



ANTIBODY SYSTEMS, INC.

1901 Norwood Drive  
Hurst, Texas 76054  
U.S.A.

817-498-8222

(Fax) 817-498-82

Ms. Patricia Holobaugh  
Chief Bioresearch Monitoring Branch  
Division of Inspections and Surveillance (HFM-664)  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike, Suite 200 N  
Rockville, MD 20852-1488  
Via Federal Express: #7900 1290 7490

12/29/03

Re: Warning Letter (CBER-03-010) to the North Texas IRB

Dear Ms. Holobaugh:

This is a follow-up to the response of May 7, 2003 to the warning letter issued to the North Texas IRB, dated April 14, 2003. As stated in the response, Antibody Systems, Inc. assisted the IRB with its response and we trust that the response was sufficient to address FDA's concerns.

It has come to my attention that the FDA has placed the warning letter on its website. As a respected member of the scientific community, the publication of the warning letter, in its current form, has caused significant loss of privacy and embarrassment to me and my firm, Antibody Systems, Inc. As scientific institutions, colleagues, prospective clients and scientific collaborators scan the internet for information concerning Antibody Systems, Inc. and Terry Fredeking, they are confronted with information, which contains a warning letter from the FDA, which inappropriately conveys the impression that the deficiencies attributable to the North Texas IRB may also be attributable to Antibody Systems, Inc. and Terry Fredeking its president. This impression is incorrect and inappropriate.

As you are aware Antibody Systems, Inc. was the sponsor of a number of clinical investigations during the period of 1991 through 2001, which utilized the North Texas IRB. While Antibody Systems, Inc., fulfilled its responsibilities as sponsor, and assisted the North Texas IRB with administrative support, it did not have the responsibility for the compliance status of the IRB with regulatory requirements. The separate responsibilities of sponsors, IRBs and clinical investigators are articulated in FDA's regulations, and the interrelationship of these organizations with one another is provided in FDA's, "Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update". The interrelationship and interaction of these entities is recognized as very complex, and that there are occasions where direct contact between

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the IRB and sponsor is appropriate. The guidance further points out that it is not the sponsor's responsibility to determine IRB compliance with the regulations, although the regulations have been misinterpreted, at times, in that regard. Consistent with the guidance document's interpretation of sponsor's responsibilities FDA's compliance program, "Sponsors, Contract Research Organizations and Monitors" (# 7348.810), identifies 12 specific responsibilities of sponsors (Part I-Background), none of which involves determining the IRB's compliance with the regulations.

FDA has clearly identified in the Regulatory Procedures Manual (RPM), Background and Procedures sections, that the recipients of warning letters are those with the responsibility for the violations and/or for their correction. As the regulations, compliance program and FDA's BI-MO information guidance sheets indicate, neither sponsors, such as Antibody Systems, Inc., or their management is that responsible party.

The stated basis for sending the warning letter issued to the North Texas IRB, c/o Terry Fredeking, president of Antibody Systems Inc. includes the conclusion that Terry Fredeking has played a significant role in the IRB's operation and that FDA investigators met with him during the IRB inspection. The North Texas IRB is not owned or operated by Antibody Systems, Inc. or Terry Fredeking. As stated earlier, Antibody Systems, Inc. has provided administrative support for the IRB, such as recording meeting minutes, providing typing and document filing support. While the IRB chairman chose to consult with Terry Fredeking periodically, as a matter of management style, the control of the substantive operation of the IRB resided fully with the IRB members, and not with Antibody Systems, Inc. or Terry Fredeking.

With respect to Terry Fredeking participating in the IRB inspection, the participation was at the request of the IRB. The IRB had concluded that more than 3 years had passed from the conclusion of a number of studies it reviewed, and therefore records were no longer required to be retained, nor available when requested during the inspection. The IRB suggested that Antibody Systems, Inc. may have copies of some of the requested records, which included meeting minutes, protocols and investigator brochures. Terry Fredeking's involvement in the IRB inspection was by request of the IRB and limited to providing copies of certain documents requested by FDA.

#### **REQUEST**

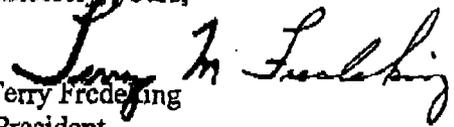
In view of the clearly identified responsibilities of the clinical investigator and IRB itself for determining IRB compliance with the regulations, and the inappropriate and incorrect impression that the sponsor (Antibody Systems, Inc.) may have such responsibility for the deficiencies described in the warning letter, I am requesting that FDA take action to correct this situation. Specifically, I am requesting that FDA take prompt action to redact the names of Antibody Systems, Inc. and Terry Fredeking from all sections of warning letter (CBER-03-010), including the addressee, salutation, paragraphs 2, 5 and the penultimate paragraph on the last page, on FDA's website, and on copies which may be provided pursuant to FOI requests. Such redaction is consistent with FDA's operating policies concerning the purging of confidential commercial information and information to protect the privacy of individuals in copies of warning letters, which are made public

pursuant to FOI requests or when placed on the internet. To the best of my knowledge, neither Antibody Systems, Inc. nor its contractors involved in the clinical trials associated with the North Texas IRB has made public their working relationship, which is consistent with the non-disclosure agreements signed by each party. FDA's operating policy with respect to redacting appropriate warning letter information is reflected in several recent warning letters, including the letter to the North Texas IRB, issued by CBER under the Bioresearch monitoring program, and currently on FDA's website:

1. CBER-03-008, which has a sub-investigator's name redacted
2. CBER-03-003, which has an IRB member's name as well as a clinical investigator's name redacted.
3. CBER-03-010, which has an IRB member's name redacted.

This request for redaction of the names of Antibody Systems, Inc. and Terry Fredeking from the warning letter (CBER-03-010) currently on FDA's website, and on copies which may be provided prospectively pursuant to FOI requests, is consistent with FDA's stated and operating policies and procedures. Thank you for your prompt consideration of this important request.

Sincerely yours,

  
Terry Fredeking  
President

cc: Steven A. Masiello  
Director Office of Compliance and Product Quality (HFM-600)  
1401 Rockville Pike  
Rockville, MD 20852  
Via Federal Express: #7923 9877 5200