Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
April 12, 2013 Public Teleconference/Webinar Meeting
Docket Number: EPA–HQ–ORD–2013-0115
HSRB Website: http://www.epa.gov/osa/hsrb

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

Date and Time:	Friday, April 12, 2013, 11:00 a.m. – 12:30 p.m. EDT (See *Federal Register* Notice – Attachment B)	
Location:	Via Teleconference and Webinar	
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:	Rebecca Parkin, Ph.D., M.P.H.
	Vice Chair:	Jewell H. Halanych, M.D.
	Board Members:	George C.J. Fernandez, Ph.D. Sidney Green, Jr., Ph.D. Elizabeth Heitman, Ph.D. Dallas E. Johnson, Ph.D. John C. Kissel, Ph.D. José E. Manautou, Ph.D. William J. Popendorf, Ph.D. Nu-May Ruby Reed, Ph.D., D.A.B.T. Leonard Ritter, Ph.D., ATS 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.	

COMMENCEMENT OF PUBLIC MEETING

Mr. Jim Downing, Designated Federal Officer (DFO) of the HSRB, commenced the teleconference/webinar meeting and welcomed Board members on behalf of the EPA. He noted that the Agency appreciates the Board members' time and diligence in preparing for the meeting and deliberations. He also welcomed EPA colleagues and members of the public. The purpose of this teleconference/webinar meeting is to review the decisions made by the Board at the January 17, 2013, HSRB meeting and to finalize the Board's report from that meeting.

Mr. Downing took roll to determine which Board members were present on the call; a quorum of members was present.

MEETING ADMINISTRATIVE PROCEDURES

Mr. Downing as DFO serves as the liaison between the HSRB and EPA and ensures that Federal Advisory Committee Act (FACA) provisions 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.

At the teleconference/webinar meeting, the Board will review the draft final report from the January 2013 HSRB meeting and will finalize the report for submission to the Agency. Mr. Downing reminded participants that meeting times listed on the agenda would be approximate, and that participants should state their names before speaking to ensure proper attribution. Copies of the meeting materials, supporting documents and public comments will be available at *http://www.regulations.gov* under docket number EPA-HQ-ORD-2013-0115 and most are available on the HSRB website at *http://www.epa.gov/osa/hsrb*. At the appropriate time, members of the public may provide public comments; these must be limited to 5 minutes. No individuals preregistered to provide public comments. The draft final report will be displayed, reviewed and modified on the website at *https://epa.connectsolutions.com/hsrbtele* during the teleconference/webinar. Mr. Downing encouraged the participants to log in to the webinar, which will enable the Board to follow along as revisions to the draft document are made in real time during the deliberations.

According to FACA requirements, meeting minutes will be prepared, including descriptions of the topics discussed and conclusions reached by the Board. These minutes will be reviewed and certified by the Chair within 90 days of the meeting and posted at *http://www.regulations.gov* and on the HSRB website. Mr. Downing expressed appreciation to the Board members for their participation and earnestness to finalize the report from the January 2013 meeting. Mr. Downing turned the meeting over to the HSRB Chair, Dr. Rebecca Parkin.

MEETING PROCESS

Dr. Parkin thanked all of the Board members for their diligent work at the January 2013 HSRB meeting and their efforts in developing the draft meeting report and preparing for the teleconference. She expressed confidence that the Board would finalize the report and expedite its progress toward public access. Dr. Parkin described the meeting process, explaining that she would lead the discussion sequentially through each section of the report to ensure that all issues are covered. After Dr. Parkin announces a section and directs the Board members to the line number of the section, the Board members will have an opportunity to offer comments about that particular section. Dr. Jewell Halanych will edit the document in real time in response to Board members' comments. Dr. Parkin cautioned that participants who are not participating in the webinar might see different line numbers than the working draft that is presented and edited online. The Board will address the draft cover letter at the end of the discussion.

The webinar "chat" feature can be used to send a message to all participants. Clicking on the raised hand icon on the top of the screen will allow a participant to agree or disagree with the current conversation topic. Participants also can use the webinar functions to indicate if they need to leave the call momentarily. Dr. Parkin clarified that Board members should access the webinar at *https://epa.connectsolutions.com/hsrbtele*. All participants can just log in as a guest.

