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**April 25, 2007**

**Minutes of the**
**United States Environmental Protection Agency (EPA)**
**Human Studies Review Board (HSRB)**
**April 10, 2007 Public Teleconference**
**Docket Number: EPA-HQ-ORD-2006-0998**

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

Dates and Times: Tuesday, April 10, 2007, 1:00 PM – 3:00 PM
(See Federal Register Notice – Attachment B)

Location: via teleconference

Purpose: The EPA Human Studies Review Board (HSRB) provides advice, information, and recommendations on issues related to the scientific and ethical aspects of human subjects research.

Attendees:

Chair: Celia B. Fisher, Ph.D.

Board Members:

David C. Bellinger, Ph.D.
William S. Brimijoin, Ph.D.
Gary L. Chadwick, PharmD, MPH, CIP
Janice Chambers, Ph.D., D.A.B.T.
Richard Fenske, Ph.D., MPH
Susan S. Fish, PharmD, MPH
Suzanne C. Fitzpatrick, Ph.D., D.A.B.T.
Kannan Krishnan, Ph.D.
KyungMann Kim, Ph.D., CCRP
Michael D. Lebowitz, Ph.D., FCCP
Sean M. Philpott, Ph.D.
Richard Sharp, 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.

**Introductory Remarks, Meeting Administrative Procedures, and Meeting Process**

Dr. Celia Fisher (HSRB Chair) opened the teleconference meeting with an introduction and identification of the HSRB, or Board, members participating in the call. Dr. Fisher explained that the purpose of the meeting was to review and approve the January 24, 2007 draft

HSRB meeting report (Attachment D) and respond to questions raised by EPA's Office of Pesticide Programs (OPP).

Dr. Paul Lewis (Designated Federal Officer [DFO], HSRB, Office of the Science Advisor [OSA], EPA) thanked Dr. Fisher and the Board for their participation in the teleconference and the efforts they put into their review of the report from the January 24, 2007 meeting. Dr. Lewis explained that the HSRB is subject to Federal Advisory Committee Act (FACA) requirements. As the DFO, Dr. Lewis serves as liaison between the HSRB and EPA. He works with the appropriate officials to ensure compliance with all appropriate ethics regulations. Each member of the Board has filed a standard government financial disclosure form that has been reviewed by EPA to ensure that all ethics disclosures have been met.

Dr. Lewis asked Board members and public commenters to identify themselves each time they speak for the purposes of the audio recording and meeting minutes. He requested that members of the public hold their remarks until the designated public comment period and limit their remarks to 5 minutes.

Dr. Lewis stated that the documents discussed by the HSRB, including the draft January 24, 2007 HSRB meeting report, are available at the public docket; the address for the docket was included in the *Federal Register* notice announcing this teleconference meeting. As per FACA requirements, the meeting minutes will include descriptions of matters discussed and the conclusions reached by the Board. As the DFO, Dr. Lewis will prepare the minutes and have them certified by the HSRB Chair within 90 calendar days of the meeting. In addition, the minutes will be available at the public docket and posted on the HSRB Web site.

**Public Comments**

Dr. Fisher invited oral public comment on the January 2007 HSRB meeting report. No oral public comments were presented.

**Board Discussion and Decision on Report**

Dr. Fisher introduced the written comments submitted by EPA's Office of Pesticide Programs (OPP) and stated that these comments would be discussed during the teleconference. Dr. Alicia Carriquiry was unable to attend the teleconference, but sent Dr. Fisher her response to OPP's comments.

For the tick repellency study, EMD-003, OPP suggested that the Complete Protection Time (CPT) range of 6.5 to 12 hours be changed to 6.5 to 15 hours for the pump spray (p. 11, line 28). This revision was accepted by the Board.

