10/12/06

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD (HSRB)
OCTOBER 18-19, 2006 *
PUBLIC MEETING

Wednesday, October 18, 2006
One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

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

- **8:30 AM** **Introduction and Identification of Board Members** – Celia Fisher, Ph.D. (HSRB Chair)
- **8:45 AM** **Welcome –** Kevin Teichman, Ph.D. (Acting Deputy Assistant Administrator for Science, Office of Research and Development, EPA)
- **8:55 AM** **Opening Remarks –** Mr. Jim Jones (Director, Office of Pesticide Programs, EPA)
- **9:05 AM** **Meeting Administrative Procedures** - Paul Lewis, Ph.D. (Designated Federal Officer [DFO], HSRB, OSA, EPA)
- **9:10 AM** **Meeting Process –** Celia Fisher, Ph.D. (HSRB Chair)
- **9:20 AM** **Update on EPA Follow-up of HSRB Recommendations –** Mr. William Jordan (OPP, EPA)
- **9:30 AM** **EPA Human Studies Research Review Official –** Warren Lux, MD (Human Subjects Research Review Official, OSA, EPA)

Chromium Repeat Open Application Test

- **9:35 AM** **HSRB Review of Science and Ethics Criteria for Completed Human Exposure Studies** - Celia Fisher, Ph.D. (HSRB Chair)
- **9:45 AM** **Chromium Repeat Open Application Test –** John Liccione, Ph.D. (OPP, EPA) and Mr. John Carley (OPP, EPA)
- **10:30 AM** **Break**
- **10:45 AM** **Public Comments**
- **11:15 AM** **Board Discussion**

Hexavalent chromium is a component of a pesticide product intended to be used as a wood preservative. Members of the general public may experience dermal exposure to residues of hexavalent chromium remaining on wood treated with a wood preservative. Because chromium has caused allergic contact dermatitis (ACD) in occupational settings, EPA has determined that it should assess the potential for ACD in the general public resulting from exposure to hexavalent chromium on wood treated with acid copper chromate (ACC).

1. *Scientific considerations:*

   The Agency has concluded that the study contains information sufficient for assessing human risk resulting from potential dermal exposure to wood treated with ACC, containing hexavalent chromium.

   Please comment on whether this study is sufficiently sound, from a scientific perspective, to be used to estimate a safe level of repeated dermal exposure to residues of ACC on treated wood.

2. *Ethical considerations:*

The Agency requests that the Board provide comment on the following:

a. Is there clear and convincing evidence that the conduct of the hexavalent chromium ROAT study was fundamentally unethical?

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

• 12:15 PM Lunch

IR3535 Insect Repellent Product Efficacy Protocols

• 1:15 PM HSRB Review of Science and Ethics Criteria for Proposed Human Exposure Studies - Celia Fisher, Ph.D. (HSRB Chair)
• 1:25 PM Science and Ethics of IR3535 Insect Repellent Product Efficacy Protocols - Clara Fuentes, Ph.D. (OPP, EPA) and Mr. John Carley (OPP, EPA)
• 2:15 PM Public Comments
• 2:45 PM Break
• 3:00 PM Board Discussion

1. *Study EMD-003 from Carroll-Loye Biological Research*

   a. Does the proposed research described in Study EMD-003 from Carroll-Loye Biological Research appear likely to generate scientifically reliable data, useful for assessing the efficacy of a test substance for repelling ticks?

   b. Does the proposed research described in Study EMD-003 from Carroll-Loye Biological Research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

2. *Study EMD-004 from Carroll-Loye Biological Research*

a. Does the proposed research described in Study EMD-004 from Carroll-Loye Biological Research appear likely to generate scientifically reliable data, useful for assessing the efficacy of a test substance for repelling mosquitoes?

b. Does the proposed research described in Study EMD-004 from Carroll-Loye Biological Research appear to meet the applicable requirements of 40 CFR part 26, subparts K and L?

3. Review format

Please comment on the format used for EPA's science and ethics reviews of Dr. Carroll's protocols in terms of:

a. whether future use of this format is likely to produce reviews that adequately explain the basis for EPA's position regarding the ethical and scientific acceptability of the proposed research; and

b. whether presentation of future EPA reviews in such a format will assist the Board's review of proposed protocols.

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

- **4:30 PM** **Background –** Mr. John Carley (OPP, EPA)
- **5:15 PM** **Adjournment**

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- **8:30 AM** **Convene Meeting** – Celia Fisher, Ph.D. (HSRB Chair)
- **8:40 AM** **Follow-up From Previous Day's Discussion –** Mr. William Jordan (OPP, EPA)

Draft EPA Guidance To the Public Concerning Submission of Proposed and Completed Human Research To EPA For Review by the HSRB (continued)

- **8:50 AM** **Public Comments**
- **9:20 AM** **Board Discussion**

Please comment on the approach, as described in EPA's draft PR Notice, to organizing materials submitted under 40 CFR § 26.1125 for EPA and HSRB review. In particular, please address whether this approach is appropriate for anticipated types of studies involving intentional exposure of human subjects, and whether EPA should provide different guidance for various types of research.

- **10:15 AM** **Break**

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

- **10:30 AM** **Introduction –** Mr. William Jordan (OPP, EPA)
- **11:40 AM** **CBI Legal Issues –** Mr. Donald Sadowsky (Office of General Counsel, EPA)
- **10:50 AM** **OPP Process for Handling CBI -** Mr. John Carley (OPP, EPA)
- **11:00 AM** **Federal Advisory Committee Review of CBI –** Ms. Marilyn Kuray (Office of General Counsel, EPA)
- **11:15AM** **Conclusion -** Mr. William Jordan (OPP, EPA)
- **11:25 AM** **Public Comments**
- **12:00 PM** **Lunch**
- **1:00 PM** **Board Discussion**
- **2:00 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 or Maria Szilagyi via telephone: (202) 564-6809 or email: szilagyi.maria@epa.gov