Minutes of the
U. S. Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
March 17, 2017, Public Meeting
HSRB Website: www.epa.gov/osa/human-studies-review-board

Committee Members:	(See EPA HSRB Members List—Attachment A)	
Date and Time:	Friday, March 17, 2017, 2:00–4:00 p.m. EDT	
	(See *Federal Register* Notice—Attachment B)	
Location:	Via Teleconference and Webinar	
Purpose:	The EPA HSRB provides advice, information and recommendations on issues related to the scientific and ethical aspects of human subjects research.	
Attendees:	Chair:	Liza Dawson, Ph.D.
	Vice Chair:	Edward Gbur, Jr., Ph.D.
Board Members:		Jennifer Cavallari, Sc.D., CIH Gary Chadwick, Pharm.D, M.P.H., CIP Alesia Ferguson, Ph.D. Kyle L. Galbraith, Ph.D. Jewell H. Halanych, M.D., M.Sc. Walter T. Klimecki, D.V.M., Ph.D. Randy Maddalena, Ph.D. Jun Zhu, Ph.D.
Consultant to the Board:		Kendra L. Lawrence, Ph.D., BCE, PMP
Meeting Summary:	Meeting discussions generally followed the issues and timing as presented in the Meeting Agenda unless noted otherwise.	

Introduction of Board Members and Convening of the Public Meeting

Mr. Jim Downing, (Designated Federal Officer [DFO], HSRB [or Board], Office of the Science Advisor, EPA [or Agency]), convened the meeting at 2:00 p.m. and welcomed Board members, EPA colleagues and the public. This meeting will finalize the report from the January 25–26, 2017, meeting and will continue the review of the discussion topic Mosquito Repellency Testing. Mr. Downing expressed the Agency's appreciation to the Board members for their time and efforts preparing for the meeting and for their deliberations in developing the final report.

Mr. Downing noted that in his role as DFO under the Federal Advisory Committee Act (FACA), he functions as liaison between EPA and the HSRB and is responsible for ensuring that all FACA provisions are met regarding the operations of the HSRB. As the DFO, his responsibility is to work with appropriate Agency officials to ensure that all appropriate ethics regulations are satisfied. HSRB members were briefed on provisions of the federal ethics and conflict-of-interest laws and have completed government financial disclosure reports, which have been reviewed to ensure that all ethics requirements are satisfied.

Meeting Administrative Procedures

Mr. Downing informed the Board members that they would review the draft Final Report from the January 2017 meeting and finalize the report for submission to the Science Advisor and the Agency. He mentioned that the times on the agenda are approximate and reminded speakers to state their name before presenting. Mr. Downing reminded the meeting participants to keep their telephones on mute when not speaking and, when speaking, to unmute their phones to identify themselves. Mr. Downing also told the audience that the public would be allowed to comment at the appropriate time and that public comments would be limited to 5 minutes. He indicated that no individuals had pre-registered to provide public comments.

In accordance with FACA requirements, meeting minutes that include a description of the matters discussed and decisions reached by the Board will be prepared and must be certified by the meeting Chair within 90 calendar days of this meeting. The approved minutes will be accessible through the HSRB website. He thanked the Board members for their participation in the meeting and expressed his interest in finalizing the January 2017 report. Mr. Downing turned the meeting over to Dr. Liza Dawson, HSRB Chair, to discuss the meeting process.

Meeting Process

In response to Dr. Dawson's request, Mr. Downing conducted the roll call of the Board members, then asked the members to introduce themselves, providing their names, affiliations and role in the HSRB. In reviewing the meeting process, Dr. Dawson mentioned the Adobe Connect site for making comments and voting on decisions regarding various studies discussed during the meeting. She described the meeting process and noted the two items on the agenda: (1) Board Discussion and Decision on the January 25–26, 2017, Final Report and (2) Board Discussion and Recommendations on Mosquito Repellency Testing.

Topic 1: Board Discussion and Decision on January 25–26, 2017, Final Report

Dr. Dawson called for a final approval of the Final Report from January 25–26, 2017, pending minor editorial corrections and clarification. She solicited comments and discussion, reminding the Board that substantive changes to the report cannot be made without adherence to FACA procedural requirements.