OPP questioned the Board's recommendation regarding use of different statistical analysis procedures across studies EMD-003 and EMD-004, and protocol SCI-001. At the January 24, 2007 HSRB meeting, the Board suggested transitioning to more accurate methods of calculating efficacy, but recognized that a change in analytical techniques might limit the ability to compare new studies to older studies and create confusion for consumers (p. 13, lines 15-20



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and p. 19, lines 6-12). Dr. Michael Lebowitz questioned how EPA, manufacturers, or investigators can compare results of new studies to those of older studies and whether there are clear, easily referenced EPA guidelines regarding appropriate statistical analysis of efficacy studies. The HSRB should review any current EPA guidelines before suggesting changes to the current analysis processes. Mr. William Jordan (OPP, EPA) responded that OPP has internal procedures for conducting efficacy studies that describe how to conduct statistical analysis. Given the comments at the January 24, 2007 HSRB meeting and in the Board's draft meeting report, OPP is reevaluating this issue. There are consistency issues regarding statistical analysis procedures used by different EPA offices. EPA intends to address this situation with input from the Board at a future HSRB meeting. Questions also have arisen concerning how to reconcile protection times calculated using previous or current methods with those determined using new methods. Mr. Jordan expects that once a plan is established for the conduct of new studies and analysis of results, EPA will discuss with the Board this new process.

Dr. Fisher asked for a description of EPA's current guidelines and whether the Board could have access to them. Mr. Jordan explained that when EPA receives results from companies, the company has typically performed a statistical analysis and presents the analysis to EPA. EPA evaluates the results, but performs its own analysis if it believes the approach used by the company is not appropriate. Mr. Jordan added that he did not know if there were formal documents describing EPA guidelines and offered to obtain the information and present it to the HSRB at a future meeting.

Dr. KyungMann Kim commented that his impression from the January 24, 2007 HSRB meeting was that the analyses were not checked by an EPA staff member who is trained in statistics. He explained that the Kaplan Meier estimate he described at the January 2007 meeting is not a new technique, but rather has been widely used for more than 50 years in human clinical studies. Mr. Jordan agreed that EPA needs to revisit its approach to the statistical analysis of these studies. Work is underway to address this issue, but no conclusions regarding the use of new approaches or transitioning to these approaches have been reached. Dr. Fisher stated that the HSRB will have difficulty making recommendations on this matter if specific guidelines for analytical techniques are not available.

Mr. Jordan commented that he did not have a full understanding of the extent to which EPA has consistently used the same approach for statistical analysis in past years. In recent years, analyses have been relatively consistent. However, in some of the older repellant efficacy studies evaluated by EPA, the approaches used for statistical analyses are unknown. Dr. Lebowitz suggested that the Board should discuss with members of OPP and any other relevant EPA offices recommended statistical approaches for efficacy studies at a future meeting. Dr. Kannan Krishnan supported this suggestion. He added that to be fair to the proponents and OPP, comments related to analyses should be captured as a separate category in the report rather than being attached to a particular protocol. Dr. Fisher stated that she will discuss with Dr. Lewis and members of OPP how to proceed on this issue during the next administrative planning teleconference.

The Board discussed limiting comments pertaining to encouraging EPA to consider different analytical techniques to the HSRB Consensus and Rationale section of the report.



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Redundant verbiage (i.e., p. 12, line 36-45) would be eliminated. Upon review of the statement in the HSRB Consensus and Rationale for EMD-003 (p. 13, lines 15-20), the Board decided to remove the word "recent" and the second sentence was changed to read, "…how a transition to more appropriate methods of calculating efficacy for the specific data set can be introduced…" Because the issue of encouraging EPA to consider different analytical techniques pertains to EMD-003, EMD-004, and SCI-001, this change would be made in all three sections of the report.

OPP raised questions concerning the HSRB's comments on the desirability of serologic or molecular testing to ensure that field studies were conducted in areas known to be free of vector-borne diseases. The Board commented that such studies would have been desirable for EMD-003 and EMD-004, but lack of such studies did not appear to compromise the safety of the subjects (p. 21, lines 14-20). However, for SCI-001, the Board recommended that mosquitoes be collected so that serologic or molecular testing could be performed (p. 25, lines 40-42). OPP believes that these comments are inconsistent. Three conditions for testing were discussed, including the following:

1. Is it sufficient protection if field tests are conducted only in areas where known vector-borne diseases have not been detected by county and state health or vector/mosquito control agencies for at least one month?
2. If #1 is satisfied, are serologic or molecular analyses needed to confirm the zone is free of known pathogens?
3. Do serologic or molecular analyses need to always be conducted post-study to confirm the absence of pathogens for specific mosquitoes that landed on participants?

Dr. Lebowitz commented that public health agencies usually trap and test mosquitoes using serologic techniques in addition to monitoring a sentinel flock and testing them serologically as well. For the protection of the subjects, trapping landing mosquitoes for serologic testing is desirable because it would allow subjects to be warned of the potential presence of vector-borne pathogens and treated if necessary. Option #2 would not be necessary if option #3 was performed.

