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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

September 22, 2015

MEMORANDUM

SUBJECT: Materials for Review by the Human Studies Review Board for its October 20, 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 20, 2015. During the October 20th discussion, EPA will ask the Board to address scientific and ethical issues surrounding:

1. A new protocol from S.C. Johnson & Son, Inc. and i2LResearch USA, Inc. describing proposed efficacy testing to establish the duration of protection of various skin-applied tick repellent products. Testing will occur in a laboratory setting against three species of ticks. The resulting data is intended to support the products' use of EPA's repellency awareness graphic on the product labels.

Protocol Submission Package – Laboratory Testing of S.C. Johnson Personal Tick Repellent Products to Support their use of the EPA Repellency Awareness Graphic:

The Board will also consider a new protocol from S.C. Johnson & Son, Inc. and i2LResearch USA, Inc. describing proposed research to determine the complete protection time of up to eighteen EPA-registered S.C. Johnson skin-applied repellent products in a laboratory setting against three species of ticks. 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 §26.1603 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 protocol, and has concluded that the research, with revisions requested by EPA, 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.

Charge Questions:

If the S.C. Johnson & Son, Inc. and i2LResearch protocol is revised as suggested in EPA's review and if the research is performed as described:

1. Is the protocol "Testing of S.C. Johnson Personal Tick Repellent Products to Support their Use of the EPA Repellency Awareness Graphic" likely to generate scientifically reliable data, useful for estimating the complete protection time of various EPA-registered S.C. Johnson skin-applied tick repellents in the laboratory against three species of ticks?

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

Documents for Review:

a. EPA Science and Ethics Review of a Protocol for Laboratory Testing of S.C. Johnson Skin-Applied Tick Repellent Products (dated September 22, 2015) (93 pages)

(Please note: Attachments 9 – 11 are provided in separate files.)

b. S.C. Johnson and i2LResearch USA, Inc. Protocol Submission (dated July 28, 2015) (353 pages)