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**Minutes of the**
**United States Environmental Protection Agency (EPA)**
**Human Studies Review Board (HSRB)**
**August 14, 2007 Public Teleconference**
**Docket Number: EPA-HQ-ORD-2007-0216**

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

| | | |
|---|---|---|
| Dates and Times: | Tuesday, August 14, 2007, 3:00 PM – 5:00 PM<br>(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: | Gary L. Chadwick, PharmD, MPH, CIP<br>Janice Chambers, Ph.D., D.A.B.T.<br>Richard Fenske, Ph.D., MPH<br>Susan S. Fish, PharmD, MPH<br>KyungMann Kim, Ph.D., CCRP<br>Michael D. Lebowitz, Ph.D., FCCP<br>Jerry A. Menikoff, M.D.<br>Sean M. Philpott, 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 April 18-20, 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 for their review of the draft April 18-20, 2007 HSRB meeting report. 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 requirement 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 April 18-20, 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 draft April 18-20, 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/OPP and stated that the Board discussion during the teleconference would focus on questions and points of clarification raised by OPP. Dr. Fisher suggested that the Board adopt all OPP recommendations that were factual or editorial corrections.

In the summary letter to Dr. George Gray (Science Advisor, EPA) (p. 3, lines 45-46 and p. 4, lines 1-2), OPP requested clarification of the Board's conclusion concerning the Repeated Insult Patch Test (RIPT). "The Board concluded that, because (1) there was insufficient IRB [Institutional Review Board] review of all products to which subjects were exposed, (2) information concerning research procedures within the consent form itself was inadequate, and (3) the limited if any scientific validity of the study did not produce a positive risk-benefit ratio, there was clear and convincing evidence that the conduct of the study was significantly deficient relative to the ethical standards prevailing when the study was conducted." OPP inquired whether it was fair to apply these tests *ex post facto* to the conduct of research and if the Board's conclusion addressed the conduct of the research itself or the adequacy of IRB review.
Dr. Sean Philpott clarified that the first two points concerning IRB review and information on the test products pertained to the adequacy of the IRB review and the third point was based on assessment of the science. Dr. Fisher proposed the text be revised as follows: "The Board concluded that there was insufficient IRB review of all products to which subjects were asked to agree to be exposed. In addition, information concerning research procedures within the consent form itself was inadequate, and the limited if any scientific validity of the study did not produce an *a priori* positive risk-benefit ratio. For these reasons, the Boarc concluded there was clear and



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convincing evidence that the conduct of the study was significantly deficient relative to the ethical standards prevailing when the study was conducted." Board members agreed to delete the final sentence of the paragraph describing prevailing ethical standards.

**Completed Repellent Efficacy Studies: IR3535 Aerosol (EMD-003.3 and EMD-004.3)**

EMD-003.3: Tick Repellency with Aerosol Spray Formulations

OPP commented that the phrase "as suggested by the HSRB" should be deleted (p. 15, line 29), as well as the word "passive" (p. 15, lines 29 - 30). Dr. Janice Chambers agreed with these deletions. Dr. Fisher asked if any Board members wanted to suggest changes to the HSRB Consensus and Rationale related to scientific considerations (p. 18, lines 22-26). No Board members requested changes. There also were no changes to the HSRB Consensus and Rationale related to ethical considerations (p. 21, lines 12-13).

EMD-004.3: Mosquito Repellency with Aerosol Spray Formulations

The Board agreed to accept factual changes suggested by OPP concerning clarification of test sites for EMD-004.3 (p. 21, lines 45-46 and p. 22, lines 1-2).

Dr. Fisher asked if Board members had comments or changes for the HSRB Consensus and Rationale related to scientific considerations (p. 23, lines 37-39). No changes were suggested. There also were no changes to the HSRB Consensus and Rationale related to ethical considerations for this study (p. 27, lines 9-11).

**Carroll-Loye Mosquito Repellent Efficacy Protocol WPC-001**

OPP's written comments clarified that the sample size proposed for Mosquito Repellent Efficacy Protocol WPC-001 was 10 treated and 2 untreated subjects per field site, rather than 6 treated and 1 untreated subject as stated in the Board's draft report (p. 27, line 36). While Dr. KyungMann Kim agreed with this clarification; he advised that the Board's conclusion concerning the potential inadequacy of the sample size remains accurate.

