

May 11, 2005

Via Facsimile 301 927 6830

Lyle Jaffe  
Food and Drug Administration  
Department of Health and Human Services  
Division of Dockets Management Branch  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: Citizen Petition of Terry Fredeking and Antibody Systems, Inc.

Dear Mr. Jaffe:

This will confirm our telephone conversation earlier today to the effect that we do not object to two of the exhibits attached to our Citizen's Petition, Exhibit Numbers 6 and 8, from being disclosed.

The Exhibit Numbers contain the term, "confidential", but for this Citizen Petition they are not.

Please call me if you have any further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Bob McConachie", is written over the typed name.

Charles R. McConachie

CRM/qlc  
cc: Antibody Systems, Inc.

CONFIDENTIAL

Ms. Patricia Holobaugh  
Division of Inspections and Surveillance (HFM-664)  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research  
1401 Rockville Pike,, Suite 200N  
Rockville, MD 301-827-6347

Fed Exd  
May 7

Re: CBER-03-010 Addressed to the North Texas IRB

May 7, 2003

Dear Ms. Holobaugh:

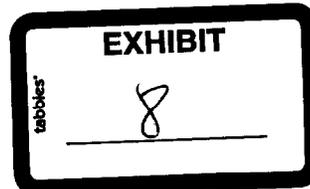
We have received the above letter from Director Masiello regarding the North Texas IRB and have discussed it with Dr. Dishon. Dr. Dishon was the IRB Chairman during the period of when research was conducted under the IRB. We also have reviewed many of the IRB records which Dr. Dishon has been maintaining. We appreciate both the letter and the discussion we held about the letter and inspection. The actions that the IRB and Antibody Systems Inc. (ASI) have and will take with respect to the letter are detailed below.

As indicated in Dr. Dishon's letter in response the Notice of Observations, the North Texas IRB has not undertaken review or supervision of any new work since early 2000, and no research under its supervision has occurred since mid-2000. Since then, the activity of the IRB has been and will remain limited solely to maintaining the records of that work until the end of the record retention period set forth in 21 CFR §56.115(b). As described below, the actions that will be taken include the IRB's commitment it will not undertake any new work, and will fully disband once the record keeping period has ended.

#### Actions Taken

1. **IRB Disbanding** The North Texas IRB will not undertake reviews, approvals or other actions on any research. Its activities will be solely limited to maintaining the records in its possession until the end of the required retention period. To the best of Dr. Dishon's and ASI's knowledge, all research carried out under the authority of the IRB was completed by August 1, 2000. Accordingly, within the next 30 days, a letter will be sent to the parties listed in the IRB records, or otherwise believed by ASI, to have been the sponsors for the clinical studies conducted under the IRB's approval. This letter, a proforma copy of which is attached, will inform those parties that the IRB intends to disband following final disposition of the records to occur shortly after August 1, 2003. Sponsors will be permitted to obtain the records of the studies they sponsored after that date. Unclaimed records will be handled in accordance with applicable laws and regulations and the IRB will be fully disbanded. Please see the below list of studies:

**Study #1:** "Production of Hyperimmune Plasma Following Immunization with Pseudomonas Aeruginosa and Klebsiella Vaccines." Conducted during 1990-



1998. Research believed completed by December 31, 1997 as no further research activities have occurred since that date.

**Study #2:** "Towne Strain of CMV: A Phase I Study of the Toxicity of Increasing Doses." Conducted during 1991-1996. Research believed completed by December 31, 1997 as no further research activities have occurred since that date.

**Study #3:** "Production of Hyperimmune Plasma Following Immunization with Pertussis Toxoid Vaccine." Conducted during 1991-1997. Research believed completed by December 31, 1997 as no further research activities have occurred since that date.

**Study #4:** "The Study of Safety and Immunogenicity for the production of Hyperimmune Plasma Following Immunization with Escherichia coli O-Polysaccharide: Toxin A Vaccine, Polyvalent." Conducted during 1991-1998. Research believed completed by December 31, 1998 as no further research activities have occurred since that date.

**Study #5:** "Production of Hyperimmune Plasma Following Immunization with Pseudomonas Aeruginosa, Klebsiella, and Escherichia coli Vaccines." Conducted during 1990-1998. Research believed completed by December 31, 1998 as no further research activities have occurred since that date.

**Study #6:** "Evaluation of the Safety and Immunogenicity of a Staphylococcus aureus Conjugate, Bivalent Vaccine/Immunizing Agent in Plasma Donors and the Identification and Recovery of Immune Source Plasma Targeted Against Staphylococcus aureus." Conducted during 1993-1995. Research believed completed as December 31 1996, as no further research activities have occurred that date.

**Study #7:** "Production of Hyperimmune Plasma Following Immunization with Rabies Virus Vaccine, Inactivated." Conducted during 1995-1997. Research believed completed by December 31 1997, as no further research activities have occurred since that date.

