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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

January 5, 2012

MEMORANDUM

SUBJECT: Materials for Review by the Human Studies Review Board for its
January 26, 2012 Meeting

TO: Jim Downing
Designated Federal Official
Human Studies Review Board
Office of Science Advisor (8105R)

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This memorandum describes the materials that the Environmental Protection Agency's (EPA's) Office of Pesticide Programs is providing for review by the Human Studies Review Board (HSRB or Board) at the meeting scheduled for January 26, 2012. At this meeting, EPA will ask the Board to address scientific and ethical issues surrounding these two topics, each of which is discussed further below:

1. A new scenario design and associated protocol from the Agricultural Handler Exposure Task Force (AHETF) describing proposed research to measure dermal and inhalation exposure to workers who mix, load, and apply liquid pesticides in managed horticultural facilities using powered handgun equipment.
2. A report from the Antimicrobial Exposure Assessment Task Force II (AEATF) of completed research monitoring the dermal and inhalation exposure of professional janitorial workers as they applied a liquid antimicrobial pesticide product for indoor surface disinfecting using a pressurized aerosol can.

1. **AHETF Protocol: Mixing, Loading, and Applying Liquid Pesticides in Managed Horticultural Facilities Using Powered Handgun Equipment (AHE600)**

At this meeting, the Board will consider a proposal for research monitoring the potential exposure of workers mixing, loading, and applying liquid pesticide products in managed horticultural facilities using powered handgun equipment. Because the proposed research involves scripted exposure, it meets the regulatory definition of “research involving intentional exposure of a human subject” and thus is covered by subparts K and L of EPA’s amended rule for the protection of human subjects of research. The rule at 40 CFR §26.1125 requires a sponsor or investigator to submit to EPA, before conducting a study involving intentional exposure of human subjects, the protocol and related materials describing the proposed human research. In addition, EPA’s regulation at 40 CFR §26.1601 requires EPA to perform science and ethics reviews of the submitted proposal and to seek HSRB review of the proposed research. EPA has reviewed the scenario design and protocol, and has concluded that the research, with minor revisions, is likely to generate scientifically sound, useful information and to meet the applicable provisions of the EPA regulations in 40 CFR part 26, subparts K and L.

Charge Questions:

If the AHETF study proposal AHE600 is revised as suggested in EPA’s review and if the research is performed as described:

1. Is the research likely to generate scientifically reliable data, useful for assessing the exposure of workers mixing, loading, and applying pesticides in managed horticultural facilities using powered handgun equipment?
2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Documents: EPA is providing for HSRB review the following documents concerning the AHETF protocol AHE600:

- a. EPA Science and Ethics Review
 - b. AHETF Protocol Submission
 - c. Reference Files
 1. AHETF Governing Document Version 2 - August 2010
 2. IIRB, Inc. Human Research Protection Plan 11-3-10
 3. IIRB, Inc. Current Membership Roster 9-12-11
 - d. Charge Questions
2. **Completed AEATF research on exposure of professional janitorial workers when applying liquid antimicrobial pesticide product for indoor surface disinfecting using a pressurized aerosol can**

In October 2009, the HSRB reviewed a protocol for research to measure the dermal and inhalation exposure of professional janitorial workers as they applied a liquid antimicrobial pesticide product for indoor surface disinfecting using a pressurized aerosol can. Following favorable HSRB review and after revisions to address EPA, HSRB, and CDPR comments, this

research was conducted in summer 2010 and summer 2011. The completed report was submitted to EPA in November 2011.

If the data for this scenario are accepted by EPA, the resulting data will be posted to the Biocide Handlers Exposure Database (BHED®). EPA intends to use these data generically to estimate daily dermal and inhalation exposures of those who apply antimicrobial pesticides to indoor surfaces using an aerosol can.

Because this research involved scripted exposure, it meets the regulatory definition of “research involving intentional exposure of a human subject” and thus was covered by subparts K and L of EPA’s amended rule for the protection of human subjects of research. The rule at 40 CFR §26.1303 requires the submitter of reports of completed human research to document its ethical conduct. The rule at 40 CFR §26.1602(a) requires EPA to “review the material submitted under §26.1303 and other available, relevant information, and [to] document its conclusions regarding the scientific and ethical conduct of the research.” The rule at 40 CFR §26.1602(b) further requires EPA to submit the data and EPA’s review to the HSRB if it decides to rely on the data.