Dr. Fisher requested comments or changes from Board members concerning the HSRB Consensus and Rationale related to scientific considerations (p. 28, lines 13-20) and ethical considerations (p. 29, lines 26-28) for the protocol WPC-001. There were no changes to either conclusion.

**Completed Patch Test Studies**

**Part I. 48-Hour Dermal Irritation Patch Test**

Dr. Fisher asked Board members for comments or changes concerning the HSRB Consensus and Rationale related to scientific considerations for the completed 48-Hour Dermal Irritation Patch Test (p. 33, lines 28-42). There were no changes to the Board's conclusion.



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OPP's written comments clarified that three of the test materials used in the 48-Hour Dermal Irritation Patch Test were research and development samples, not "currently marketed cosmetic products" (p. 34, line 26). Dr. Susan Fish agreed with OPP's proposed change to the meeting report.

Dr. Fisher requested comments or changes from Board members concerning the HSRB Consensus and Rationale related to ethical considerations for this study (p. 37, lines 25-33). No changes were made to the Board's conclusion.

OPP's written comments requested clarification on the Board's concern about inadequate justification for use of human subjects in the 48-Hour Dermal Irritation Patch Test (p. 36, lines 21-23). "The only rationale provided by the submitter for testing the combination in humans is a policy of avoiding unnecessary experimentation with animals and thus the sponsor chose not to do the usual studies in animals prior to testing it in humans." OPP inquired as to why this concern was not raised for the RIPT study. Dr. Fish agreed that although this matter was not discussed by the Board, this issue does apply to the RIPT study as well as the 48-Hour Dermal Irritation Patch Test. Dr. Jerry Menikoff agreed that the lack of animal testing before testing on human subjects was an important point for the ethics assessment and should be added to the discussion of the RIPT study.

Dr. Fisher asked the Board for ways to clarify that the submitter's desire not to test on animals is not a legitimate ethical reason to perform human testing as defined by current ethical regulations, while avoiding comment on the submitter's philosophy against animal testing. Dr. Gary Chadwick stated that the submitter's philosophy against animal testing was the only reason the submitter cited for justification for exposure of human subjects to potential risk. This single reason was insufficient to make a decision to conduct human testing. Board members agreed to revise the statement in the draft meeting report (p. 36, lines 21-23) as follows: "The Board felt that with respect to federal regulations, this argument alone provides insufficient justification for exposure of human participants to potential risk." The Board also agreed to add this statement to the discussion of the RIPT study (p. 44, lines 35-38).

**Part II. Repeated Insult Patch Test**

OPP's written comments clarified information regarding the removal of test patches in the RIPT study (p. 40, lines 7-17). Dr. Fish agreed with OPP's corrections, but added that the changes did not affect the Board's assessment of the study. Dr. Richard Fenske commented that there appears to be ambiguity in EPA's understanding of the information provided by the sponsor and that statements to this effect should be reflected in the text. Dr. Fenske also agreed that because the clarifications made by Mr. John Carley (OPP, EPA) were based on additional information received by EPA, the changes should be accepted.

Dr. Fisher asked Board members for comments or changes concerning the HSRB Consensus and Rationale related to scientific considerations for this study (p. 41, lines 32 - 38). No changes were made to the Board's conclusion.

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Board members agreed with OPP's suggestion to mention that different consent documents reported the schedule of events related to patch placement, patch removal, and readings in contradictory ways (p. 45, line 15 - 16). Dr. Fish also noted a typographical error in the word "planned" in the last sentence of Point 3 (p. 45, line 15).

In the HSRB Consensus and Rationale related to ethical considerations (p. 46, lines 32-42), Board members agreed to remove the last sentence (p. 46, lines 41-42).

