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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June 18, 2008

MEMORANDUM

SUBJECT: Transmission of additional materials for review by the Human Studies Review Board for its June 2008 Meeting

TO: Paul I. Lewis, Ph.D.
Designated Federal Official
Human Studies Review Board
Office of Science Advisor (8105R)

FROM: William L. Jordan
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This memorandum describes additional materials OPP is providing for review by the Agency's Human Studies Review Board (HSRB or Board) at the meeting scheduled for June 24-25, 2008. These materials consist of reviews of the sampling strategy proposed in the protocols submitted by the Agricultural Handlers Exposure Task Force (AHETF) describing research to monitor exposure of subjects who apply an agricultural pesticide using airblast equipment in closed cabs ("CCAB protocols"). These reviews were prepared under a contract with EPA by Dr. Louise Ryan, Harvard University, and Warren Strauss, Battelle Memorial Institute (Battelle).

Let me provide some background. As you know, in previous meetings the Board has raised issues concerning the sampling strategies being proposed by the industry task forces that are planning to conduct research to develop data on handler exposures to pesticides. As a consequence of these discussions, in late 2007 EPA contacted Dr. Louise Ryan, Chair of the Department of Biostatistics at the Harvard University School of Public Health, who agreed to help the Office of Pesticide Programs (OPP) in its review of proposed handler exposure protocols. The Agency eventually arranged to obtain the

services of Dr. Ryan through a contract with Battelle. Dr. Ryan collaborated with Warren Strauss, a statistician at Battelle.

In April OPP provided Ryan and Strauss with the CCAB protocol materials submitted by the AHETF, as well as EPA's reviews of the CCAB protocols and information about the discussions among EPA, the Board, the industry task forces, and Dr. Maiti.

In late May, Ryan and Strauss provided an initial review in which they recommended that EPA should consider asking the AHETF to replace the proposed purposive diversity sampling strategy with a stratified, probability-based sampling strategy in order to strengthen the design. In OPP's view, the Ryan and Strauss recommendations rested on mistaken assumptions about the costs and technical feasibility of their suggested alternative proposal. Accordingly, we discussed with them our perceptions of the practical implications of their approach and, in a written work assignment, asked them to consider certain questions and, if appropriate, to revise or supplement their initial review. On June 6, they provided a supplemental report. The June 6 supplement contains OPP's questions as an attachment.

At the June meeting OPP intends to address the comments made by Ryan and Strauss in our presentations to the HSRB on the CCAB protocols.

I will separately transmit to you electronic files containing the following Ryan and Strauss documents:

1. "Review of AHETF Sampling Design Documentation" by Warren Strauss and Louise Ryan (May 22, 2008) (17 pages).
2. "Supplemental Materials in Response to EPA Follow-up Questions" by Warren Strauss and Louise Ryan (June 6, 2008) (4 pages).