PUBLIC COMMENTS

Mr. Downing noted that there were no preregistered public comments, and no public participants had identified themselves on the teleconference line. He invited participants to comment publically on the draft January 2013 HSRB meeting report. No public comments were presented to the Board.

BOARD DISCUSSION AND DECISION ON THE FINAL REPORT

A completed study report from the Antimicrobial Exposure Assessment Task Force II (AEATF) in which the dermal and inhalation exposure of professional janitorial workers was monitored as they poured liquid antimicrobial pesticide products from conventional or reduced-splash containers into different sizes and types of receiving containers

Dr. Parkin directed the participants to the draft report Introduction that started on line 137. She asked the Board members to contribute any concerns or suggested revisions. Hearing none, Dr. Parkin moved sequentially through the Review Process and Overview of the Study sections to solicit comments.

Moving on to the Science section, Dr. Parkin asked if there were any Board member concerns about the Response to the Charge, HSRB Recommendation, or HSRB Detailed Recommendations and Rationale as written. There being no comments, Dr. Parkin called for comments within the Limitations section. In the Limitations section beginning on line 267, Dr. Leonard Ritter questioned the intent of the sentence, "The Board does not fully support the Agency's conclusion that the fact that 'the test subjects spilled the product on their hands when performing their pouring tasks indicated that perhaps pouring liquids is not an experienced-based skill.'" He asked for clarification if the Board was agreeing or disagreeing with the statement. Dr. Parkin clarified that as indicated by the HSRB recommendations, the Board agrees with the Agency's conclusion and understands that the AEATF complied with the study as proposed. The rest of the paragraph indicates why the Board does not agree fully. Dr. Elizabeth Heitman proposed removing the clause "the fact that" to add clarity. Dr. Ritter noted an apparent contradiction between the sentence beginning on line 267 and the one beginning on line 275, which states "This observation (along with the fact that 5 of these 8 changes were noted on the subject's second of two MEs) suggests that the participants' prior work 'experience' was not as strong a factor in their handling of their assigned containers as the selection criteria might suggest." Dr. Parkin acknowledged the lack of clarity. Dr. Dallas Johnson explained that the discussion concerned the comparison of expertise between professional custodians versus general consumers. Dr. Ritter suggested removing the sentence beginning on line 267 because it did not contribute value to the paragraph and presented a contradiction. Drs. Halanych and

Johnson agreed that the sentence was unclear and could be removed. No Board members dissented, and the sentence was removed.

Dr. Parkin proceeded through the Limitations section, soliciting comments for each bullet point in turn. She directed the Board members to consider the footnote text as well. Dr. Ritter voiced a concern with the sentence beginning on line 385, which read, "The first part of item #7 describes the Agency's desire to continue using exposures normalized by AaiH as a default condition despite the results herein in which dermal exposures are not proportional with AaiH (Leighton and Cohen, *EPA Science Review*, 2012, 47)." He opined that the sentence appeared to indicate that the Board was disregarding an observation that deviated from the expected results. Dr. Parkin asked Dr. Ritter for an approach to clarify the sentence. Dr. William Popendorf explained that the sentence had historical context. Dr. Heitman noted that the first sentence in the paragraph describes the Agency's current procedures, and the rest of the paragraph indicates the Board's response. She suggested placing a period after the word "condition" and removing the second part of the sentence. The new sentences read, "The first part of item #7 describes the Agency's desire to continue using exposures normalized by AaiH as a default condition (Leighton and Cohen, *EPA Science Review*, 2012, 47). The Board concurs with the scientific validity…" All Board members agreed with the change.

Dr. José Manautou suggested replacing the word "lumping" with "combining" on line 422 of the Limitations section to read "Concerns were raised about combining hand and non-hand exposures for reasons over and above statistical dissimilarities between the respective data sets." Participants agreed that "combining" sounded more scientifically appropriate.