Dr. Sean Philpott noted that for molecular or serologic testing, mosquitoes are pooled. This would provide an alert to the group as a whole, not to individuals. He agreed with Dr. Lebowitz that there should be no requirement to conduct post-study testing if an independent control agency has confirmed that the test area is pathogen-free in the previous month. Dr. Fisher asked Board members to consider whether a lack of post-study testing would place subjects at unacceptable risk of harm or if post-study testing would be ideal if possible. The Board agreed to change references to "recommended" post-study testing for SCI-001 (p. 25, line 40) to "suggested" post-study testing.

Dr. Fisher related a series of questions and requests for clarification from OPP regarding research design comments for SCI-001. OPP asked whether the comments made for *Experimental design* and *Statistical analysis* (p. 23, lines 31-39) were consensus recommendations. Drs. Fisher and Janice Chambers said that although there is no reason to believe the products will be more or less effective on a given limb, the conservative approach



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would be to randomize the limb used in the testing protocol. Dr. Krishnan noted that while randomization is used in the protocol, it is ignored in the data analysis. The Board agreed that the comments under *Experimental design* should be considered by OPP to be suggestions, not recommendations.

Concerning the comments under *Statistical analysis* (p. 23, lines 36-43 and p. 24, lines 1-8), OPP explained that the goal of this research is to establish CPT and not necessarily to compare CPTs across products. Dr. Kim remarked that Board comments should be taken as a suggested approach to develop more sensitive or appropriate comparisons. Dr. Krishnan agreed that the primary objective of the study was to test efficacy; comparison of products was a secondary goal. Dr. Fisher stated that the Board's recommendation is that if comparisons are made, use of the analytical approach suggested by the Board should be considered.

Dr. Fisher introduced discussion on *Interpretation of results* (p. 24, lines 9-14). OPP questioned the Board's comments concerning whether the sample used in SCI-001 was a representative sample, considering the Board had accepted use of a similar sample for EMD-003 and EMD-004. Dr. Kim stated that the sample sizes used in EMD-003 and EMD-004 are not properly justified for statistical analysis. Measures of variability and between-treatment effect size are needed to appropriately determine sample size. Statements made in the analyses concerning p values and adequate power are baseless. Dr. Kim clarified that sample sizes will be inconsistent across different studies because of differences in variability and effect size. The use of the same sample size in all of these studies indicates that the investigators did not have adequate justification for sample size. Submissions of protocols to EPA should ensure that there is appropriate justification for use of a given sample size. Dr. Fisher explained that the Board suggests that EPA consider these recommendations and asks investigators to provide justification for their analyses. The Board will then evaluate whether the data generated will be useful to EPA. Board members decided that the report should include a statement indicating that justification of sample size and other analytical techniques is essential.

Also under *Interpretation of results*, the Board considered the composition of the sample and whether it was representative. Dr. Chambers noted that because the sample did not include the elderly, people sensitive to mosquitoes, children, or pregnant or nursing women, the sample is not truly representative. Dr. Fisher remarked that under the ethics rules applied to these studies, these individuals cannot be included. Drs. Susan Fish and Chambers expressed concern about the small sample size. In the population, people can vary in their "attractiveness" to mosquitoes by as much as 100-fold; additionally, people who are sensitive to mosquito bites probably would not agree to participate in these studies. Differences in attractiveness could impact efficacy of the repellants. Given this degree of variability in sensitivity and attractiveness to mosquitoes, it is unlikely that the 10 subjects included in the sample span this range of variability. Dr. Fisher agreed that because the sample is unlikely to include individuals with a wide range of sensitivity, the data must be interpreted judiciously. The Board members agreed that the use of "friends, neighbors, and academic associates" of Dr. Carroll was less of a concern than that the sample is not a true random sample. Drs. Chambers and Kim noted that rarely are truly representative samples used in intervention studies; they agreed that a statement should be made concerning interpretation of results, given that the sample is not random. The Board

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agreed to delete the statement concerning the inclusion of "friends, neighbors, and academic associates" of Dr. Carroll in the study (p. 24, line 13).

The Board discussed *Inclusion/Exclusion criteria* (p. 24, lines 26-30). Dr. Fisher proposed that the bullet title be changed to "Sample Size Considerations for Subject Drop-Outs." This change was accepted by the Board. The Board agreed that better development or explanation of inclusion/exclusion criteria was needed, along with an explanation of how data from these individuals would be used in the analysis.