Study: Cimetidine-Carbaryl Interaction in Humans: Evidence for an Active Metabolite of Carbaryl, authored by D. G. May, R. J. Naukam, J. R. Kambam, and R. A. Branch. Journal of Pharmacology and Experimental Therapeutics *(1992) 262(3): 1057–61*.

Dr. Dawson opened a discussion regarding the study design, statistical aspects and generalizability of the cimetidine-carbaryl article discussed during the January 25–26 meeting. In response to the charge question to the Board—"Is the research described in the published article scientifically sound, providing reliable data?"—the Board concluded from the January meeting that the data were reliable for the proposed purposes but raised questions about the generalization of the data to a larger human population. The Board was asked by EPA's Office of Pesticide Programs (OPP) to comment on the fact that the wording in the Board's consensus statement written in the report differed from statements made orally during the January meeting. OPP inquired whether the concern about the ability to generalize from the data related solely to the sample size in the study. Dr. Dawson noted that sample size in addition to other factors may affect whether the findings can generalize to larger groups.

Dr. Dawson solicited comments from the Board members on whether they agreed with the wording of the draft report and with possibly adding "small sample sizes" or "small sample sizes plus other considerations" to the statement about generalizability in the report.

An HSRB member suggested leaving the wording as it is and to not add the description of small sample sizes in the draft report because the study had the limitation of including only males. He cautioned against possibly identifying additional limitations in the response to the charge question. Another HSRB member agreed that the report's wording should not be changed and referred to the list of parameters (limitations) on page 6 of the report that define the applicability or non-applicability to larger populations.

Ms. Michelle Arling (OPP, EPA) recommended including this statement in the report: "Provides reliable data for the purposes EPA described." She mentioned that EPA's goal is to not generalize data, but rather use specific measurements that were derived from the data set in pharmacokinetic (PBPK) modeling. She requested the Board's consensus on the recommended statement regarding the reliability of the data when used for model validation and on distinguishing these from the considerations that may affect generalization of the data more broadly.

Dr. Dawson alluded to the last paragraph on page 6 of the report, which describes the Board's assertion that the data are reliable and useful for EPA's purposes. She questioned how much of the descriptive content of the report should be included in the response to the charge question; the question only addresses reliability, not aspects of generalizability or purpose. An HSRB member agreed with Dr. Dawson's comment and recommended removing the description of the aspects of generalizability from the first sentence of the response to the charge question, adding it to the discussion section. The HSRB member commented that the charge question relates to internal validity, whereas generalizability is an external validity question. Another HSRB member agreed with the idea of removing the description but proposed adding specific wording to the charge question itself, as well as to the response, that addresses the issue of generalizability. Mr. Downing stated that the charge question could not be changed retrospectively, but the Board's response to the charge may include such specific language.

In response to an HSRB member's comment, Dr. Dawson agreed that it is appropriate to include in the introduction to the report some background provided by the Agency at the last meeting that explains the proposed use of the data. Dr. Dawson indicated that the Board will vote on this issue.

One HSRB member raised a concern about the language in the response that says, "It [the data] is scientifically sound and provides reliable data for the purposes discussed by EPA." Previously, the Board may not have understood what these purposes are regarding modeling; he recommended describing the proposed use more clearly in the response to the charge question. Concerning the purpose of the data, another HSRB member suggested the possibility of incorporating the statement: "Provides reliable data for validating relevant PBPK models."

EPA staff said that the Agency plans to use the PBPK model for simulations that will be for the representative population. The concern for the generalizability of data is irrelevant because the data will be used for validation purposes.

Dr. Dawson recommended including in the detailed response to the charge question that generalizability is a concern that may arise for certain uses of the data, but that it is not relevant for the model validation as proposed by the Agency. She cautioned against adding the issue of generalizability to the Board's response to the charge question. In reply to an HSRB member's point, Dr. Dawson added that it is important to have a good understanding of what are reliable data and the different aspects of study design. Specifically, the Board should clearly define the Agency's use of the data and revise its response to the charge question accordingly.

