





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Terry M. Fredeking
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Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

OCT 5 2004

Dear Dr. Fredeking:

This is in response to your September 15, 2004, letter to the Office of Compliance and Biologics Quality in the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) regarding our Warning Letter dated April 14, 2003, for the North Texas Institutional Review Board.

Your letter requests that we post your September 15, 2004, letter under the *FDA Pilot Program for Posting Warning Letter Responses on FDA's Website*, Federal Register Notice of June 23, 2003, Docket No. 1999P-1656.

In accordance with the provisions of the pilot program, we have reviewed your September 15, 2004 letter, and have decided not to post your response on the FDA website. This decision is based upon our review and assessment that your response would likely mislead the public concerning the facts pertinent to the matter for the following reason: The September 15, 2004 letter does not address the issues described in the Warning Letter. As stated in our letter of August 26, 2004, you may wish to consider requesting that FDA post your May 7, 2003 response to the Warning Letter.

For the reasons that FDA denied your request to withdraw the Warning Letter and repost it after redacting your name and your company's name from it, we refer you to our letter dated August 26, 2004.

If you have any questions regarding this letter, you may contact: Patricia Holobaugh, Chief, Bioresearch Monitoring Branch (HFM-664), Division of Inspections and Surveillance, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, Maryland, 20852-1448, and by telephone at 301-827-6347.

Sincerely,

James S. Cohen, J.D.
Acting Director
Office of Compliance and Biologics Quality