**Framework for Developing Best Practices for Subject Recruitment for Handler Exposure Research**

In OPP's written comments it was noted that the draft framework contained all of the requested additional elements for consent documents. Dr. Fenske inquired whether all the additional elements were described fully in the consent forms. Dr. Menikoff suggested that Dr. Lewis determine whether all elements have been included; if so, Point 9 requesting additional elements could be removed from the meeting report. Drs. Lewis and Fisher agreed with this approach, and decided to change "mention the elements" to "mention each element" if the additional elements were not included.

**Follow-up on AHETF and AEATF Protocols**

Concerning the Board Response to the Charge for Follow-up on Agricultural Handler Exposure Task Force (AHETF) and Antimicrobial Exposure Assessment Task Force (AEATF) protocols, Board members agreed that they wished to continue to learn more about EPA's approach to this issue and discuss the task forces' activities at future HSRB meetings (p. 51, lines 30 – 36).

Dr. Fisher requested comments or changes from Board members concerning the HSRB Consensus and Rationale related to scientific considerations for these protocols (p. 53, lines 35 - 45 and p. 54, lines 1-8). No changes were made to the Board's conclusion.

**Summary and Next Steps**

Dr. Fisher requested other comments on the document; no other comments were made. Dr. Fisher asked each Board member for their approval of the revised April 18-20, 2007 draft meeting report, including acceptance of the points of factual clarification and grammatical changes raised by OPP which were not discussed during the teleconference. All Board members in attendance at the teleconference meeting approved the report.

Dr. Lewis thanked Board members for their participation. Dr. Lewis stated that he and Dr. Fisher will revise the report based on comments made during the teleconference. The revised report will be released at regulations.gov and posted on the HSRB Web site. The next face-to-face HSRB meeting is scheduled for October 23-26, 2007.

The meeting was adjourned by the Chair.



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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. 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

| | |
|---|---|
| Attachment A | HSRB Members |
| Attachment B | Federal Register Notice Announcing Meeting |
| Attachment C | Meeting Agenda |
| Attachment D | April 18-20, 2007 EPA Human Studies Review Board Meeting Proposed Final Draft Report |

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**Attachment A**

**EPA HUMAN STUDIES REVIEW BOARD 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**

**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

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

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**Susan S. Fish, PharmD, MPH**
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., DABT***
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 Canada

**Michael D. Lebowitz, Ph.D.**
Research Professor of Medicine & Epidemiology/Public Health
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.**
National Institute of Health
Office of Human Subjects Research
Bethesda, MD

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

**Richard Sharp, Ph.D.***
Assistant Professor of Medicine
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 April 18-20, 2007 HSRB Meeting**

[Federal Register: July 26, 2007 (Volume 72, Number 143)]
[Notices]
[Page 41073-41074]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr26jy07-47]

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ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-ORD-2007-0216; FRL-8446-6]

Human Studies Review Board (HSRB); Notification of a Public Teleconference To Review Its Draft Report From the April 18-20, 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 April 18-20, 2007 HSRB meeting.

DATES: The teleconference will be held on August 14, 2007, from 3 to approximately 5 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, to request a current draft copy of the Board's report or to obtain further information, may contact Crystal Rodgers-Jenkins, EPA, Office of the Science Advisor, (8105), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; or via telephone/voice mail at (202) 564-

5275. General information concerning the EPA HSRB can be found on the EPA Web site at http://www.epa.gov/osa/hsrb/.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2007-0216, 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-2007-0216. 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-2007-0216. 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

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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 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 April 18-20, 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.

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-2007-0216 in the subject line on the first page of your request.

1. Oral comments. Requests to present oral comments will be accepted up to August 7, 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

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no later than noon, eastern time, August 7, 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 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, August 7, 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 April 18-20, 2007 HSRB meeting. Background on the April 18-20, 2007 HSRB meeting can be found at Federal Register 72 57, 14101 (March 26, 2007) and at the HSRB Web site http://www.epa.gov/osa/hsrb/.

The Board may also discuss planning for future HSRB meetings.

