EMD

November 9, 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 the attached reports of studies of personal insect repellents, which were conducted by Carroll-Loye Biological Research ("Carroll-Loye") pursuant to Human Studies Review Board ("HSRB") reviewed Protocols EMD-003 and EMD-004. The study reports are submitted at this time for the purposes of HSRB review. Full registration applications for three EUPs will be submitted by EMD Chemicals at a later date.

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 you know, Carroll-Loye and EMD Chemicals have had to conduct the studies and produce reports in less than three weeks since the HSRB met to consider the protocols. Moreover, until yesterday we were under the misimpression that we were not required to comply with all provisions of PR Notice 86-5 in making submissions for purposes of HSRB review. Nonetheless, despite the extraordinary time pressures and the need for last-minute updates to these materials, we are pleased to submit the attached reports which demonstrate the excellent efficacy of IR3535. We are quite confident that Carroll-Loye has endeavored to conduct studies that meet high scientific and ethical standards. Should there be minor errors, we ask only that the EPA and HSRB take into consideration the extraordinary time pressure under which we have been working.

You will note that the study reports submitted herewith deal with two proposed products, a lotion product containing 10% IR3535 and a pump spray product containing 20% IR3535. There is a third product EMD intends to register which is an aerosol also containing 20% IR3535. Unfortunately, in an example of Murphy's Law at work, we recently discovered that the contract manufacturer that produced the products for testing purposes mistakenly made up the aerosol

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with 22% IR3535. New product has now been produced that meets the proper specifications; however, Carroll-Loye did not receive the product until this week. Accordingly, testing of that product is not yet completed. We are expecting to be able to complete testing and submit final reports by no later than December 1. We would respectfully request that the EPA and HSRB agree to accept the final two reports on the aerosol product at that time and include their review in the agenda of the January HSRB meeting.

Alternatively, it occurs to us that since the aerosol product has precisely the same active concentration as the pump spray product and contains inert ingredients that are all either on EPA's 4A or 4B lists and/or permitted for use in cosmetics by the FDA, you may wish to consider accepting the data on the spray product as bridgeable to the proposed aerosol product and avoid the need for additional human testing. Unless we hear otherwise from EPA, we will be conducting the testing on the aerosol product and submitting it by December 1.

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,

Dan Giambattisto
Sales and Marketing Director, BioActives

cc: Amy Morton – Garvey, Schubert, Barer

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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, pump and aerosol varieties of an IR3535 mosquito repellent.

3. Transmittal Date

November 9, 2006

4. List of Submitted Documents

Volume 1 **Efficacy Report Number EMD-003.1 (Lotion)** **46979001**

Volume 2 **Efficacy Report Number EMD-003.2 (Pump)** **46979002**

Volume 3 **Efficacy Report Number EMD-004.1 (Lotion)** **46979003**

Volume 4 **Efficacy Report Number EMD-004.2 (Pump)** **46979004**

5. Company Contact:

Signature: _____
Study Monitor or Monitor's Agent

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

Signature: Date: November 8, 2006

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