretation of the data, it agreed overall with the Agency's assessment that the *Moeimen et al* study provided some potentially useful baseline information on dermal absorption of silver from nanosilver-containing wound dressings. The Board also concluded that the *Moiemen et al* study could be used to support the Agency's conclusion that the dermal absorption for silver from nanosilver was less than 0.1 percent as part of an overall weight of evidence. The Board, however, recommended that the Agency clarify its assumptions in estimating the dermal absorption of silver from nanosilver, and that the Agency consider alternatives for estimating dermal absorption based on the study. The Board's recommendations and rationale begin on line 1210 and continue to line 1286. Dr. Philpott commented that Dr. William Popendorf also had submitted a statement to the Agency proposing some alternative approaches for estimating dermal absorption based on this study. Dr. Philpott asked if any Board members had questions or comments about the recommendations and rationale. No members offered comments.

The ethics charge to the Board on the *Moiemen et al* study asked the Board to consider whether there was adequate information to support a determination that the study was conducted in substantial compliance with procedures at least as protective as those in subparts A through L of 40 CFR part 26. The Board concurred with the Agency's assessment that there was sufficient information regarding the value of the research to society, subject selection, risks and benefits, independent ethics review, informed consent and respect for potential and enrolled subjects to conclude that the study was conducted in substantial compliance with procedures at least as protective as the relevant subparts of 40 CFR part 26. The Board's detailed recommendations and rationale begin on line 1306 and continue to line 1380. He asked if any Board members had questions or comments on the recommendations and rationale. No members offered comments.

SUMMARY AND NEXT STEPS

Dr. Philpott commented that the lack of comments reflects well-written discussions submitted for inclusion in the report, and the high-quality of both the sponsors' submissions and the Agency's review. He thanked both the Agency and the sponsors for their hard work. Dr. Michael Lebowitz stated that it was surprising, given the complicated nature of these studies, that the Board has conducted the review so well. As a longtime member of the Board, he was very impressed by the Board's review at the October 2011 meeting and the Agency's review. Dr. Philpott asked if the Agency representatives on the call had any questions, and they did not. He asked that the Board move to the procedural vote to approve the final draft pending the modifications discussed during the teleconference. Dr. Philpott called on each member in turn for a vote, and all members on the call who had attended the October 2011 meeting voted to approve the report unanimously. New members Drs. Jewell Halanych and Leonard Ritter abstained from voting because they had not been members at the time of the October 2011 deliberations.

Mr. Downing thanked the members for a successful meeting and for their diligent work on the final report. He noted that the next face-to-face HSRB meeting would be held January 26, 2012, at the EPA Conference Center at Potomac Yard South in Crystal City, Virginia. He adjourned the meeting at 1:45 p.m.

Respectfully submitted:

Jim Downing
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:

Sean Philpott, Ph.D., M.S., Bioethics
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public teleconference meeting reflect diverse ideas and suggestions offered by Board members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect definitive consensus advice from the Board members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final report prepared and transmitted to the EPA Science Advisor following the public meeting.

Attachments

Attachment A	HSRB Members
Attachment B	Federal Register Notice Announcing Meeting
Attachment C	Meeting Agenda

Attachment A

EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

*Sean Philpott, Ph.D., M.S. Bioethics — Term: 3/27/2006-8/31/2012
Director, Research Ethics
The Bioethics Program
Union Graduate College-Mt. Sinai School of Medicine
Schenectady, NY

Vice Chair

*^Rebecca T. Parkin, Ph.D., M.P.H — Term: 10/1/2007-8/31/2013
Professorial Lecturer (EOH)
School of Public Health and Health Services
The George Washington University
Washington, DC

Members

*Janice Chambers, Ph.D., D.A.B.T. — Term: 3/27/2006-8/31/2012
William L. Giles Distinguished Professor
Director, Center for Environmental Health Sciences
College of Veterinary Medicine
Mississippi State University
Mississippi State, MS

*George C.J. Fernandez, Ph.D. — Term: 5/1/2010-8/31/2013
Statistical Training Specialist
SAS Institute, Statistical Training and Technical Services
Sparks, NV

*^Vanessa Northington Gamble, M.D., Ph.D. — Term: 10/19/2009-10/31/2012
University Professor of Medical Humanities
Gelman Library
The George Washington University
Washington, DC

