



FOR US POSTAL SERVICE DELIVERY:

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September 21, 2001

Bruce G. Lindsey, Ph.D.
Interim Vice President for Research
University of South Florida
4202 E. Fowler Avenue, ADM 200
Tampa, FL 33620-5950.

J. Thomas Danzi, Sr., M.D.
Vice President and Chief Medical Officer
Tampa General Healthcare
P.O. Box 1289
Tampa, FL 33601

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)
M-1284**

**Research Project: An Ascending Dose Safety and Feasibility Study of OSSIGEL in the
Management of Stable and Unstable Closed Diaphyseal Fractures of the Tibia**

Principal Investigator: Roy W. Sanders, MD

Project Number: 5194

Dear Dr. Lindsey and Dr. Danzi:

The Office for Human Research Protections (OHRP) has reviewed your report of August 28, 2001, regarding the above referenced research conducted at Tampa General Healthcare, which has an inter-institutional amendment with University of South Florida (USF).

Based upon its review, OHRP finds that the corrective actions taken by USF adequately address the previous findings, questions and concerns outlined by OHRP and are appropriate under the USF Multiple Project Assurance (MPA). As a result, OHRP is closing this case and there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates your institution's continued commitment to the protection of human research subjects. Do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,

Kristina C. Borrer, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Barry B. Bercu, Chair, USF IRB 01, 01b, and 02
Dr. Martin Klemperer, Chair, USF IRB 03
Dr. Ramon Lopez del Valle, Chair, USF IRB 04
Dr. Roy Sanders, Tampa General Healthcare
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. John Mather, VA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Jeffrey M. Cohen, OHRP
Mr. George Gasparis, OHRP
Mr. Barry Bowman, OHRP