



**FOR US POSTAL SERVICE DELIVERY:**

Office for Human Research Protections  
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March 27, 2001

George E. Walker, Ph.D.  
Vice President for Research and  
Dean of the Graduate School  
Indiana University  
Research and the University Graduate School  
Bryan Hall, Room 104  
Bloomington, Indiana 47405-7000

**RE: Human Research Subject Protections Under Multiple Project Assurance  
(MPA) M-1167**

**Research Project: Duloxetine Bioequivalence Study**

Dear Dr. Walker:

The Office for Human Research Protections (OHRP) has reviewed your January 25, 2001 report regarding the above referenced research project.

OHRP acknowledges your report that the above referenced research project (i) was not supported in any way, even partially or indirectly, by the Department of Health and Human Services, and (ii) was conducted solely by the Lilly Clinic which is not covered under the Indiana University (IU) MPA.

As a result, OHRP has determined that it does not have jurisdiction over this research and is closing its compliance oversight investigation of this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

March 27, 2001

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,



Michael A. Carome, M.D.

Director, Division of Compliance Oversight

cc: Ms. Shelley Bizila, Director, Research Compliance, IU  
Dr. John Bradley, Chair, IRB-02, IU  
Commissioner, FDA  
Dr. David Lepay, FDA  
Dr. James F. McCormack, FDA  
Dr. John Mather, Department of Veterans Affairs  
Dr. Greg Koski, OHRP  
Dr. Melody H. Lin, OHRP  
Dr. Jeffrey Cohen, OHRP  
Mr. George Gasparis, OHRP  
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Mr. Barry Bowman, OHRP