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

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

September 30, 2016

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review Board for its October 19-20, 2016 Meeting

TO: Jim Downing
Designated Federal Official
Human Studies Review Board
Office of Science Advisor

FROM: Maureen Lydon
Human Research Ethics Review Officer
Office of the Director
Office of Pesticide Programs

This memorandum identifies 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 teleconference and virtual meeting scheduled for October 19-20, 2016. During the October discussion, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

1. Protocol for Laboratory Evaluation of Mosquito Bite Protection from Permethrin-treated Clothing for the U.S. Army after 0, 20 and/or 50 washings; and

2. A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of Two Solid Formulations Containing an Antimicrobial.

Protocol for Laboratory Evaluation of Mosquito Bite Protection from Permethrin-treated Clothing for the U.S. Army after 0, 20 and/or 50 washings

EPA has reviewed the aforementioned protocol for a laboratory test of permethrin-treated clothing for the United States Army from both scientific and ethics perspectives. The EPA review evaluates the scientific aspects of the proposed research for an efficacy study to assess permethrin-treated U.S. Army uniforms after 0, 20 and/or 50 washings. Ethical aspects of the proposed research are assessed in terms of the standards defined by 40 CFR 26 subparts K and L. This study is designed to determine the bite protection level of up to two permethrin-treated military uniforms, specifically U.S. Army Combat Uniforms (ACU) and U.S. Army Flame Resistant

Army Combat Uniforms (FRACUs). The permethrin-treated materials will be tested unwashed, 20 times washed, and 50 times washed, for protection against bites by mosquitoes. The fabric is treated with permethrin via the Invexus™ process. The data collected in the study will be used to support product registration. Invexus™ Insecticide Treatment is a process by which the fabrics are treated with permethrin in a continuous, roll to roll treatment process in factory. The permethrin formulation is applied and adhered to fabric via a proprietary process that minimizes energy usage and process waste. The target levels of mean bite protection are ≥90% for the unwashed, 20 times washed, and 50 times washed permethrin-treated fabrics. The research has societal value because U.S. military personnel serving domestically and abroad are at risk of contracting mosquito-borne diseases, but the data supporting currently registered military uniforms impregnated with permethrin do not show ≥90% efficacy through 50 washes in human studies. The rationale for this testing is to collect data to show that military uniforms impregnated with permethrin through the Invexus™ process will provide ≥90% mean bite protection against mosquitoes for up to 50 washings. As intended, the data resulting from this proposed study will be used to support registration of either or both of LaunchBay's Invexus™ treated ACU and FRACU.

The charge questions for the HSRB's consideration are provided below:

Charge to the Board - Science:

- Is the protocol "Laboratory evaluation of mosquito bite protection from permethrin-treated clothing for the U.S. Army after 0, 20 and/or 50 washings" likely to generate scientifically reliable data, useful for estimating the level of mosquito bite protection provided by the different textiles treated with permethrin?

Charge to the Board - Ethics:

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

A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of Two Solid Formulations Containing an Antimicrobial

EPA conducted a science and ethics review of available information concerning the research reported by the Antimicrobial Exposure Assessment Task Force II (AEATF II) in "A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of Two Solid Formulations Containing an Antimicrobial," also referred to as study AEA07. The study was conducted to determine the potential dermal and inhalation exposure to occupational workers and consumers associated with the pouring and/or scooping of solid formulation antimicrobial products. Study AEA07 tested two solid formulations of antimicrobial products -- powders and granules. The objective was to generate four baseline dermal and inhalation unit exposures: one for pouring granules in occupational scenarios, one for pouring powders in occupational scenarios, one for pouring granules in residential scenarios, and one for pouring powders in residential scenarios. The data from this study will be used to assess consumer and occupational exposure and risks from the handling and pouring of solid formulation antimicrobials.

The science review of the AEATF solid pour study has been transmitted to the HSRB with the exception of its Appendix A, which will include a supporting in-depth statistical analyses of the data. As you will see in the science review memorandum, EPA determined the hand wash removal efficiency correction factor used by the AEATF II to correct the hand/face/neck was incorrect. Therefore, EPA reanalyzed the data without this correction factor. As a result, there is a delay in providing the Board members with a copy of Appendix A; however, the science review is complete and results are based on post-correction factor removal. Appendix A is anticipated to be emailed to the Board on Monday October 3rd. Thank you for your patience.

The charge questions for the HSRB's consideration are provided below:

Charge to the Board - Science:

- Is the research in study AEA07 likely to generate scientifically reliable data, useful for assessing the exposure of occupational workers and consumers who manually pour or scoop solid formulation antimicrobial products?

Charge to the Board - Ethics:

- 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 for Review

The documents provided to the HSRB for review are listed below. EPA appreciates the HSRB members taking the time to review these materials in advance of the October HSRB meeting.

A. Protocol for Laboratory Evaluation of Mosquito Bite Protection from Permethrin-treated Clothing for the U.S. Army after 0, 20 and/or 50 washings

1. EPA Science and Ethics Review of Protocol;
2. Attachment 2 to EPA's science and ethics review;
3. IRB Approved Protocol for Laboratory Evaluation of Mosquito Bite Protection from Permethrin-treated Clothing for the U.S. Army after 0, 20 and/or 50 washings;
4. Revised protocol which incorporates EPA's comments, as discussed in EPA's science and ethics review. EPA thought this would facilitate the HSRB's review. **Please Note: This is the protocol on which EPA believes the HSRB should focus;**
5. IRB correspondence between i2LResearch and the overseeing IRB;
6. EPA's comments on the informed consent form (which are referenced in EPA's review memo);
7. EPA's comments on the telephone screening script; and
8. Additional IRB correspondence which EPA received on September 30, 2016 from SAIRB.

B. A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of Two Solid Formulations Containing an Antimicrobial

1. AEATF II Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of Two Solid Formulations Containing an Antimicrobial;
2. EPA's Science Review of Study AEA07;
3. EPA's Ethics Review of Study AEA07;
4. Additional IRB Correspondence Provided for Study AEA07;
5. Attachments 5, 6 and 9 to EPA Ethics Review (provided in separate file for HSRB);
6. Appendix A to EPA science review which should be email on October 3, 2016.