January 29, 2007

Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
January 18, 2007 Public Teleconference
Docket Number: EPA-HQ-ORD-2006-0798

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

Dates and Times:	Thursday, January 18, 2007, 1:30 PM – 4:00 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:	William S. Brimijoin, Ph.D. David C. Bellinger, Ph.D. Alicia Carriquiry, 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. KyungMann Kim, Ph.D., CCRP Michael D. Lebowitz, Ph.D., FCCP Jerry A. Menikoff, M.D. 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 Board members participating in the call. Dr. Fisher explained that the purpose of the meeting was to review and approve the October 18-19, 2006 draft HSRB meeting report (Attachment D).

Following Dr. Fisher's opening remarks, Dr. William Benson (Acting Chief Scientist, Office of the Science Advisor [OSA], EPA) thanked HSRB members for their participation and expressed appreciation for their comprehensive and thoughtful analyses of topics reviewed by the HSRB. He welcomed members of the public to the meeting and informed them that EPA is fully committed to an open and transparent process.

Dr. Paul Lewis (Designated Federal Officer [DFO], HSRB, 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 October 18-19, 2006 meeting. Dr. Lewis explained that the HSRB is subject to Federal Advisory Committee Act (FACA) requirements. As the DFO, Dr. Lewis serves as a liaison between the HSRB and EPA. He works with the appropriate officials to ensure that all appropriate ethics regulations are satisfied. Each member of the Board has filed a standard government financial disclosure form that has been reviewed by the Agency to ensure that all ethics disclosures have been met.

Dr. Lewis noted that there would be slight changes in the order of items listed in the Agenda because of scheduling conflicts. He 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 October 2006 HSRB meeting report and public comments submitted, 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 October 2006 HSRB meeting report. No oral public comments were presented Dr. Fisher stated that one written public comment was received from Exponent, Inc.

Draft EPA Guidance to the Public Concerning Submission of Proposed and Completed Human Research to EPA for Review by the HSRB

Dr. Fisher requested comments from the Board on the 11 recommendations made by the HSRB concerning the Draft EPA Guidance to the Public Concerning Submission of Proposed and Completed Human Research to EPA for Review by the HSRB and EPA (p. 27-29). No comments were received and Dr. Fisher proceeded.

Handling of Material Claimed to be Confidential Business Information (CBI) for HSRB Consideration

Dr. Fisher asked for comments from the Board on the five recommendations made to EPA about the handling of material claimed to be CBI (p. 29). No comments were received from the Board. Dr. Fisher added that this topic would be discussed in more detail at future meetings. She indicated that during the Chair's planning meeting teleconference between herself and EPA, productive discussions on this topic have continued and EPA has been responsive to the Board's concerns about this issue.

IR3535 Insect Repellent Product Efficacy Protocols

Study EMD-003 from Carroll-Loye Biological Research

Following a reading by the HSRB Chair of the Board's conclusions on the scientific and ethical considerations of study EMD-003 (p. 2, lines 27-41), Dr. Fisher asked for comments from the Board. No other comments were received and Dr. Fisher proceeded.

Study EMD-004 from Carroll-Loye Biological Research

Dr. Fisher read the Board's conclusions on the scientific and ethical considerations of study EMD-004 (p. 3, lines 1-18). Dr. Fisher requested comments from the Board. No other comments were received and Dr. Fisher proceeded.

Letter to Dr. George Gray, EPA's Science Advisor

Dr. Fisher informed the Board that EPA had suggested adding a sentence to the transmittal letter to Dr. Gray. The sentence should read, "In addition, at the Board's request, EPA provided background information and discussion regarding the handling of material claimed to be CBI." This revision was accepted by the Board.

Chromium Repeat Open Application Test (ROAT)

Dr. Fisher introduced the written comments submitted by Exponent, Inc. and indicated that the comments provided additional information and suggested changes to the meeting report for the Board's consideration.