OPP requested clarification of the Board's comments concerning the *Assumption of normality of CPT measurements* (p. 24, lines 31-37). Dr. Kim explained that if CPT is determined for SCI-001 the same way as for EMD-003, the normality assumption is inappropriate. If the sample size is only 10 per group, the data will not be normally distributed. Dr. Carriquiry's comments noted that the statistical analysis methods used in this protocol rely on the assumption that the measurements are normal. Because of the small sample size, departures from normality can have significant consequences on the validity of the proposed methodology. The Board agreed to recommend that the appropriate analyses and models, given the true distribution of the data, should be used by the investigator. Dr. Fish proposed the text be changed to, "In choosing the appropriate statistical analysis methods, one should consider the distribution of the data." The Board agreed to this change and determined that mention of specific models would be deleted.

The Board agreed to delete the bullets titled *Comparison to Ultrathon* (p. 24, lines 44-45) and *Typo* (p. 24, line 46). The Board agreed to accept the typographical changes suggested by OPP.

The Board agreed that the HSRB Consensus and Rationale for Scientific Considerations (p. 25, lines 2-12) should be modified to indicate that the Board raised concerns about sample size and statistical design and analyses that should be addressed; the statement concerning comparison of the recommendations to Agency guideline requirements should be deleted. Dr. Kim questioned the wording of the first bullet under Scientific Considerations for SCI-001 (p. 3, lines 13-15). The Board agreed to delete this bullet.

Dr. Fisher opened discussion on Ethical Considerations for SCI-001. In the report, the Board stated that the protocol does not describe how untreated controls would be recruited (p. 26, lines 11-12). OPP requested clarification of the Board's comments concerning the qualification of the Independent Investigational Review Board (IIRB) (p. 26, lines 36-40). OPP asked if the Board was requiring EPA to assess IIRB qualifications for this protocol. Dr. Fisher and the Board agreed that although information on IIRB qualifications would be reassuring, at this point the statement is a comment, not a recommendation.

Dr. Krishnan asked the Board to discuss the summary comments on page 3 concerning the statistical design of protocol SCI-001 (bullet 1, lines 13-15). The Board agreed to delete this comment because they currently do not have information on EPA guidelines concerning statistical design of efficacy protocols. They agreed that this issue should be discussed at a future HSRB meeting.



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Dr. Philpott asked for clarification of OPP's suggested deletion of Subpart L from the ethical requirements for EMD-003 (p. 16, line 11). Subpart L specifically excludes children and nursing or pregnant women from studies, such as EMD-003. Dr. Fisher agreed that Subpart L would not be deleted and that she and Dr. Lewis would discuss with Mr. John Carley (OPP, EPA) why OPP had indicated in its comments that only Subpart K applied to the protocol.

Regarding the HSRB Consensus and Rationale for Scientific Considerations for EMD-004 (p. 19, lines 1-13), no changes were made aside from the deletion of the comments about use of different statistical analysis techniques. No changes were made to the HSRB Consensus and Rationale for Ethical Considerations for EMD-004 (p. 22, lines 14-26).

Dr. Fisher asked each Board member for their approval of the revised January 24, 2007 draft meeting report. All Board members in attendance at the teleconference meeting approved the report. Dr. Fisher thanked Board members for their participation.

Dr. Lewis reminded HSRB members that the next face-to-face meeting would be held April 18-20, 2007 in Arlington, Virginia. The June 2007 HSRB meeting will cover agenda topics and also will provide time for the HSRB to review and approve the report from the April 2007 meeting.

The meeting was adjourned by the Chair.

Respectfully submitted:

Paul I. Lewis, Ph.D.
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:

Celia B. Fisher, Ph.D.
Chair
Human Studies Review Board
United States Environmental Protection Agency

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.



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Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice for 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.

