December 15, 2006

Mr. John Carley
ENVIRONMENTAL PROTECTION AGENCY
Office of Prevention, Pesticides and Toxic Substances
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: **EMD Chemicals Efficacy Data for End Use Insect Repellent Products Containing IR3535®**

Dear Mr. Carley,

EMD Chemicals herewith submits revised reports of studies for the pump and lotion varieties of an IR3535 mosquito repellent that were originally submitted on November 9, 2006. These reports have been revised in response to comments provided by EPA staff. The attached reports were conducted by Carroll-Loye Biological Research ("Carroll-Loye") pursuant to Human Studies Review Board ("HSRB") reviewed Protocols EMD-003 and EMD-004 and are submitted at this time for the purposes of HSRB review.

Protocols EMD-003 and EMD-004 were also utilized in connection with studies conducted on the aerosol variety of the IR3535 mosquito repellent. The aerosol reports were submitted to EPA on December 13, 2006. EMD intends to submit complete registration applications for the three proposed products (pump, lotion and aerosol) immediately upon satisfactory review by the HSRB.

EMD regrets that it was not able to submit the aerosol product study report at the same time as its pump and lotion submissions. Nonetheless, we respectfully urge EPA staff and the HSRB to review all three product study reports at the January HSRB meeting. We respectfully suggest that it would be most efficient to consider and act upon all of the studies that were conducted pursuant to the approved protocols at the same time.

As you know, Carroll-Loye and EMD Chemicals conducted the studies and produced initial versions of the IR3535 pump and lotion reports in less than three weeks after the HSRB met to consider the protocols. The aerosol studies were delayed pending the resolution of technical issues regarding the composition of the product. The aerosol studies were still completed and reports submitted within seven weeks of the HSRB meeting, however. As a result of the extraordinary time pressure under which we were working, there were several minor errors in those initial pump and lotion submissions. Clara Fuentes has kindly reviewed the initial submissions and provided suggestions for their improvement. We are therefore submitting these updated and corrected versions of the pump and lotion reports, which incorporate Ms. Fuentes' suggestions.

For your convenience, we provided the following listing of information that has been updated:

- Various minor typographical and pagination errors have been corrected;
- The Dosimetry Analyses contained in the "Test Results" portions of the reports have been significantly expanded;
- The "Conclusions" portions of the reports have been significantly expanded;
- Typographical errors in Appendix 3 of the reports have been corrected;
- Appendix 5 ("Deviations from the Protocol and their Consequences") has been revised;
- Extra pages included in Appendix 8 ("Completed Dosimetry Data Capture Forms") have been eliminated; and
- A Certificate of Analysis has been added as Appendix 9

Please note that we have included both the initial study completion date and the revision date in the heading of each report. If any member of the HSRB would like to see the changes that have been made pursuant to Ms. Fuentes' comments, please let us know and we will provide electronic or paper versions highlighting the updated material.

At this time, we are not claiming any confidentiality protection under § 10 of FIFRA for the enclosed studies. We respectfully request, however that the HSRB refrain from publicly releasing the information contained in the reports. Rather, should a member of the public wish to review the information or documentation contained herein, we believe that access should be requested under the Freedom of Information Act and pursuant to its provisions.

As always, we sincerely appreciate your efforts to assist us in this matter and are willing to provide any additional information or assistance you may require in order to ensure an expeditious review of these materials by the HSRB.

If you have any questions or comments regarding these materials, or have any additional requests, please contact Dan Giambattisto at 914-592-4660 (ext. 232).

Sincerely,

Study Monitor or Monitor's Agent

Dan Giambattisto
Senior Business Development Manager
Date: December 15, 2006

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

EMD Chemicals, Inc.
7 Skyline Drive
Hawthorne, New York
10532

Agent

Ann Gochman
Telephone: 914-492-4660 (ext. 292)

2. Regulatory Action for which this Package is Submitted

This material is submitted for HSRB review of Mosquito Repellent Reports related to HSRB reviewed protocols EMD-003 and EMD-004. The reports include efficacy data for lotion and pump varieties of an IR3535 mosquito repellent.

3. Transmittal Date

An initial version of these reports was submitted on November 9, 2006; these replacements versions are being submitted on December 15, 2006.

4. List of Submitted Documents

Volume 1 **Efficacy Report Number EMD-003.1 (Lotion); Replacement for MRID 46979001**

Volume 2 **Efficacy Report Number EMD-003.2 (Pump); Replacement for MRID 46979002**

Volume 3 **Efficacy Report Number EMD-004.1 (Lotion); Replacement for MRID 46979003**

Volume 4 **Efficacy Report Number EMD-004.2 (Pump); Replacement for MRID 46979004**

5. Information Regarding Specific Changes to the Reports

The following information has been updated in the revised reports.

- Various minor typographical and pagination errors have been corrected;
- The Dosimetry Analyses contained in the "Test Results" portions of the reports have been significantly expanded;
- The "Conclusions" portions of the reports have been significantly expanded;
- Typographical errors in Appendix 3 of the reports have been corrected;
- Appendix 5 ("Deviations from the Protocol and their Consequences") has been revised;
- Extra pages included in Appendix 8 ("Completed Dosimetry Data Capture Forms") have been eliminated; and
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6. Company Contact:

Signature: Study Monitor or Monitor's Agent Date: December 15, 2006

Dan Giambattisto
EMD Chemicals, Inc.
Phone: 914-592-4660 (ext. 232)

Signature: Date: December 15, 2006

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