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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 23, 2009

MEMORANDUM

SUBJECT: Materials for review by the Human Studies Review Board for its February 17, 2009 Teleconference Meeting

TO: Paul I. Lewis, Ph.D.
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 the teleconference meeting scheduled for February 17, 2009.

As requested, OPP is responding to the HSRB's questions concerning testing of products intended to repel insects from outdoor spaces. To supplement those responses OPP is also providing a fact sheet summarizing the current regulatory status of space repellent products.

At this meeting EPA will ask the Board to address scientific and ethical issues surrounding:

1. The report of a completed field study, SPC-001, conducted by Carroll-Loye Biological Research (CLBR) to evaluate the mosquito repellent efficacy in the field of three repellent formulations containing picaridin.

2. The report of a completed laboratory study, SPC-002, conducted by Carroll-Loye Biological Research (CLBR) to evaluate the tick repellent efficacy in the laboratory of three repellent formulations containing picaridin.

1. Completed CLBR Mosquito Repellent Field Study SPC-001

In its October 2007 meeting the HSRB favorably reviewed protocol SPC-001 from Carroll-Loye Biological Research (CLBR) for a field study to evaluate the mosquito repellent efficacy of several repellent formulations containing picaridin as the active ingredient.

Following that meeting and after the HSRB released its final report, CLBR revised the protocol to address EPA and HSRB comments. After IRB approval of final amendments CLBR executed the research in March-May 2008, and in September the sponsor submitted the primary report dated August 19 to EPA. The investigator supplemented the primary report with additional documents submitted to EPA on November 7. EPA is presenting to the HSRB, for review at this meeting, the August 19, 2008 report of the execution of protocol SPC-001, as supplemented.

The Agency's regulation, 40 CFR §26.1602, requires EPA to seek HSRB review of an EPA decision to rely on the results of these studies. The sponsor has submitted these data to support registration of the tested materials. EPA has reviewed the research, applying the standard in 40 CFR §26.1705, which states:

> Except as provided in §26.1706, in actions within the scope of §26.1701, EPA shall not rely on data from any research initiated after April 7, 2006, unless EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part . . . This prohibition is in addition to the prohibition in §26.1703.

OPP has determined that the data are scientifically sound, and that there is adequate information to determine that the conduct of the study was in substantial compliance with EPA's rules for the protection of human subjects of research. OPP proposes to accept and rely on the results in support of the cited registrations—both the three formulations tested and those to which the results are proposed to be extrapolated.

1. EPA is providing the following materials on the completed Carroll-Loye field study of mosquito-repellent efficacy SPC-001:

    a. MRID 47535201 SPC-001 Primary Report (8/19/08)

    The primary report of the study, with appendices including the final IRB-approved protocol and consent form and IRB approval letters

    b. E-mail supplement to SPC-001 Primary Report (11/7/08)

    The transmittal, including clarifying comments and responses to questions, and three attachments relevant to SPC-001

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c. EPA Science and Ethics Review of SPC-001 Protocol (9/24/07)

The EPA Joint Science and Ethics Review of the protocol and supporting materials presented to the HSRB in October 2007

d. HSRB Report of Review of SPC-001 Protocol (3/6/08)

An extract from the HSRB final report of its October 2007 meeting, including all comments and recommendations concerning this protocol

e. SPC-001 Summary Fact Sheet

As requested by the HSRB, a brief fact sheet summarizing this study

f. EPA Science Review: SPC-001 (1/23/09)

EPA's science review of the completed study

g. EPA Ethics Review: SPC-001 (1/23/09)

EPA's ethics review of the completed study

Charge Questions:

a. Is the CLBR study SPC-001 sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy against mosquitoes of the three formulations tested?

b. Does available information support a determination that study SPC-001 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?

2. Completed CLBR Tick Repellent Laboratory Study SPC-002

In its October 2007 meeting the HSRB favorably reviewed protocol SPC-002 from Carroll-Loye Biological Research (CLBR) for a laboratory study to evaluate the tick repellent efficacy of several repellent formulations containing picaridin as the active ingredient.

Following that meeting and after the HSRB released its final report, CLBR revised the protocol to address EPA and HSRB comments. After receiving IRB approval of final amendments, CLBR executed the research in March 2008, and the sponsor submitted the primary report dated August 19 to EPA in September. The investigator supplemented this primary report with additional documents submitted to EPA on November 7. EPA is presenting to the HSRB, for review at this meeting, the August 19, 2008 report of the execution of protocol SPC-002, as supplemented.

The Agency's regulation, 40 CFR §26.1602, requires EPA to seek HSRB review of an EPA decision to rely on the results of these studies. The sponsor has submitted these data to support registration of the tested materials. EPA has reviewed the research, applying the standard in 40 CFR §26.1705, which states:

> Except as provided in §26.1706, in actions within the scope of §26.1701, EPA shall not rely on data from any research initiated after April 7, 2006, unless EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part . . . This prohibition is in addition to the prohibition in §26.1703.

OPP has determined that the data are scientifically sound, and that there is adequate information to determine that the conduct of the study was in substantial compliance with EPA's rules for the protection of human subjects of research. OPP proposes to accept and rely on the results in support of the cited registrations—both the three formulations tested and those to which the results are proposed to be extrapolated.

2. EPA is providing the following materials on the completed Carroll-Loye study of tick-repellent efficacy in the laboratory SPC-002:

   a. MRID 47535202 SPC-002 Primary Report (8/19/08)

      The primary report of the study, with appendices including the final IRB-approved protocol and consent form and IRB approval letters

   b. E-mail supplement to SPC-002 Primary Report (11/7/08)

      The transmittal, including clarifying comments and responses to questions, and three attachments relevant to SPC-002
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   c. EPA Science and Ethics Review of SPC-002 Protocol (9/24/07)

      The EPA Joint Science and Ethics Review of the protocol and supporting materials presented to the HSRB in October 2007

   d. HSRB Report of Review of SPC-002 Protocol (3/6/08)

      An extract from the HSRB final report of its October 2007 meeting, including all comments and recommendations concerning this protocol

   e. SPC-002 Summary Fact Sheet

      As requested by the HSRB, a brief fact sheet summarizing this study

f. EPA Science Review: SPC-002 (1/23/09)

EPA's science review of the completed study

g. EPA Ethics Review: SPC-002 (1/23/09)

EPA's ethics review of the completed study

Charge Questions:

c. Is the CLBR study SPC-002 sufficiently sound, from a scientific perspective, to be used to assess the repellent efficacy against ticks of the three formulations tested?

d. Does available information support a determination that study SPC-002 was conducted in substantial compliance with subparts K and L 40 CFR Part 26?