Hearing no further comments, Dr. Dawson called for a vote on the following changes to the report: (1) In the introduction to this section of the report, specify the proposed uses of the data from the carbaryl study—validation of PBPK models by the Agency, (2) add the wording "reliable data for the proposed use by the Agency" to the response to the charge question, and (3) remove the comments regarding generalizability from the response to the charge question, and incorporate them into the "Detailed Recommendations and Rationale" section of the report.

The Board reached a consensus and agreed to the proposed changes.

Dr. Dawson opened the floor for additional questions. EPA asked about a reference to incorrect statements made by EPA (the last paragraph on page 6 of the report) describing the carbaryl study. The statements addressed the possible additive combined effect of carbaryl and cimetidine. EPA also sought clarification regarding the inconsistencies in sample sizes. An HSRB member replied that these were areas of minor inconsistencies in the article but did not warrant questioning the internal validity of the data.

Hearing no further comments, Dr. Dawson called for a vote to add a clarification sentence at the end of the paragraph on page 6, stating that these discrepancies do not reduce the confidence in the use of the data for the purposes proposed.

The Board reached a consensus and agreed to the proposed addition to the report.

Study: "A Randomized Double-Blind Ascending Single Oral Dose Study With Malathion to Determine the No-Effect Level on Plasma and RBC Cholinesterase Activity" and "Determination of Residues of Malathion Dicarboxylic Acid, Malathion Monocarboxylic Acid, Dimethyl Phosphate, Dimethyl Thiophosphate, and Dimethyl Dithiophosphate in Human Urine."

Dr. Dawson opened a discussion regarding the statistical aspects and generalizability of the malathion study discussed during the January meeting. In response to the charge question to the Board—"Does the research described in the unpublished study provide scientifically sound, reliable data?"—the Board conceded during the January meeting that the data were reliable for the proposed purposes and may or may not be generalizable to large groups.

The following changes to the report were recommended: (1) add a description regarding the Agency's intended use of the data, (2) remove the issue of generalizability from the response to the charge question, and (3) mention in the response that the Board agrees that the data are reliable for the purposes proposed by the Agency.

An HSRB member commented that the detailed recommendations and rationale for the charge question make no specific mention about generalizability that should concern the Board because of the larger sample size in the study. In response, Dr. Dawson replied that some statistical comments in the discussion of the report might indicate that the data are not generalizable according to statistical analysis.

EPA acknowledged that in the malathion study, the statistical analysis was inadequate for the acetylcholinesterase inhibition data, which the Agency will not use because it is not relevant for their purposes. Additionally, population-level inference is not relevant for the uses proposed by the Agency. Dr. Dawson suggested not only including the description of the Agency's proposed use of the PBPK data but also incorporating the elements of the study that the Agency intends to use and not use.

Hearing no further comments, Dr. Dawson called for a vote on the following proposed changes to the report: (1) Include a description of the Agency's proposed use of the PBPK data and also incorporate the elements of the study that the Agency intends to use and not use, (2) remove the mention of generalizability from the response to the charge question, and (3) state in the response to the charge question that the Board agrees that the data are reliable for the purposes proposed by the Agency.

The Board reached a consensus and agreed to the proposed changes.

Studies:

Methylisothiazolinone (MI) Contact Allergy and Dose-Response Relationships, authored by M. D. Lundov, C. Zachariae, and J. D. Johansen. Contact Dermatitis *(2011) 64(6): 330–6.*

Methylisothiazolinone in Rinse-off Products Causes Allergic Contact Dermatitis: A repeated Open-Application Study, authored by K. Yazar, M. D. Lundov, A. Faurschou, M. Matura, A. Boman, J. D. Johansen, and C. Lidén. British Journal of Dermatology *(2015) 173(1): 115–22.*

An Evaluation of Dose/Unit Area and Time as Key Factors Influencing the Elicitation Capacity of Methylchloroisothiazolinone/Methylisothiazolinone in MCI/MI-Allergic Patients, authored by C. Zachariae, A. Lerbaek, P. M. McNamee, J. E. Gray, M. Wooder, and T. Menné. Contact Dermatitis *(2006) 55(3): 160–6.*

