



May 3, 2005

Ms. Patricia A. Holobaugh  
Division of Inspections and Surveillance (HFM-664)  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research  
Woodmont Office Complex I  
1401 Rockville Pike, 400S  
Rockville, Maryland 20852

Re: CBER-03-310, Warning Letter, North Texas Institutional Review Board.

Dear Ms. Holobaugh:

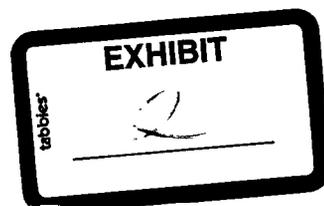
On April 13, 2003, CBER sent a Warning Letter to the North Texas Institutional Review Board (NTIRB) in care of Terry M. Fredeking, President of Antibody Systems, Inc. Subsequently, the Warning Letter was posted on the FDA Web Page. A search on that page under Mr. Fredeking's name calls up the NTIRB Warning Letter.

In a Citizen's Petition by Mr. Fredeking submitted in May, 2005, one action requested was that the Commissioner publish this letter as well as the May 7, 2003, letter from Mr. Fredeking that made substantive responses to each item listed in the Warning Letter. The May 7, 2003, letter is attached to this letter and incorporated by reference for all purposes.

The purpose here is to set forth the reasons why Mr. Fredeking should not have received the Warning Letter. The Warning Letter should not have been sent to either Antibody Systems, Inc. or Terry Fredeking. The December, 2002, inspection of NTIRB took place at its offices. The former chairman of the IRB received both the FD-482 and FD-483. As pointed out in attached May 7<sup>th</sup> letter the NTIRB ceased operations in 1999 and the inspection did not occur until late 2002. The Chairman of NTIRB responded to the FD-483 in writing on or about January 22, 2003. Each observation was discussed in full.

The EIR for the inspection was sent to the Chairman of NTIRB, not Antibody Systems, Inc. or Terry Fredeking. The EIR on page 3 states that the Chairman "... is the most responsible person and has knowledge of all the previous activities of the board." The EIR also provides that "all correspondence should be sent to him..."

Because Antibody Systems, Inc. and Terry Fredeking were sent the Warning Letter the response on May 7<sup>th</sup> came from Mr. Fredeking. At the time Mr. Fredeking was unaware that Warning Letters and Responses could be



posted on FDA's Web site. Otherwise the statements above that the Warning Letter was sent to the wrong person would have been included in the May 7<sup>th</sup> letter.

This second letter posted on FDA's Web Site will complete the record of the inspection, the substantive response to each observation and that we think the Warning Letter under FDA regulations and practices either should not have been sent or not sent to Mr. Fredeking.

Sincerely,