Dr. Fisher stated that points A, B, C, E, and F on pages 8 and 9 of Exponent's report provided comments related to factual details. She asked the Board if any of these suggested changes should be incorporated into the meeting report. Dr. Richard Fenske discussed Exponent's comments. For Point A, he stated that the Board's report misstated the issue associated with the test solution; this mistake should be corrected. Thus, the sentence on page 11, lines 24-25 "Ten additional subjects not sensitive to hexavalent chromium serves as controls using the highest concentration of copper contained within the wood treatment solution" was deleted. Dr. Fenske indicated that Point B was a clarification; therefore, it was not necessary to include this in the report. He stated that Point C provided corrected numbers and percentages,

which were initially incorrect in the draft report and thus should be changed. Thus page 13, beginning on line 32 should read "There was a clear gender discrepancy regarding the severity of patch test responses: for the 1+ responses, 33% occurred in males (11/33), and 67% in females (22/33); whereas, for the 2+ or 3+ responses, 52% occurred in males (14/27), and 48% in females (13/27)." Dr. Fenske noted that Point D provided a commentary that did not include specific corrections and that Point F referred to an ethics issue. Dr. Michael Lebowitz agreed with Dr. Fenske that the suggested changes provided in Points A and C should be incorporated into the report.

Dr. Sean Philpott suggested two changes to the report to more accurately reflect both Exponent's and the Board's points of view. The draft language (p. 16, line 7) was: "One hundred subjects agreed to participate and met the initial inclusion criteria." Dr. Philpott recommended that the sentence be changed to: "100 subjects agreed to participate and met the initial inclusion criteria, including completion of chromium sensitivity testing." The second change would address concerns raised by Exponent about issues of verbal consent in the initial telephone interview (p. 18, lines 8-16). The draft language (p. 18, line 13-15) was: "Although verbal consent may have been obtained for the telephone interview, no documentation of such consent was provided to the HSRB." Dr. Philpott recommended the sentence be changed to: "Verbal consent was obtained for the telephone interview, but no documentation of such consent was provided to the HSRB." All Board members agreed with these corrections.

Dr. Fisher read the Board's conclusions on the ethical considerations of the ROAT study (p. 2, lines 12-21). Dr. Fisher requested any further comments from the Board on the ethics recommendations for this study. No other comments were received.

Dr. Fisher read the Board's four conclusions on the scientific considerations of the study and requested Board comments. No comments were received on the first and second conclusions; however, discussion on the third and fourth conclusions ensued.

Concerning the third conclusion (p. 2, lines 1-6), Exponent's report inquired whether it would be possible for EPA to examine each test item or data to determine whether the response is allergic or irritant. Dr. Fenske commented that EPA could not perform a case-by-case evaluation without employing an expert dermatologist. He added that he did not know to what degree the 10 percent minimum elicitation threshold value (MET_{10}) would be affected if a few cases that would be considered allergic under the current protocol would instead be considered irritant. Dr. Lebowitz agreed that it would be difficult for EPA to assess individual cases and that the MET_{10} would not be changed considerably. The Board agreed that no changes would be made to the third conclusion.

Dr. Fisher stated that Exponent's report devoted several pages to discussion on the use of the North American Contact Dermatitis Group (NACDG) database for adjustment or normalization of study results. She asked for comments from the Board on the fourth conclusion (p. 2, lines 8-10). Dr. Fenske explained that the normalization process was described in Exponent's original submission, and involves using patch test data, determining the proportions of responses, and making a proportional adjustment.

Dr. Fisher asked for comments from the Board on the fourth conclusion. Dr. Fenske commented that the additional information provided by Exponent was helpful, but the NACDG database was unlikely to be sufficiently representative of the population to be used to adjust the numbers that will be used for this risk assessment activity. The NACDG database was not designed to collect data from a representative sample of the United States population. Dr. Lebowitz agreed that, given the critical differences in populations, the NACDG database should not be used for normalization. Dr. Fisher concluded that the fourth conclusion would not be modified.

General Board Discussion/Decision

Dr. Fisher summarized the changes to be made to the Board's report. The Board agreed to the following changes to the October 2006 meeting report:

- Incorporating the factual information in Points A and C listed on page 8 of Exponent's report
- Accepting Dr. Philpott's suggested changes to the ethics section on the chromium repeat open application test, and
- Accepting EPA's suggested change to the letter to Dr. Gray.

Dr. Fisher asked each Board member for their approval of the revised October 18-19, 2006 HSRB draft meeting report. All Board members in attendance at the teleconference approved the report.