Dr. Dawson introduced a discussion regarding the three Repeat Open Application Test (ROAT) dermatological-related published studies that were reviewed for scientific reliability by Drs. Alesia Ferguson and Randy Maddalena during the January meeting. These articles assessed the various ways that dermal products can be tested. Dr. Dawson reminded the meeting participants that the charge to the Board was whether these studies provided scientifically sound, reliable data. For each study, the Board reached consensus that the results provided reliable and sound data; some caveats and concerns related to the study design were expressed, however.

Dr. Dawson solicited comments on whether the report accurately captured the Board's responses.

Dr. Ferguson agreed that the report captured her responses accurately and reminded the Board that EPA is using these three studies for risk assessments, which require a more in-depth review of all of the study factors and the numerous variables that can be considered.

EPA recommended correcting some details in the Board's commentary on the Zachariae et al. article. On page 26 of the draft report, "aged under 18" should be corrected to read "18 years of age and older." An additional recommendation was to correct the description of the scale used for skin sensitivity grading that is mentioned in table 2 of the Zachariae et al. article. The draft report describes the table as using the scale "weak", "moderate" or "strong," but OPP noted that the scale used in that table was different. Another recommendation was to make an addition to the statement in the draft report (page 27) regarding the description of the ROAT studies: "Application to the same area following a rinse-out period might be expected to result in more rapid sensitivity for the ROAT 2 arm." In fact, EPA staff had contacted the study team about this issue and found that a different area was used for the second application. An additional statement should clarify this point.

Hearing no further comments, Dr. Dawson called for a vote to accept these three corrections to the draft report, namely, the correct description of the age group included in the study, the correct scale for skin sensitivity for table 2, and the additional information about application of the product to different areas in ROAT 1 and ROAT 2.

The Board reached a consensus and agreed to the three proposed changes.

Dr. Dawson introduced a discussion on the proposed combined use of the three ROAT studies for a weight-of-evidence (WOE) approach to risk assessment. The WOE approach is intended to determine the point of departure (POD) for risk assessment of *methylisothiazolinone* (MI) in these studies. The Board was asked to comment on whether the report accurately reflects its response to the charge question, "Do the three studies provide a scientific WOE in support of establishing a POD for the determination of an elicitation threshold for MI?"

Dr. Ferguson confirmed that the studies provided a WOE in support of establishing "a" POD, not "the" POD; the actual POD is unknown in these articles. Regarding the scientific approach of these studies, she suggested that a lower product concentration may be applied in sensitized individuals for safety reasons. She also verified that the information on the bottom of page 33 of the report accurately captures her conclusions.

Hearing no further comments, Dr. Dawson called for a vote that the Board agrees with the conclusions expressed in the report regarding the use of the data from the three studies.

The Board reached a consensus and agreed to the proposed changes regarding POD; Dr. Dawson indicated that she will work with Dr. Ferguson to change the response to the charge question. The finalized report will be submitted to Mr. Downing.

Noting no further discussion, Dr. Dawson called for public comments.

Public Comments

Joanne Ryder (The Dow Chemical Company) wondered how the submitted comments from the product manufacturing companies will be incorporated into the report. The comments were related to perceived significant deficiencies in the ethics, statistical power and overall usefulness of the study.

Dr. Dawson reiterated that the meeting minutes accurately reflect all of the statements that were made in discussion, per FACA procedures for public comments. Mr. Downing added further clarification of the process by saying that the Board takes into consideration all of the public comments that are made before and during the meetings; they are considered in the Board's deliberations and in response to the charge questions, as reflected in the report. The HSRB is not required to respond to public comments in its response to the charge questions; however, the Board does take these comments into consideration as it deliberates and prepares a final report.

Hearing no further public comments, Dr. Dawson introduced a discussion of Topic 2, Mosquito Repellency Testing.