*^Sidney Green, Jr., Ph.D., Fellow ATS — Term: 10/19/2009-10/31/2012
Department of Pharmacology
Howard University College of Medicine
Howard University
Washington, DC

*Jewell H. Halanych, M.D. Term: 11/14/2011-8/31/2014
Assistant Professor
Department of Medicine
Division of Preventative Medicine
University of Alabama at Birmingham
Birmingham, AL

*Dallas E. Johnson, Ph.D. Term: 8/31/2007-8/31/2013
Professor Emeritus
Department of Statistics
Kansas State University
Manhattan, KS

*Michael D. Lebowitz, Ph.D., FCCP Term: 3/27/2006-8/31/2012
Retired Professor of Public Health
(Epidemiology) & Medicine & Research Professor of Medicine
University of Arizona
Tucson, AZ

*^José E. Manautou, Ph.D. Term: 5/1/2010-8/31/2013
Associate Professor of Toxicology
Department of Pharmaceutical Sciences
School of Pharmacy, University of Connecticut
Storrs, CT

Jerry A. Menikoff, M.D. Term: 3/27/2006-8/31/2012
Director, Office for Human Research Protections
Department of Health and Human Services
Rockville, MD

*William J. Popendorf, Ph.D. Term: 10/19/2009-10/31/2012
Professor Emeritus
Department of Biology
Utah State University
Logan, UT

*Leonard Ritter, Ph.D. Term: 11/14/2011-8/31/2014
Professor Emeritus (Toxicology)
School of Environmental Sciences
University of Guelph
Guelph, Ontario, Canada

*^Bernard A. Schwetz, D.V.M., Ph.D. Term: 11/14/2011-8/31/2014
Retired Director
Office of Human Research Protections
Department of Health and Human Services
Cadott, WI

Virginia Ashby Sharpe, Ph.D. Term: 5/1/2010-8/31/2013
National Center for Ethics in Health Care
Veterans Health Administration
Department of Veterans Affairs
Washington, DC

*Linda J. Young, Ph.D. Term: 3/28/2008-8/31/2012
Department of Statistics
Institute of Food and Agricultural Sciences
University of Florida
Gainesville, FL

*Special Government Employee (SGE)
^Not in attendance at the January 11, 2012 teleconference meeting

Attachment B

FEDERAL REGISTER NOTICE ANNOUNCING MEETING

[Federal Register Volume 76, Number 240 (Wednesday, December 14, 2011)]
[Notices]
[Pages 77825-77827]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2011-32060]

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2011-0953; FRL-9506-6]

Human Studies Review Board; Notification of a Public Teleconference

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The EPA Office of the Science Advisor announces a public teleconference of the HSRB to discuss its draft report from the October 19-20, 2011 HSRB meeting.

DATES: The teleconference will be held on Wednesday, January 11, 2012 from approximately 1 p.m. to approximately 4 p.m. Eastern Time. Comments may be submitted on or before Wednesday, January 4, 2012.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2011-0953, by one of the following methods:

Internet: http://www.regulations.gov: Follow the Web site instructions for submitting comments.

Email: ORD.Docket@epa.gov.

Mail: Environmental Protection Agency, EPA Docket Center EPA/DC, ORD Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

Hand Delivery: The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue NW., Washington, DC 20460. The hours of operation are 8:30 a.m. to 4:30 p.m.

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Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202) 566-1744 or email the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available online at http://www.epa.gov/epahome/dockets.htm.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2011-0953. The Agency's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comments includes information claimed to be Confidential Business Information or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or email. The http://www.regulations.gov Web site is an “anonymous access” system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through http://www.regulations.gov, your email address will be automatically

captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comments and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Any members of the public who wish to receive further information should contact Jim Downing on telephone number (202) 564-2468; fax (202) 564-2070; email address downing.jim@epa.gov or Lu-Ann Kleibacker on telephone number (202) 564-7189; fax: (202) 564-2070; email address kleibacker.lu-ann@epa.gov; mailing address Environmental Protection Agency, Office of the Science Advisor, Mail Code 8105R, 1200 Pennsylvania Avenue NW., Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA Web site at http://www.epa.gov/osa/hsrb.

SUPPLEMENTARY INFORMATION:

Location: The meeting will take place via telephone only.

