Carroll-Loye Biological Research

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15 May 2006

William Jordan
Environmental Protection Agency (HQ)
Office of Pesticide Programs
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: EMD Chemicals Proposed Registration of End Use Insect Repellent Products Containing IR 3535

Dear Bill:

This letter responds to your email dated May 11, 2006, in which you replied to my request for review of two proposed protocols for research on the efficacy of various formulations of the EMD IR3535 insect repellent product. In that email, you noted that additional materials would need to be submitted in order to comply with the requirements of the recently promulgated regulation regarding protections for subjects in human research (71 Fed. Reg. 6138).

Specifically, you noted that I must submit information including (1) certain records that the Institutional Review Board (the "IRB") is required to maintain pursuant to 40 CFR 26.1115; (2) a discussion of key issues which are required to be considered by the IRB in the research approval process (see 40 CFR 26.1125(a) – (d)); and (3) documentation of the IRB's approval of the proposed research (see 40 CFR 26.1125(f)). You also requested that this additional information be provided by the close of business on Tuesday, May 16, 2006.

In an effort to fully comply with these requests, I have been working closely with my colleagues Matthew Schneider, Esq., of Garvey Schubert Barer and Ronald Slesinski, Ph.D., of ENVIRON Health Sciences. With the cooperation of the IRB, we have compiled and are providing to you the requested information in both hard copy and electronic form. Twelve copies of the materials, organized in binders, have been delivered to the EPA Office of Pesticide Programs along with a CD-ROM containing the same materials. Additionally, we have electronically mailed all of the information to you.

Please note that we have drafted two summary outlines, organized to reflect the requirements of 40 CFR 26.1115 and 26.1125. These outlines, which are included as the first two documents in each binder, contain discussions relevant to each section and sub-section, as well as references to appropriate underlying documentation. This underlying documentation has been attached in an appendix, with the location of specific materials noted in the outline.

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

If you have any questions or comments regarding these materials, or have any additional requests, please contact Scott Carroll at (530)297-6080.

Sincerely,

Scott P. Carroll, Ph.D.
Director