Topic 2: Board Discussion of Mosquito Repellency Testing

In a previous meeting, OPP had requested that HSRB review and comment on a proposed draft guidance for investigators regarding field testing of mosquito repellents. The Board was tasked to review the draft guidance and make formal recommendations on guidance for repellency field testing. These field studies assess the duration of repellency of personal repellent products for the purpose of consumer product labeling, which is important given the recent risk of vector-borne illnesses, such as Zika virus (ZIKV). OPP developed a guidance document on mitigating the risk of ZIKV in human subjects participating in these repellency studies. The HSRB sought to elicit expert input on this topic by inviting

subject-matter experts (e.g., in the fields of vector biology and epidemiology) who can provide insight on the risks of these vector-borne diseases.

Dr. Dawson welcomed Dr. Kacey Ernst (University of Arizona, Mel and Enid Zuckerman College of Public Health), who has expertise in the epidemiology of vector-borne diseases and who had previously provided Dr. Dawson with some input by telephone regarding ZIKV transmission and field testing. Dr. Ernst provided comments regarding vector-borne (arbovirus) disease surveillance and the assessment of ZIKV transmission. Dr. Ernst described her research interests and explained that a passive disease surveillance system exists in each health jurisdiction in the United States. The requirements that warrant testing for ZIKV transmission are state-specific, and the decision for testing varies across counties. Dr. Ernst reviewed the current testing recommendations for pregnant women and other individuals who travel.

Dr. Dawson wondered about the feasibility of surveillance for ZIKV in mosquito populations versus in humans. Dr. Ernst replied that it varies between cities, but most arbovirus cases typically are recognized by conducting human surveillance. She confirmed that ZIKV is more likely detected in humans before detection in mosquitos; humans are the primary reservoirs for ZIKV, Chikungunya virus and Dengue virus (DENV), whereas avian species are reservoirs for West Nile virus. Dr. Ernst speculated that although ZIKV might be transmitted more easily by mosquitos than DENV, this is not an absolute indicator of locally acquired transmission. In response to Dr. Dawson's question, Dr. Ernst stated that various factors influence detectable transmission in travel-acquired cases, such as the distribution of the *Aedes aegypti* mosquito, which is in the southern United States (i.e., Arizona, Florida, Georgia, Mississippi and Southern California), the level of travel, and the duration of the *A. aegypti* season. Dr. Ernst also noted that the usefulness of repellency data depends on the mosquito species, which have different responses to repellents. Repellency testing of *A. aegypti* is of greater importance than for other species because it is most implicated in transmission.

An HSRB member asked whether species information would be captured in a repellency study of an area with several different species of mosquitoes. Dr. Ernst replied that such a study requires a control, baseline species distribution, traps and careful selection of the area that certain mosquitos are known to exist in. Expounding further, Dr. Ernst said that testing should be done during peak biting times of the *A. aegypti* (i.e., late afternoon, early evening) and also should determine the landing pressure of the mosquito.

Dr. Dawson pointed out that the typical charge question for the Board is to review the trials involving human subjects and to determine their ethical acceptability, which includes an assessment of risk to human study participants. She questioned Dr. Ernst on how to assess the possible risk of transmission if field studies are set up in an area that has not experienced ZIKV transmission. Dr. Ernst replied that the assessment of risk depends on the testing location and time of testing (i.e., transmission season); repellency should not differ in areas of high population density of *A. aegypti* that may or may not have transmission history.

In reply to Dr. Dawson's request for guidance on the best sources of information for determining the most suitable field sites for repellency studies, Dr. Ernst recommended selecting local counties and mosquito control districts with known active surveillance. She also suggested contacting the U.S. Centers for Disease Control and Prevention (CDC) about laboratories that have been certified for human and mosquito ZIKV testing. Also, important information from each jurisdiction may be collected by contacting state epidemiologists, who can be identified through the Council of State and Territorial Epidemiologists. To minimize risk of exposure to ZIKV, it is important to eliminate locales with a transmission history of other *A. aegypti*-transmitted arboviruses.

