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

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

September 30, 2015

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review Board for its
October 19, 2015 Meeting

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

FROM: Maureen Lydon
Human Research Ethics Review Officer
Office of the Director (*On detail*)
Office of Pesticide Programs (7501P)

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 teleconference and virtual meeting scheduled for October 19, 2015. During the October 19th discussion, EPA will ask the Board to address scientific and ethical issues surrounding:

1. A completed "Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military." Unpublished 2015 document prepared by United States Department of Agriculture – Agricultural Research Service, Center for Medical, Agricultural and Veterinary Entomology. Authors: Ulrich Bernier, Ph.D., Jenny Staeben, J.D., Ph.D., Rob Hummel, Ph.D. July 30, 2015. 285 p. (MRID 49684002) (D429130)

Completed Study - Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military

The Board will consider a completed study, the purpose of which was to determine the bite protection level of the etofenprox-treated U.S. military Fire Resistant Army Combat Uniforms (FRACUs) treated initially at an application rate of approximately 0.9% (wt/wt), and to assess bite protection performance prior to washing (0x) and after washing 20 times (20x), 50 times (50x), and 75 times (75x). Among the insecticide-treated uniform types that the U.S. military personnel use, the more open weave construction of the FRACU uniform makes this

uniform the most difficult to prevent bite-through. It has relatively low efficacy compared to other military uniform types; as a result, it was selected as the worse-case scenario for treatment of military uniforms.

The protocol for this study was approved by the overseeing institutional review board, the Western Institutional Review Board (WIRB), and previously submitted to EPA for review. The protocol and EPA's review, dated March 20, 2014, were discussed in a public meeting by the Human Studies Review Board (HSRB) on April 9, 2014. As documented in the final HSRB meeting report, dated June 25, 2014, the HSRB concluded, with respect to ethics, that "the protocol submitted for review, if modified in accordance with EPA...and HSRB recommendations, is likely to meet the applicable requirements of 40 CFR 26, subparts K and L."

Because this research involved 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 §26.1303 requires the submitter of reports of completed human research to document its ethical conduct. The rule at 40 CFR §26.1603 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 §26.1603 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 completed study and other materials being transmitted to the Board at this time and has concluded that the research provides scientifically sound, useful information, and was conducted in substantial compliance with the ethics requirements at 40 CFR part 26, subparts K and L. The charge questions and documents being transmitted to the HSRB for review are listed below.

Charge Questions:

1. Is the research reported in the completed study sufficiently sound, from a scientific perspective, to be used to evaluate the bite protection level of etofenprox-treated military clothing?
2. Does available information support a determination that the research was conducted in substantial compliance with 40 CFR part 26, subparts K and L?

Documents for Review:

- a. EPA Science Review of Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military conducted with Human Subjects (dated September 25, 2015) (15 pages)
- b. EPA Ethics Review of Completed Study entitled, "Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military" (dated September 28, 2015) (17 pages)

- c. Final Report for “Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military” (dated July 30, 2015) (285 pages)
- d. Volume 3: Sielken, Jr., R. L., and L. R. Holden. 2014. Statistical Methods: Supplemental Information, Sielken & Associates Consulting, Inc.
- e. Bite Protection Dataset and SAS Zip File which includes the following folders:
 - 1. Final Data 23 July 2015.xlsx = the original excel data file
 - 2. Final Data 23 July 2015.csv = the same data file saved as a comma-separated variable (CSV) text file.
 - 3. Macros Bite Protection SAS = SAS macro command file containing some useful utility commands
 - 4. Analyses Bite Protection SAS = the SAS program file that reads the CSV file and analyzes the bite protection data
 - 5. Analyses Bite Protection LIS = the SAS output listing file with the analysis results (Note: this listing is in appendix VI)
- f. WIRB July 20, 2015 Correspondence and Certificate of Approval Package
- g. July 13, 2015 Request to WIRB
- h. WIRB May 28, 2015 Correspondence and Certificate of Approval Package
- i. WIRB April 7, 2015 Correspondence and Certificate of Approval Package
- j. WIRB-Approved Clean Version of Protocol in electronic file dated July 20, 2015. (Note that this is the July 13th protocol but it was approved by the WIRB on July 20, 2015.)
- k. WIRB-Approved Track Changes Version of Protocol dated July 13, 2015
- l. WRIB Minutes
- m. WRIB Updated Membership Packet
- n. Final HSRB Meeting Report dated June 25, 2014

Please note that the WIRB correspondence files are lengthy. The HSRB members may wish to consider viewing the electronic version of the WIRB files and only printing the pages they need for follow-up reference.