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## Attachments

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| Attachment A | HSRB Members |
| Attachment B | Federal Register Notice Announcing Meeting |
| Attachment C | Meeting Agenda |
| Attachment D | January 24, 2007 EPA Human Studies Review Board Meeting Proposed Final Draft Report |

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**Attachment A**

**EPA HSRB Members**

**Chair**

**Celia B. Fisher, Ph.D.**
Marie Ward Doty Professor of Psychology
Director, Center for Ethics Education
Fordham University
Bronx, NY

**Vice Chair**

**William S. Brimijoin, Ph.D.**
Chair and Professor
Molecular Pharmacology and Experimental Therapeutics
Mayo Foundation
Rochester, MN

**Members**

**David C. Bellinger, Ph.D.**
Professor of Neurology
Harvard Medical School
Professor in the Department of Environmental Health
Harvard School of Public Health Children's Hospital
Boston, MA

**Alicia Carriquiry, Ph.D. ***
Professor
Department of Statistics
Iowa State University
Ames, IA

**Gary L. Chadwick, PharmD, MPH, CIP**
Associate Provost
Director, Office for Human Subjects Protection
University of Rochester
Rochester, NY

**Janice Chambers, Ph.D., D.A.B.T.**
William L. Giles Distinguished Professor
Director, Center for Environmental Health Sciences
College of Veterinary Medicine
Mississippi State University
Mississippi State, MS

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**Richard Fenske, Ph.D., MPH**
Professor
University of Washington
Department of Environmental and Occupational Health Sciences
Seattle, WA

**Susan S. Fish, PharmD, MPH**
Associate Professor, Biostatistics & Epidemiology
Boston University School of Public Health
Co-Director, MA in Clinical Investigation
Boston University School of Medicine
Boston, MA

**Suzanne C. Fitzpatrick, Ph.D., D.A.B.T.**
Senior Science Policy Analyst
Office of the Commissioner
Office of Science and Health Coordination
U.S. Food and Drug Administration
Rockville, MD

**KyungMann Kim, Ph.D., CCRP**
Professor and Associate Chair
Department of Biostatistics & Medical Informatics
School of Medicine and Public Health
University of Wisconsin-Madison
Madison, WI

**Kannan Krishnan, Ph.D.**
Professor
Département de santé environnementale et santé au travail
Faculté de médicine
Université de Montréal
Montréal, QC

**Michael D. Lebowitz, Ph.D., FCCP**
Professor of Public Health & Medicine
University of Arizona
Tucson, AZ

**Lois D. Lehman-Mckeeman, Ph.D. ***
Distinguished Research Fellow, Discovery Toxicology
Bristol-Myers Squibb Company
Princeton, NJ

**Jerry A. Menikoff, M.D. ***
Associate Professor of Law, Ethics & Medicine
Director of the Institute for Bioethics, Law and Public Policy
University of Kansas Medical Center
Kansas City, KS

**Sean M. Philpott, Ph.D.**
Policy and Ethics Director
Global Campaign for Microbicides
Program for Appropriate Technology in Health
Washington, DC

**Richard Sharp, Ph.D.**
Assistant Professor of Medicine with the Center for Medical Ethics and Health Policy
Baylor College of Medicine
Houston, TX

* Not in attendance at teleconference

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**Attachment B**

**Federal Register Notice Announcing Meeting**

**Human Studies Review Board (HSRB); Notification of a Public Teleconference To Review Its Draft Report From the January 24, 2007 HSRB Meeting**

[Federal Register: March 13, 2007 (Volume 72, Number 48)]
[Notices]
[Page 11358-11359]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr13mr07-51]

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ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-ORD-2006-0998; FRL-8287-2]

Human Studies Review Board (HSRB); Notification of a Public Teleconference To Review Its Draft Report From the January 24, 2007 HSRB Meeting

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

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SUMMARY: The EPA Human Studies Review Board (HSRB) announces a public teleconference meeting to discuss its draft HSRB report from the January 24, 2007 HSRB meeting.

DATES: The teleconference will be held on April 10, 2007, from 1 to approximately 3 p.m. (Eastern Time).
Location: The meeting will take place via telephone only.
Meeting Access: For information on access or services for individuals with disabilities, please contact the DFO 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 Unit I.D. of this notice.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain the call-in number and access code to participate in the telephone conference, request a current draft copy of the Board's report or who wish further information may contact Lu-Ann Kleibacker, EPA, Office of the Science Advisor, (8105R), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or via telephone/voice mail at (202) 564-7189. General information concerning the EPA HSRB can be found on the EPA Web site at http://www.epa.gov/osa/hsrb/.