An HSRB member described relevant factors when conducting repellency studies—ascertaining the actual risk of transmission and how this would best translate to informed consent of a study participant residing in a region that may have ZIKV. Dr. Ernst added that incorporating exclusion criteria into the study (i.e., pregnant or soon-to-be pregnant women and their partners) is important. Mr. Downing reminded the meeting participants that OPP proposed including men and women who plan to conceive in the exclusion criteria. The CDC recommends that ZIKV-infected men wait a period of at least 6 months before sexual activity.

Dr. Dawson mentioned that although there are various methods to manage risk (e.g., reproductive intentions), the majority of women who become pregnant do not plan their pregnancies. She recommended further discussion with the Board regarding the inclusion factors for risk. Dr. Ernst suggested that incorporating a questionnaire for female study subjects regarding their use of birth control may be a suitable approach to manage risk in these types of studies.

Summary and Next Steps

Dr. Dawson pointed out that further suggestions for consideration and final approval of the Board's recommendation on repellency testing will occur at the next meeting. She will write a draft response to EPA's guidance and submit it to the Board for consideration during the next meeting.

Adjournment

Dr. Dawson thanked Dr. Ernst for her insight and turned the meeting over to Mr. Downing. Mr. Downing thanked the Board members for their contributions. He announced that the next HSRB meeting is scheduled for April 27, 2017. Notification of the final schedule will be posted on the HSRB website.[1]

Mr. Downing adjourned the meeting at 4:04 p.m. EDT.

Respectfully submitted:

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

Certified to be true by:

Liza Dawson, Ph.D.
Chair
Human Studies Review Board
United States Environmental Protection Agency

[1]The HSRB website is available at www.epa.gov/osa/human-studies-review-board.

NOTE AND DISCLAIMER: The minutes of this public 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.

Attachment A

EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

Liza Dawson, Ph.D.
Research Ethics Team Leader
Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD

Vice Chair

Edward Gbur, Jr., Ph.D.
Professor of Statistics
Director, Agricultural Statistics Laboratory
University of Arkansas
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Members

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George C. J. Fernandez, Ph.D.
Statistical Training Specialist
SAS Institute
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Kyle L. Galbraith, Ph.D.
Human Subjects Protection
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Jewell H. Halanych, M.D., M.Sc.
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Internal Medicine Residency Program
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Walter T. Klimecki, D.V.M., Ph.D.
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Departments of Pharmacology and Toxicology
The University of Arizona Health Sciences
Tucson, AZ

Randy Maddalena, Ph.D.
Physical Research Scientist
Indoor Environment Group
Lawrence Berkeley National Laboratory
Berkeley, CA

Members (continued)

Jun Zhu, Ph.D.
Professor of Statistics and of Entomology
Department of Statistics
University of Wisconsin–Madison
Madison, WI

Consultant to the Board

Kendra L. Lawrence, Ph.D., BCE, PMP
Health Sciences Product Manager
U.S. Army Medical Materiel Development Activity
Fort Detrick, MD

Attachment B

***FEDERAL REGISTER* NOTICE ANNOUNCING MEETING**

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9957-50-ORD]

Human Studies Review Board; Notification of a Public Meeting

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Office of the Science Advisor announces two separate public meetings of the Human Studies Review Board to advise the Agency on the ethical and scientific reviews of EPA research with human subjects.

DATES: A public virtual meeting will be held on January 25–26, 2017, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time each day. A separate, subsequent teleconference meeting is planned for Friday, March 17, 2017, from 2:00 p.m. to approximately 3:30 p.m. for the HSRB to finalize its Final Report of the January 25–26, 2017 meeting.

ADDRESSES: Both of these meetings will be conducted entirely by telephone and on the Internet using Adobe Connect. For detailed access information, visit the HSRB Web site: http://www2.epa.gov/osa/human-studies-review-board.

FOR FURTHER INFORMATION, CONTACT: Any member of the public who wishes to receive further information should contact Jim Downing on telephone number (202) 564–2468; fax number: (202) 564–2070; email address: downing.jim@epa.gov; or 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/hsrb.