Dr. Ritter raised a concern with the sentence that read, "EPA has traditionally assumed that a fixed fraction of material reaching the skin will be absorbed; however, the Board asserts that this is a very poor assumption." He commented that it is a general assumption, not specific to EPA. Dr. Parkin clarified that the Board's assertion in the second half of the sentence was intended to be specific to this situation and not a general point. Dr. Ritter commented that it was a profound statement for the Board to make without a thoughtful and comprehensive debate on the topic. Dr. John Kissel claimed responsibility for the assertion, stating that no scientific rationale exists to support a fixed fraction absorption rate. He referred the participants to a paper on the topic that he had published in 2011 and agreed to send the reference to Mr. Downing, who would distribute it to the rest of the Board members. The participants agreed that his publication should be cited within the report. Following further discussion, the bullet point was revised to read, "EPA has traditionally assumed that a fixed fraction of material reaching the skin will be absorbed. However, the Board notes that absorption varies with both loading conditions and time of exposure (Kissel, 2011)." The HSRB members agreed that the revised wording did not suggest support for or against the conventional wisdom and was worded more diplomatically. Dr. Parkin commented that the topic of absorption warrants placement on the agenda during a future Board meeting.

Dr. Parkin presented the Technical Issues section and solicited feedback from the Board members on each bullet point sequentially. There being no comments, she directed participants through each bullet point in the Statistical Analysis section. Dr. Johnson had submitted several revisions to the draft section beginning on line 472, which had been incorporated by

Dr. Halanych. Dr. Parkin asked Dr. Johnson and the participants if they were satisfied with the modifications or had additional comments. Dr. Linda Young suggested changes to one sentence to read, "However, the purpose of generating five imputed values for each non-detect is to reflect the variability in the data and imputations." This statement indicates both sources that are being captured. Dr. Popendorf expressed some concerns with the references to the "single value" at several sites. Following discussion, the sentence beginning on line 483 now reads, "By averaging the five imputed values for each non-detect, as was done in the analysis of this completed study, the variance of the average of the five imputed values would be less than the variance of a single imputed value, leading to a more biased overall variance estimate, than would have been the case had a single value been imputed for each non-detect." The HSRB members approved the revised sentence.

Dr. Heitman, referring to the bullet point that began on line 505, expressed concern with the use of the word "assumed": "In the derivation, it is incorrectly assumed that the errors are constant." She commented that as discussed previously, the Board should be careful with stating assumptions. Dr. Young explained that this is a statistical use of the word "assumed." The researchers assumed that the errors were constant, and they were not. The participants decided that the section should read, "In the derivation, the errors were assumed to be constant. However, both the pounds of active ingredient (ai) and the error differ with each observation…"

Dr. Parkin proceeded through the rest of the Statistical Analysis section, reminding the participants to consider the footnotes on each page in their evaluation of the draft. There being no additional comments within the Science section, Dr. Parkin moved to the Ethics section. She solicited feedback about each subsection within the HSRB Recommendation and the HSRB Detailed Recommendations and Rationale, starting with the Societal Value of Proposed Research and Subject Selection. Dr. Virginia Ashby Sharpe mentioned that the bullet on line 630 did not belong in the section. The bullet read, "Protections were adequate," and was more relevant to the Risk section. Participants agreed that the bullet should be removed. Dr. Sharpe pointed out a typographical error on line 648. The word "reserved" in the sentence, "There were no reported or reserved adverse reactions," should be replaced with "observed." There were no additional member concerns or comments about the Benefits, Risk/Benefit Balance, Independent Ethics Review, Informed Consent, or Respect for Subjects sections.

The Board members reviewed the Reference list, noting that the Kissel reference will be added. Dr. Popendorf commented that a previous draft had included the Kissel reference as well as an additional reference by Duist *et al.* (2009). Dr. Kissel explained that the Duist publication is a review paper that provides empirical evidence for the load effect; his 2011 paper describes a theoretical explanation of the rationale. He asserted that both references could be cited. There were no Board member objections to citing both references.

Dr. Parkin directed the Board members to review the cover letter and solicited any revisions or clarifications. She explained that no changes had been made to the recommendations during the HSRB's deliberations. Hearing no change requests, Dr. Parkin asked the Board members to review their names and contact information and send any corrections to Mr. Downing to be incorporated in the final draft.

SUMMARY AND NEXT STEPS

Dr. Parkin thanked the Board members for a successful meeting and for their insightful comments. She expressed appreciation for the Board members' patience as each section was considered in turn to ensure that all concerns were addressed. Dr. Parkin thanked Dr. Halanych for using the webinar to make and display the revisions to the draft document in response to the Board's deliberations during the meeting.