**Study #8:** "Safety and Immunogenicity of Vivotig Berna L Vaccine Typhoid Vaccine Live Oral Attenuated Ty21a in Healthy Adults." Conducted during 1997-1999. Research believed completed by December 31, 1999 as no further research activities have occurred since that date. Letter from sponsor received October 17, 2002 reiterating that no further work is contemplated.

**Study #9:** "Collection of Source Plasma that Contains Antibodies to Trypanosoma cruzi." Sponsored by Ortho Clinical Diagnostics. No research was done, nor will be done under this IRB. All work will be done under a new IRB (*see Action 2 below*).

**Study #10:** "Safety and Immunogenicity of *Vibrio cholerae* CVD 103-HgR in Healthy Adult Volunteers 45-65 Years of Age." Conducted during 1997-99. Research believed completed as of December 31, 1999, as no further research activities have occurred since that date.

**Study #11:** "Transcutaneous Immunization Using Tetanus Toxoid Non-Absorbed with Heat-Labile Enterotoxin from *E. coli* as Adjuvant." Conducted during 1999-2000. Letter from Principal Investigator to IRB indicating closure of project on July 10, 2000.

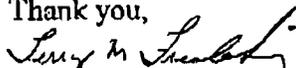
**Study #12:** "Transcutaneous Immunization Using Tetanus Toxoid Non-Absorbed with Heat-Labile Enterotoxin from *E. coli* as Adjuvant." Letter from Principal Investigator to IRB indicating closure of project on July 10, 2000.

**Study #13:** "Doxycycline Cytokine Receptors Stimulation." Sponsored by Antibody Systems, Inc and conducted during July 2000. Research completed with no further action since July 30, 2000.

2. **ASI Non-Use of North Texas IRB** ASI has not and will not use the services of the North Texas IRB. For any future work, ASI will only use an independent IRB that provides full assurance compliance with all regulatory obligations. At this time, ASI's intention is to use a professional, full-time, independent IRB.
3. **Records Location** ASI will again undertake a comprehensive effort to assist the IRB in locating any records still subject to retention under 21 CFR §56.115(b), and if found, will place those records into the IRB's files.
4. **ASI Web Site:** We have removed the reference to IRB services from the ASI Web Site; a copy of the current web page that the reference appeared on ([http://www.antibodysystems.com/Therapeutic\\_Division.html](http://www.antibodysystems.com/Therapeutic_Division.html)) is attached.

ASI believes that its actions were limited to providing secretarial and similar administrative support requested by the North Texas IRB chair. Nevertheless, because we share FDA's desire to resolve this matter promptly, ASI will facilitate the NTIRB's response and disbanding. As discussed in our teleconference, we understand that above actions will provide an acceptable response to the Agency's concerns in this manner. Please let me know if there are any questions or problems with the proposed response.

Thank you,

  
Terry M. Fredeking  
President

Attachment: Web Page: [http://www.antibodysystems.com/Therapeutic\\_Division.html](http://www.antibodysystems.com/Therapeutic_Division.html)

cc: Dr. Neil Dishon, Chief of Staff University of Texas at Arlington  
Michael A Chappell, District Director, FDA/ORR Dallas TX Office  
Dr. Kristin Borrow, Chief Compliance Oversight Branch, OHRP

**North Texas Institutional Review Board**

May \_\_, 2003

BY MAIL.

[Sponsor Contact]  
[Sponsor Address]

Re: [Study Title/Identification and Performance Date]  
**IRB Notice of Intent to Disband and Cease Record Retention**

Dear [Sponsor Contact]:

Our records indicate that the above study, sponsored by your company, was conducted during the date indicated above under the authority of the North Texas Institutional Review Board. Our records indicate this research under the NTIRB was completed no later than [Ending Date]. Accordingly, on August 1, 2003 the record keeping period required under 21CFR §§56.115(b) will have expired. On or after that date the NTIRB intends to disband, and records related to this study in its possession will be destroyed or otherwise handled in accordance with applicable laws and regulations.

If your company wants to obtain these records, then please contact Dr. Neil Dishon, Chief of Staff University of Texas at Arlington **on or before July 1, 2003**. Since Dr. Dishon is now retired, you may contact Mr. Terry Fredeking, President of Antibody Systems, Inc., if you have difficulty in contacting Dr. Dishon. Please see contact information below.

For Dr. Neil Dishon

The University of Texas at Arlington Health  
Services  
Dr. Neil Dishon, Chief of Staff  
605 S. West Street  
Arlington, TX 76019  
Phone: 817.272.2771  
Fax: 817.272.2715

For Mr. Terry Fredeking

Antibody Systems, Inc.  
1901 Norwood Drive  
Hurst, TX, 76054  
Phone: 817.498.8222  
Fax: 817.498.8277  
Email: tfredeking@antibodysystems.com

Feel free to contact either Dr. Dishon or Mr. Fredeking if there are any questions about the actions to be taken.

Sincerely,

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