SUPPLEMENTARY INFORMATION:

Meeting access: These meetings are open to the public. Meeting materials are available at the HSRB Website: http://www2.epa.gov/osa/human-studies-review-board for questions on document availability, or if you do not have access to the Internet, consult with Jim Downing listed under **FOR FURTHER INFORMATION CONTACT.**

Special accommodations. For information on access or services for individuals with disabilities, or to request accommodation of a disability, please contact Jim Downing listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

How May I Participate in This Meeting?

The HSRB encourages the public's input. You may participate in these meetings by following the instructions in this section.

1. Oral comments. Requests to present oral comments during either conference call will be accepted up to Noon Eastern Time on Wednesday, January 18, 2017, for the January 24-25, 2017 meeting and up to Noon Eastern Time on Friday, March 10, 2017 for the March 17, 2017 conference call. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments during either call at the designated time on the agenda. Oral comments before the HSRB are generally limited to five minutes per individual or organization. If additional time is available, further public comments may be possible.

2. Written comments. Submit your written comments prior to the meetings. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments by Noon Eastern Time on Time on Wednesday, January 18, 2017, for the January 24–25, 2017 conference call and up to Noon Eastern Time on Friday, March 10, 2017 for the March 17, 2017 conference call. If you submit comments after these dates, those comments will be provided to the HSRB members, but you should recognize that the HSRB members may not have adequate time to consider your comments prior to their discussion. You should submit your comments to Jim Downing listed under **FOR FURTHER INFORMATION CONTACT.** There is no limit on the length of written comments for consideration by the HSRB.

Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 § 9. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research that are submitted to the Office of Pesticide Programs to be used for regulatory purposes. 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.

Topics for discussion. On Wednesday, January 25, 2017, EPA's Human Studies Review Board will consider three published articles:

1. Methylisothiazolinone Contact Allergy and Dose-Response Relationships, authored by Michael D. Lundov, Claus Zachariae, and Jeanne D. Johansen. *Contact Dermatitis* (2011) 64: 330–6.

2. Methylisothiazolinone in Rinse-Off Products Causes Allergic Contact Dermatitis: A repeated Open-Application Study, authored by K Yazar, M.D. Lundov, A. Faurschou, M. Matura, A. Boman, J.D. Johansen, and C. Lidén. *British Journal of Dermatology* (2015) 173: 115–22.

3. An Evaluation of Dose/Unit Area and Time as Key Factors Influencing the Elicitation Capacity of Methylchloroisothiazolinone/Methylisothiazolinone (MCI/MI) in MCI/MI-Allergic Patients, authored by Claus Zachariae, Anne Lerbaek, Pauline M. McNamee, John E. Gray, Mike Wooder, and Torkil Menné. *Contact Dermatitis* (2006) 55: 160–6.

Then on Thursday, January 26, 2017, the HSRB will consider:

1. Published article: Cholinesterase Activity Resulting From Carbaryl Exposure.

2. Unpublished article: A Randomized Double Blind Study With Malathion to Determine the Residues of Malathion Dicarboxylic Acid (DCA), Malathion Monocarboxylic Acid (MCA), Dimethyl Phosphate (DMP), Dimethyl Thiophosphate (DMTP), and Dimethyl Dithiophosphate (DMDTP) in Human Urine.

Meeting materials for these topics will be available in advance of the meeting at http://www2.epa.gov/osa/human-studies-review-board.

On Friday, March 17, 2017, the Human Studies Review Board will review and finalize their draft Final Report from the January 25–26, 2017 meeting. The draft report will be available prior to the conference call at http://www2.epa.gov/osa/human-studies-review-board.

Meeting minutes and final reports. Minutes of these meetings, summarizing the matters discussed and recommendations made by the HSRB, will be released within 90 calendar days of the meeting. These minutes will be available at http://www2.epa.gov/osa/human-studies-review-board. In addition, information regarding the HSRB's Final Report, will be found at http://www2.epa.gov/osa/human-studies-review-board or from Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: December 13, 2016.

Thomas A. Burke,

EPA Science Advisor.

[FR Doc. 2016-31640 Filed 12-28-16; 8:45 am]

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