Dr. Parkin called for approval of the draft final report as amended during the teleconference/webinar meeting. The webinar was used to poll webinar participants, and Board members not participating via webinar voted verbally. All members approved the report. Dr. Parkin remarked that given the full consensus, Mr. Downing will prepare the final report for transmittal to the EPA Science Advisor.

Mr. Downing described the next steps. Final corrections will be made to the report and the appropriate citations will be inserted. The final report will be certified by the HSRB Chair and DFO and then transmitted to the EPA Science Advisor.

Mr. Downing announced that the April HSRB meeting was cancelled, and the next HSRB meeting is scheduled for June 12 to 13, 2013. Details regarding agenda topics as well as the length and times of the meeting will be provided approximately 75 days prior to the meeting date. The HSRB will discuss between one and three topics, which will require a meeting length of up to 1 and 1/2 days. Dr. Manautou mentioned that he has a commitment in Alexandria, Virginia, on June 11 to 13, 2013. Mr. Downing commented that if the meeting is 1 day in length, the Board could elect to hold the meeting on June 13, 2013, if that would enable Dr. Manautou to participate.

The participants agreed that using the webinar format to view the changes to the draft document during the discussion was helpful. Dr. Popendorf remarked that the bulleted report format improved readability, and other HSRB members agreed. Mr. Downing expressed anticipation that the bulleted format would be perceived positively by the EPA Science Advisor.

ADJOURNMENT

Dr. Parkin thanked the Board members for their participation. The teleconference/ webinar meeting was adjourned by Mr. Downing at 12:15 p.m.

Respectfully submitted:

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

Certified to be true by:

Rebecca Parkin, Ph.D., M.P.H.
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public teleconference/webinar 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

+Rebecca Tyrrell 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
Lake Frederick, VA

Vice Chair

+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

Members

+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

+Sidney Green, Jr., Ph.D., Fellow, ATS — Term: 10/19/2009-8/31/2015
Department of Pharmacology
Howard University College of Medicine (Retired)
Silver Spring, MD

+Elizabeth Heitman, Ph.D. — Term: 9/1/2012-8/31/2015
Associate Professor of Medical Bioethics
Center for Biomedical Bioethics and Society
Vanderbilt University Medical Center
Nashville, TN

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

+John C. Kissel, Ph.D. Term: 9/1/2012-8/31/2015
Department of Environmental
and Occupational Health Sciences
School of Public Health
University of Washington
Seattle, WA

+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

+William J. Popendorf, Ph.D. Term: 10/19/2009-8/31/2015
Professor Emeritus
Department of Biology
Utah State University
Logan, UT

+Nu-May Ruby Reed, Ph.D., D.A.B.T. Term: 9/1/2012-8/31/2015
Retired Staff Toxicologist
California Environmental Protection Agency (Cal/EPA)
Department of Pesticide Regulation
Davis, CA

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

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

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

+Linda J. Young, Ph.D. Term: 3/28/2008-8/31/2014
Professor and Associate Chair
Department of Statistics
Institute of Food and Agricultural Sciences
University of Florida
Gainesville, FL

+ Present via telephone April 12, 2013

Attachment B

FEDERAL REGISTER NOTICE ANNOUNCING MEETING

[*Federal Register* Volume 78, Number 60 (Thursday, March 28, 2013)]
[Notices]
[Pages 18978-18979]
From the *Federal Register* Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2013-0115]

==========

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2013-0115; FRL-9794-8]

Human Studies Review Board (HSRB); Notification of a Public Webinar/Teleconference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U. S. Environmental Protection Agency (EPA) Office of the Science Advisor (OSA) announces a public Webinar/teleconference of the HSRB to discuss its draft report from the HSRB meeting held January 17, 2013.

DATES: The Webinar/teleconference will be held on Friday, April 12, 2013, from approximately 11:00 a.m. to approximately 12:30 p.m. Eastern Time. Comments may be submitted on or before Friday, April 5, 2013. Information regarding the HSRB final meeting report will be found at http://www.epa.gov/osa/hsrb and http://www.regulations.gov or from the persons listed under FOR FURTHER INFORMATION CONTACT.

