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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

September 11, 2013

MEMORANDUM

SUBJECT: Materials for Review by the Human Studies Review Board for its October 1, 2013 Meeting

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

FROM: William L. Jordan
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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 October 1, 2013.

At this meeting, the EPA will ask the Board to address scientific and ethical issues for one topic: a new scenario design and associated protocol from the Antimicrobial Exposure Assessment Task Force II (AEATF-II) describing proposed research to monitor dermal and inhalation exposure during manual pouring of solid formulation antimicrobial products. 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. The charge questions and documents being transmitted to the HSRB for review are listed below.

In addition to presenting its review of the AEATF-II protocol, at the October 1st meeting the EPA will also present background information about EPA's Repellency Awareness Program and discuss potential implications for the HSRB. No background documents are being provided on this topic, and there are no charge questions for consideration by the Board. The Agency expects to provide its presentation to the Board members in advance of the meeting.

Charge Questions for AEATF-II Protocol:

If the AEATF-II study proposal AEA07 is revised as suggested in EPA's review and if the research is performed as described:

1. Is this research is likely to generate scientifically reliable data, useful for assessing the exposure of those who pour solid formulation antimicrobial pesticide products

2. Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Documents for AEATF-II Protocol Review:

EPA is providing for HSRB review the following 9 files concerning the AEATF-II protocol AEA07:

a. EPA Science and Ethics Review of AEATF-II Solid Pour Scenario Design and Protocol for Exposure Monitoring (dated September 10, 2013)

b. Volume 1: AEATF-II Pour Solid Protocol Submission
- AEATF-II's Transmittal Letter
- 40 CFR 26.1125 Checklist
- Pour Solid Study Design Document

c. Volume 2: AEATF-II Pour Solid Protocol Submission
- Study Protocol Dated 4/26/13, Approved 4/29/13
- Approved Occupational Monitoring Informed Consent Form Dated 4/29/13
- Approved Residential Monitoring Informed Consent Form Dated 4/29/13
- Approved Spanish Translation of Informed Consent Forms dated 4/29/13
- Approved Recruitment Materials Dated 5/1/13
- Approved Spanish Translation of Recruitment Materials Dated 5/1/13
- Schulman Associates IRB (SAIRB) Approval Letter and Supporting Documents

d. Volume 3: AEATF-II Pour Solid Protocol Submission
- Records of SAIRB Review of Study AEA07 and Correspondence
- SAIRB Meeting Minutes

e. Volume 4: AEATF-II Pour Solid Protocol Submission
- CVs and Ethics Training Records
- SOPs Referenced in AEA07 Protocol

f. AEATF Supplemental Submission of Toxicity Study Summaries for Cyanuric Acid (CYA)

g. Schulman Associates IRB Standard Operating Procedures (dated December 2012)

h. Schulman Associates IRB Board Members for 2013

i. Charge Questions