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ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2006-0998, by one of the following methods:
http://www.regulations.gov Follow the on-line instructions for submitting comments.
E-mail: ORD.Docket@epa.gov.
Mail: ORD Docket, Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.
Hand Delivery: EPA Docket Center (EPA/DC), Public Reading Room, Infoterra Room (Room Number 3334), EPA West Building, 1301 Constitution Avenue, NW, Washington, DC 20460, Attention Docket ID No. EPA-ORD-2006-0998. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.
Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2006-0998. EPA'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 comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an ``anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through http://www.regulations.gov, your e-mail 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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, 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.

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 interest to persons who conduct or assess human studies, especially studies on substances regulated by 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 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 the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Access Electronic Copies of This Document and Other Related Information?

In addition to using regulations.gov, you may access this Federal Register document electronically through the EPA Internet 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

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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 in http://www.regulations.gov or in hard copy at the ORD Docket, EPA/DC, Public Reading Room, Infoterra Room (Room Number 3334), EPA West Building, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

The January 24, 2007 HSRB 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 the regulations.gov Web site and the HSRB Internet Home Page at http://www.epa.gov/osa/hsrb/. For questions on document availability or if you do not have access to the Internet, consult the person listed under FOR FURTHER INFORMATION CONTACT.

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 you used that support your views.
4. Provide specific examples to illustrate your concerns.
5. To ensure proper receipt by 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 EPA, it is imperative that you identify docket ID number EPA-HQ-ORD-2006-0998 in the subject line on the first page of your request.
1. Oral comments. Requests to present oral comments will be accepted up to April 3, 2007. 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 at the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via e-mail) to the person listed under FOR FURTHER INFORMATION CONTACT no later than noon, eastern time, April 3 2007, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB DFO to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of the



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individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are 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 these time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, there may be flexibility in time for public comments.
2. Written comments. Although you may submit written comments at any time, 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, April 3, 2007. You should submit your comments using the instructions in Unit 1.C. of this notice. In addition, the Agency also requests that person(s) submitting comments directly to the docket also provide a copy of their comments to the person listed under FOR FURTHER INFORMATION CONTACT. There is no limit on the length of written comments for consideration by the HSRB.

E. Background

The EPA Human Studies Review Board will be reviewing its draft report from the January 24, 2007 HSRB meeting. Background on the January 24, 2007 HSRB meeting can be found at Federal Register 71 249, 78200 (December 28, 2006) and at the HSRB Web site http://www.epa.gov/osa/hsrb/. The Board may also discuss planning for future HSRB meetings.
Dated: March 7, 2007.
George Gray,
EPA Science Advisor.
[FR Doc. E7-4565 Filed 3-12-07; 8:45 am]
BILLING CODE 6560-50-P

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**Attachment C**

**3/16/07**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**HUMAN STUDIES REVIEW BOARD (HSRB)**
**PUBLIC TELECONFERENCE MEETING**
**APRIL 10, 2007**
**1:00 pm -3:00 pm (Eastern Time)**

**HSRB MEETING FOR REVIEW AND APPROVAL OF**
**DRAFT JANUARY 24, 2007 HSRB MEETING REPORT ***

**HSRB WEB SITE http://www.epa.gov/osa/hsrb/**
**Docket Telephone: (202) 566 1752**
**Docket Number: EPA-HQ-ORD-2006-0998**

**Meeting location via telephone only**
**Members of the public may obtain the call in number at 202-564-7189**

**1:00 PM** **Introduction and Identification of Board Members** – Celia Fisher, Ph.D. (HSRB Chair)
**1:15 PM** **Welcome** – Warren Lux, MD (Human Studies Research Review Official, Office of the Science Advisor, [OSA])
**1:20 PM** **Meeting Administrative Procedures** - Paul Lewis, Ph.D. (Designated Federal Officer, HSRB, OSA, EPA)
**1:25 PM** **Meeting Process –** Celia Fisher, Ph.D. (HSRB Chair)
**1:30 PM** **Public Comments**
**1:45 PM** **Board Discussion and Decision on Report** - Celia Fisher, Ph.D. (HSRB Chair)

**Completed Insect Repellent Completed Efficacy Studies**
**EMD-003**
**EMD-004**

**Insect Repellent Efficacy Protocol SCI-001**
**2:45 PM** **Summary and Next Steps** - Celia Fisher, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (Designated Federal Officer, HSRB, EPA)
**3:00 PM** **Adjournment**

* Please be advised that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Paul Lewis via telephone: (202) 564-8381 or email: lewis.paul@epa.gov.