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

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

*May 24, 2010*

**MEMORANDUM**

**SUBJECT:** Materials for review by the Human Studies Review Board for its June 2010 Meeting

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

**FROM:** William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs (7501P)

This memorandum describes the materials OPP is providing for review by the Human Studies Review Board (HSRB or Board) at its meeting scheduled for June 23, 2010. At this meeting EPA will ask the Board to address scientific and ethical issues surrounding reports of two completed repellent studies conducted by Carroll-Loye Biological Research:

1. The unpublished report of the completed Carroll-Loye Biological Research, Inc. study LNX-002: Field Repellency of Two Picaridin-Based Personal Insect Repellents to Black Flies. The protocol for this study was reviewed favorably by the HSRB at their meeting in June 2009. EPA seeks the advice of the HSRB on the scientific soundness of this completed study for use to estimate the duration of complete protection against black flies provided by the tested repellents, and on whether available information supports a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR Part 26.

EPA is providing the following materials on this study:

- a. LNX-002: Field Repellency of Two Picaridin-Based Personal Insect Repellents to Black Flies. Primary Report: MRID 48053802.
- b. EPA Science and Ethics Review of Protocol LNX-002 (18 May 2009)
- c. HSRB final report of its June 2009 discussion of LNX-002 (26 October 2009)

- d. Supplemental submissions of IIRB, Inc. roster (as of 10 January 2010) and of IIRB, Inc. Human Research Protection Program Plan (as of 1 October 2009)
- e. Supplemental submission of documentation of IIRB, Inc. approval of Amendment 1. MRID 48071301
- f. EPA Ethics Review: LNX-002 (20 May 2010)
- g. EPA Science Review: LNX-002 (24 May 2010)

Charge Questions:

- a. Is the CLBR study LNX-002 sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against black flies provided by the tested repellents?
  - b. Does available information support a determination that study LNX-002 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?
2. The unpublished report of the completed Carroll-Loye Biological Research, Inc. study LNX-003: Laboratory Repellency of Two Picaridin-Based Personal Insect Repellents to Two Species of Ticks. The protocol for this study was reviewed favorably by the HSRB at their meeting in October 2009. EPA seeks the advice of the HSRB on the scientific soundness of this completed study for use to estimate the duration of complete protection against ticks provided by the tested repellents, and on whether available information supports a determination that the study was conducted in substantial compliance with subparts K and L of 40 CFR Part 26.
- a. LNX-003: Laboratory Repellency of Two Picaridin-Based Personal Insect Repellents to Two Species of Ticks. Primary Report: MRID 48053801.
  - b. EPA Science and Ethics Review of Protocol LNX-003 (21 September 2009)
  - c. HSRB final report of its October 2009 discussion of LNX-003 Protocol (16 December 2009)
  - d. Supplemental submissions of IIRB, Inc. roster (as of 10 January 2010) and of IIRB, Inc. Human Research Protection Program Plan (as of 1 October 2009)
  - e. EPA-IIRB E-mail exchange of 20 April 2010 concerning additional documentation of IRB review of Amendment 1
  - f. EPA Ethics Review: LNX-003 (20 May 2010)
  - g. EPA Science Review: LNX-003 (24 May 2010)

Charge Questions:

- a. Is the CLBR study LNX-003 sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against ticks provided by the tested repellents?
  - b. Does available information support a determination that study LNX-003 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?
3. In addition, EPA will present to the HSRB update reports on two topics of interest, without specific charge questions:
- The revised guideline for performance testing of topically applied repellent products, to be released for use by investigators and sponsors of new studies.
  - The terms of a recent settlement agreement reached between the parties to resolve litigation related to EPA's 2006 rule for the protection of human subjects of research, in which EPA has committed to initiate rulemaking to amend the 2006 rule.