EPA has reviewed the AEATF aerosol scenario report and has concluded that it provides scientifically sound, useful information, and was conducted in substantial compliance with 40 CFR part 26, subparts A through L.

Charge Questions:

1. Was the research reported in the Antimicrobial Exposure Assessment Task Force II (AEATF) completed aerosol study report faithful to the design and objectives of the protocol and governing documents of AEATF?
2. Has EPA adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating the exposure of professional janitorial workers who apply liquid antimicrobial pesticide products to indoor surfaces using pressurized aerosol cans?
3. Does available information support a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR Part 26?

Documents: EPA is providing for HSRB review the following documents:

- a. EPA Reviews
 1. EPA Science Review
 2. Appendix A – Statistical Review
 3. Appendix B – AEATF II Letter 2.17.2010
 4. Appendix B – AEATF II Letter 2.21.2010
 5. EPA Ethics Review

b. Background Documents

1. Final Study Report for AEATF Aerosol Study - 11-14-2011
2. Addendum – Protocol Amendment 4
3. SAS File
4. Data (Excel file)
5. EPA Science and Ethics Review of Aerosol Protocol 9-21-09
6. HSRB Report of Oct 2009 meeting – reviewing Aerosol Protocol
7. AEATF II SOPs
 - a. SOP Table of Contents
 - 1A.1 Organizational Structure
 - 1B.1 Personnel Responsibilities
 - 1C.1 Study Director Selection
 - 1D.1 Inspection of AEATF II Facilities Data
 - 1E.0 Communication Directives
 - 1F.0 Adverse Effects Reporting
 - 2A.1 Study Authorization and Approval
 - 2B.1 Study Number Assignment
 - 2C.1 Protocol Design and Preparation
 - 3A.1 SOP Preparation, Approval, Maintenance, and Distribution
 - 3B.1 Use of AEATF II and Contractor SOPs
 - 4A.1 Study Report Preparation
 - 5A.1 QA Personnel Administration.pdf
 - 5B.1 AEATF II QAU Responsibilities
 - 5C.1 QAU Records
 - 5E.1 Protocol and Amendment Review
 - 5F.1 Inspection Audit types and Frequency
 - 5G.1 Study Inspections
 - 5H.1 Data Audits
 - 5I.1 Facility Inspections
 - 5J.1 Report Audits
 - 5K.1 Inspection Report Distribution
 - 6A.1 Storage of Raw Data
 - 6B.1 Access to Archived Data
 - 6C.1 Specimen and Retention Sample Storage
 - 7A.1 Test, Control, and Reference Substances Receipt and Shipment
 - 7B.1 Test, Control, and Reference Substances Labeling
 - 7C.1 Disposal of Test, Control, and Reference Substances
 - 7D.1 Test, Control, and Reference Substances Chain of Custody
 - 7E.1 Test and Reference Substance Analysis
 - 8A.2 Whole Body Sampling - Inner, Outer and Socks Dosimeters
 - 8B.3 Hand Wash Samples
 - 8C.2 Dermal Face Neck Wipe Samples
 - 8D.1 Collection of Air Samples using OVS Tubes
 - 8E.1 Fortification of Matrix Samples
 - 8F.1 Sample Identification
 - 8H.0 Pre-Washing Dosimeter Garments
 - 9A.1 Body Surface Areas

- 9B.3 Field Fortification Adjustment Factors
- 9C.1 Numerical Formatting and Handling
- 9D.1 Analytical Method Number Assignment
- 9E.1 Raw Data Collection
- 9F.1 Data Corrections
- 9G.1 Raw Data Handling
- 9H.1 Preparation of True Copies
- 9I.1 Analytical Method Development and Validation
- 9J.1 Storage Stability
- 10A.1 Rotameter Calibration
- 10B.1 Packing, Handling and Shipping of Samples
- 10C.1 Worker and Study Observations
- 10D.1 Application Equipment Operation Verification
- 10E.1 Worker Sample Collection Sequence
- 10F.1 GPI Electronic Digital Flow Meter
- 10G.1 Personal Air Sampling Pump Calibration
- 11A.1 Pregnancy Testing and Nursing Status
- 11B.1 Heat Stress
- 11C.1 Emergency Procedures
- 11E.0 Heat Stress Management for Observational Worker Expos
- 11F.0 Adverse Events Reporting to IRB
- 8. IIRB, Inc. Human Research Protection Plan 11-3-10
- 9. IIRB, Inc. Current Membership Roster 9-12-11
- 10. Charge Questions