Dated: July 20, 2007.
George Gray,
EPA Science Advisor.
[FR Doc. E7-14468 Filed 7-25-07; 8:45 am]

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**Attachment C**

**8/9/07**

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**HUMAN STUDIES REVIEW BOARD (HSRB)**
**PUBLIC TELECONFERENCE MEETING**
**AUGUST 14, 2007**
**3:00 pm -5:00 pm (Eastern Time)**

**HSRB MEETING FOR REVIEW AND APPROVAL OF**
**DRAFT APRIL 18-20, 2007 HSRB MEETING REPORT ***

**HSRB WEB SITE http://www.epa.gov/osa/hsrb/**
**Docket Telephone: (202) 566 1752**
**Docket Number: EPA-HQ-ORD-2007-0216**

**Meeting location via telephone only**
**Members of the public may obtain the call in number at 202-564-5275**

- **3:00 PM** **Introduction and Identification of Board Members** – Celia Fisher, Ph.D. (HSRB Chair)
- **3:10 PM** **Meeting Administrative Procedures** - Paul Lewis, Ph.D. (Designated Federal Officer, HSRB, OSA, EPA)
- **3:15 PM** **Meeting Process –** Celia Fisher, Ph.D. (HSRB Chair)
- **3:20 PM** **Public Comments**
- **3:30 PM** **Board Discussion and Decision on Report –** Celia Fisher, Ph.D. (HSRB Chair)

**Completed Repellent Efficacy Studies: IR3535 Aerosol (EMD-003.3 and EMD-004.3)**

EMD-003.3: Tick Repellency with Aerosol Spray Formulations

a. Is this study sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy of the formulation tested against ticks?

b. Does available information support a determination that this study was conducted in substantial compliance with subparts K and L of EPA regulations at 40 CFR part 26?

EMD-004.3: Mosquito Repellency with Aerosol Spray Formulations

a. Is this study sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy of the formulation tested against mosquitoes?

b. Does available information support a determination that this study was conducted in substantial compliance with subparts K and L of EPA regulations at 40 CFR part 26?



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**Carroll-Loye Mosquito Repellent Efficacy Protocol WPC-001**

a. If the proposed research described in Protocol WPC-001 from Carroll-Loye Biological Research is revised as suggested in EPA's review, does the research appear likely to generate scientifically reliable data, useful for assessing the efficacy of the test substances for repelling mosquitoes?

b. If the proposed research described in Protocol WPC-001 from Carroll-Loye Biological Research is revised as suggested in EPA's review, does the research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

**Research Conducted After April 7, 2006: Meaning of "Substantial Compliance" with 40 CFR Part 26**

(no charge question)

**Completed Patch Test Studies**

**Part I. 48-Hour Dermal Irritation Patch Test**

a. Is this study sufficiently sound, from a scientific perspective, to be used as part of a weight-of-evidence assessment to evaluate the potential of the formulations tested to irritate human skin?

b. Is there clear and convincing evidence that the conduct of this study was fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted?

**Part II. Repeated Insult Patch Test**

a. Is this study sufficiently sound, from a scientific perspective, to be used to be used as part of a weight-of-evidence assessment to evaluate the potential of the formulations tested to cause sensitization of human skin?

b. Is there clear and convincing evidence that the conduct of this study was fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted?

**Framework for Developing Best Practices for Subject Recruitment for Handler Exposure Research**

a. What additional elements of the process of recruiting and enrolling subjects in handler exposure research should be addressed in a "Best Practices Framework"?

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b. For each of the elements in the “Best Practices Framework,” please identify any additional sources of guidance that could be useful for an investigator who is designing a process for recruiting and enrolling subjects in handler exposure research.

**Follow-up on AHETF and AEATF Protocols**

Recognizing that protocol-specific science and ethics issues will be addressed in later HSRB meetings, EPA has attempted to explain the basis for its conclusion that additional information on exposure for people who mix, load, and apply pesticides (handlers) would be useful in EPA's regulatory decision-making and therefore new research would be valuable. Do the materials provided by EPA regarding the quality of the scientific data currently available for assessing exposures for handlers contain useful information to establish the societal value of proposed new handler exposure research, assuming individual protocols would generate scientifically valid information?

What additional information, if any, would the Board want with respect either to handler research in general or to individual protocols?

- **4:45 PM** **Summary and Next Steps -** Celia Fisher, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (Designated Federal Officer, HSRB, EPA)
- **5:00 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.

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