Webcast: This meeting may be webcast. Please refer to the HSRB Web site http://www.epa.gov/osa/hsrb for information on how to access the webcast. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2013-0115, by one of the following methods:

Internet: http://www.regulations.gov: Follow the website 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. Eastern Time, Monday through Friday, excluding federal holidays. Please call (202) 566-1744 or e-mail 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-2013-0115. 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 (CBI) 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 website 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 about this Webinar/teleconference should contact Jim Downing at telephone number: (202) 564-2468; fax: (202) 564-2070; email address: downing.jim@epa.gov or Lu-Ann Kleibacker at 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, 8105R, 1200 Pennsylvania Avenue NW, Washington, DC 20460. General information concerning the HSRB can be found on the EPA website at http://www.epa.gov/osa/hsrb.

SUPPLEMENTARY INFORMATION:

Location: The meeting will take place via the Internet and telephone only. Access information can be found on the HSRB website: http://www.epa.gov/osa/hsrb or by contacting the persons listed under the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

Meeting access: For detailed information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least 10 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 (FFDCA) or the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Since other entities may also be interested, the EPA 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

[[Page 18979]]

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 by providing comments 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-2013-0115 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 Friday, April 5, 2013. 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, Friday, April 5, 2013, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official (DFO) to review the meeting agenda to provide an 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 5 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 5 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, Friday, April 5, 2013. 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 EPA 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 (FACA) 5 U.S.C. App. 2 Section 9. The HSRB provides advice, information and recommendations to the 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 the 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 January 17, 2013 HSRB meeting. The HSRB may also discuss planning for future HSRB meetings. Background on the January 17, 2013 HSRB meeting can be found at the HSRB website: http://www.epa.gov/osa/hsrb. The January 17, 2013 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 http://www.regulations.gov and the HSRB website at http://www.epa.gov/osa/hsrb. For questions on document availability or if you do not have Internet access, consult the person 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 HSRB final meeting report will be found at http://www.epa.gov/osa/hsrb or from the persons listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: March 20, 2013.
Glenn Paulson,
Science Advisor.
[FR Doc. 2013-07263 Filed 3-27-13; 8:45 am]
BILLING CODE 6560-50-P

Attachment C

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

Friday, April 12, 2013
11:00 am - 12:30 pm (Eastern Time)*

HSRB MEETING FOR REVIEW AND APPROVAL OF THE DRAFT JANUARY 17, 2013 HSRB MEETING FINAL REPORT

HSRB WEBSITE http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566 1752
Docket Number: EPA–HQ–ORD–2013-0115

Meeting location via telephone/Internet only

11:00 AM	**Convene Meeting and Identification of Board Members** – Jim Downing (Designated Federal Officer, EPA HSRB, OSA)
11:05 AM*	**Meeting Administrative Procedures** – Jim Downing, DFO
11:10 AM	**Meeting Process** – Rebecca Parkin, Ph.D., MPH (HSRB Chair)
11:15 AM	**Public Comments**
11:20 AM	**Board Discussion and Decision on Final Report** – Rebecca Parkin, Ph.D., M.P.H. (HSRB Chair)

The Board's response to EPA charge questions presented at the January 17, 2013 meeting.

A completed study report from the Antimicrobial Exposure Assessment Task Force II (AEATF) in which the dermal and inhalation exposure of professional janitorial workers was monitored as they poured liquid antimicrobial pesticide products from conventional or reduced-splash containers into different sizes and types of receiving containers

Charge to the Board – Science:

- Was the research reported in the Antimicrobial Exposure Assessment Task Force II (AEATF) completed liquid pour study report (AEA05) faithful to the design and objectives of the protocol and governing documents of the AEATF?

- Has EPA adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating the exposure of people who pour liquid antimicrobial pesticide products?

Charge to the Board – Ethics:

- If the AHETF proposal is revised as suggested in EPA's review and if the research is performed as described, is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

12:25 PM* **Summary and Next Steps –** Rebecca Parkin, Ph.D., M.P.H. (HSRB Chair) and Jim Downing (DFO)

12:30 PM* **Adjournment**

*Note that agenda times are approximate. 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.