DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Public Health and Science

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December 14, 2001

M. David Low, M.D., Ph.D.
President
University of Texas - Houston
Health Science Center
P.O. Box 20036
Houston, TX 77225

Anne Dougherty, M.D.
IRB Chair
University of Texas - Houston
G.700 John Freeman Building
P.O. Box 20036
Houston, TX 77225

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1246

Research Project: *H. Pylori* Infection in Children on the U.S.-Mexico Border (DK-97-003)
Principal Investigator: Karen Goodman, Ph.D.

Dear Dr. Low and Dr. Dougherty:

The Office for Human Research Protections (OHRP) has reviewed the reports from the University of Texas Health Science Center - Houston (UTHSC), dated June 8, 2001 and November 8, 2001, that were submitted in response to OHRP's letter of April 17, 2001.

Based upon the review of your reports, OHRP finds that UTHSC has adequately addressed the findings and concerns cited in OHRP's April 17, 2001 letter. In particular, OHRP notes the following:

(1) OHRP acknowledges that the validation study for the above-referenced research involving gastric biopsy was halted in February 1999 and there is no plan to continue with that portion of the research.

(2) OHRP acknowledges that the biopsy samples taken during the validation study were part of a clinical diagnostic procedure and that no additional biopsy samples were obtained for research purposes.

OHRP would like to stress that should tissue samples be taken, other than solely for clinical purposes, such samples would be considered part of the research and must be described in the informed consent document.

(3) OHRP acknowledges that the UTHSC utilizes a subcommittee to conduct continuing review of protocols which is then presented to the full IRB. OHRP also notes that although there appears to be a discussion of each protocol presented for continuing review the minutes of the July 20, 2001 IRB meeting indicated that a single vote for all protocols undergoing continuing review at that meeting.

Please note that the minutes of IRB meetings should document separate deliberations, actions, and votes for each protocol that requires continuing review by the convened IRB.

(4) OHRP acknowledges the efforts by UTHSC to provide a greater level of detail in the minutes of IRB meetings. OHRP notes that minutes of IRB meetings now show the action and vote for items presented at the meetings.

(5) OHRP acknowledges that the ad hoc IRB described in the UTHSC guidelines for investigators wishing to appeal a decision by the UTHSC IRB does not have the authority to overrule that decision. It is OHRP understanding that this ad hoc committee would make an independent recommendation which would then be referred back to the UTHSC IRB for reconsideration.

As a result of the above determinations, 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 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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Palmer Beasley, Dean, UT School of Public Health
Dr. Karen Goodman, UTHSC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg. Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Ms. Freda Yoder, OHRP
Mr. Barry Bowman, OHRP