Dr. Lewis stated that he will work with Dr. Fisher to revise the report based on the Board's discussion and decisions at this teleconference. He noted that the next face-to-face meeting will be held on January 24, 2007.

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. 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.

Attachments

Attachment A	HSRB Members
Attachment B	Federal Register Notice Announcing Meeting
Attachment C	Meeting Agenda
Attachment D	October 18-19, 2006 EPA Human Studies Review Board Meeting Proposed Final Draft Report

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.
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

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., 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., 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.
Associate Professor of Clinical Ethics
Albany Medical College
Associate Director
Alden March Bioethics Institute
Albany Medical Center
Albany, NY

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

Attachment B

Federal Register Notice Announcing Meeting

Human Studies Review Board (HSRB); Notification of a Public Teleconference to Review Its Draft Report from the October 18-19, 2006 HSRB Meeting

[Federal Register: December 26, 2006 (Volume 71, Number 247)]
[Notices]
[Page 77395-77397]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr26de06-50]

ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-ORD-2006-0798; FRL-8261-1]

Human Studies Review Board (HSRB); Notification of a Public Teleconference to Review Its Draft Report from the October 18-19, 2006 HSRB Meeting

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

SUMMARY: The EPA Human Studies Review Board (HSRB) announces a public teleconference meeting to discuss its draft HSRB report from the October 18-19, 2006 HSRB meeting.

DATES: The teleconference will be held on January 18, 2007, from 1:30 to approximately 4 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 person listed 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; telephone (202) 564-7189 or via e-mail at kleibacker.lu-ann@epa.gov. 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-2006-0798, 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-2006-0798. 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-2006-0798. 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, including such 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 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 October 18-19, 2006 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 and suggest alternatives.
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-2006-0798 in the subject line on the first page of your request.

1. Oral comments. Requests to present oral comments will be accepted up to January 11, 2007. To the extent that time permits, interested persons who have

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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, January 11, 2007, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official to review the meeting agenda to provide an 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 five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand 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 five business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, January 11, 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 October 18-19, 2006 HSRB meeting. Background on the October 18-19, 2006 HSRB meeting can be found at Federal Register 71 187, 56527 (September 27, 2006) and at the HSRB Web site http://www.epa.gov/osa/hsrb/. Finally, the Board may discuss planning for future HSRB meetings.

Dated: December 19, 2006.
George M. Gray,
EPA Science Advisor.
[FR Doc. E6-22052 Filed 12-22-06; 8:45 am]
BILLING CODE 6560-50-P

Attachment C

1/08/07

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE MEETING
JANUARY 18, 2006
1:30 pm -4:00 pm (Eastern Time)

HSRB MEETING FOR REVIEW AND APPROVAL OF
DRAFT OCTOBER 18-19, 2006 HSRB MEETING REPORT *

HSRB WEB SITE http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566 1752
Docket Number: EPA-HQ-ORD-2006-0798

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

1:30 PM **Introduction and Identification of Board Members** – Celia Fisher, Ph.D. (HSRB Chair)

1:45 PM **Welcome** – William Benson, Ph.D. (Acting Chief Scientist, Office of the Science Advisor, [OSA], EPA)

1:55 PM **Meeting Administrative Procedures** – Paul Lewis, Ph.D. (Designated Federal Officer [DFO], HSRB, OSA, EPA)

2:00 PM **Meeting Process –** Celia Fisher, Ph.D. (HSRB Chair)

2:05 PM **Public Comments**

2:20 PM **Board Discussion and Decision on Report –** Celia Fisher, Ph.D. (HSRB Chair)

Chromium Repeat Open Application Test
IR3535 Insect Repellent Product Efficacy Protocols
Study EMD-003 from Carroll-Loye Biological Research
Study EMD-004 from Carroll-Loye Biological Research
Draft EPA Guidance to the Public Concerning Submission of Proposed and Completed Human Research to EPA for Review by the HSRB
Handling of Material Claimed to be Confidential Business Information for HSRB Consideration

3:45 PM **Summary and Next Steps –** Celia Fisher, Ph.D. (HSRB Chair) and Paul Lewis, Ph.D. (DFO, HSRB, EPA)

3:50 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.