Meeting access: For information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least ten business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT**, so that appropriate arrangements can be made.

Procedures for providing public input: Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in section I, "Public Meeting," under subsection D, "How May I Participate in this Meeting?" of this notice.

I. Public Meeting

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of particular interest to persons who conduct or assess human studies, especially studies on substances regulated by the EPA, or to persons who are, or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT.**

B. How can I access electronic copies of this document and other related information?

You may use http://www.regulations.gov, or you may access this **Federal Register** document via the EPA's Internet site under the "**Federal Register**" listings at http://www.epa.gov/fedrgstr.

Docket: All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at http://www.regulations.gov or in hard copy at the ORD Docket, EPA/DC Public Reading Room. The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue NW, Washington, DC 20460; its hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays.

Please call (202) 566-1744, or email the ORD Docket at ord.docket@epa.gov for instructions. Updates regarding the Public Reading Room access are available at http://www.epa.gov/epahome/dockets.htm.

C. What should I consider as I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data used that support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by the EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and **Federal Register** citation.

D. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by the EPA, it is imperative that you identify Docket ID No. EPA-HQ-ORD-2011-0953 in the subject line on the first page of your request.

1. *Oral comments*. Requests to present oral comments will be accepted up to and including Wednesday, January 4, 2012. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments during the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via email) to Jim Downing or Lu-Ann Kleibacker under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, Wednesday, January 4, 2012, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official to review the meeting agenda to provide an
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appropriate public comment period. The request should identify the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are generally limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, further public comments may be possible.

2. *Written comments*. Please submit written comments prior to the meeting. For the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your comments at least five business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, Wednesday, January 4, 2012. You should submit your comments using the instructions in section I, under subsection C, "What Should I Consider as I Prepare My Comments for EPA?" In addition, the Agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Jim Downing or Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

E. Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 section 9. The HSRB provides advice, information, and recommendations to EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) Research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through the EPA Science Advisor.

1. *Topics for Discussion.* The HSRB will be reviewing its draft report from the October 19-20, 2011, HSRB meeting. The Board may also discuss planning for future HSRB meetings. Background on the October 19-20, 2011 HSRB meeting can be found at the HSRB Web site: http://www.epa.gov/osa/hsrb. The October 19-20, 2011 meeting draft report is now available. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from regulations.gov Web site and the HSRB Web site at http://www.epa.gov/osa/hsrb. For questions on document availability or if you do not have Internet access, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

2. *Meeting minutes and reports.* Minutes of the meeting, summarizing the matters discussed and recommendations, if any, made by the advisory committee regarding such matters, will be released within 90 calendar days of the meeting. Such minutes will be available at http://www.epa.gov/osa/hsrb/ and http://www.regulations.gov. In addition, information regarding the Board's final meeting report will be found at http://www.epa.gov/osa/hsrb or from the persons listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: December 7, 2011.

Paul T. Anastas,

EPA Science Advisor.

[FR Doc. 2011-32060 Filed 12-13-11; 8:45 am]

BILLING CODE 6560-50-P

Attachment C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE MEETING AGENDA

Wednesday, January 11, 2012
1:00 pm - 4:00 pm (Eastern Time)*

HSRB MEETING FOR REVIEW AND APPROVAL OF THE DRAFT OCTOBER 19-20, 2011 HSRB MEETING REPORT

HSRB Website: http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566-1752
Docket Number: EPA–HQ–ORD–2011–0953

1:00 PM	**Convene Meeting and Identification of Board Members** – Jim Downing (Designated Federal Officer, HSRB, OSA, EPA)
1:10 PM*	**Meeting Administrative Procedures** – Jim Downing (DFO)
1:15 PM	**Meeting Process –** Sean Philpott, Ph.D. (HSRB Chair)
1:20 PM	**Public Comments**
1:30 PM	**Board Discussion and Decision on Final Report –** Sean Philpott, Ph.D. (HSRB Chair)

The Board's response to EPA charge questions presented at the October 19-20, 2011 meeting.

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.

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?

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.

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?

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.

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?

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.

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?

3:55 PM **Summary and Next Steps –** Sean Philpott, Ph.D. (HSRB Chair) and Jim Downing (DFO)

4:00 PM **Adjournment**