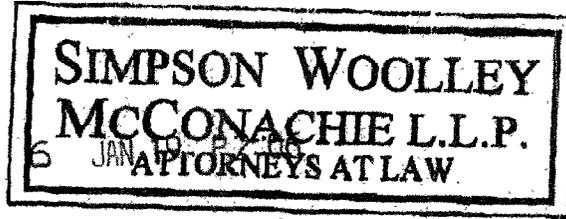


0657



November 2, 2005

Via Facsimile 301.827.0440

Dr. Jesse L. Goodman, MD, MPH  
 Director  
 Center for Biologics Evaluation and Research  
 Food and Drug Administration  
 1401 Rockville Pike  
 Rockville, Maryland 20852

Re: Docket No. 2005-0182/CP1

Dear Dr. Goodman:

This is to acknowledge receipt of your letter dated October 24, 2005, for which I thank you. In your letter you state that the agency has "not yet completed its responses to the issues. . ." the Citizen Petition of Antibody Systems, Inc, Terry Fredeking. The reason given for this delay given is "[w]e are still considering your requests. . ." The authority given for this delay is 21 CFR 10.30(e)(2).

I write to respectfully take issue with both the failure of FDA to give us a final response to our Citizen's Petition and the basis for the delay.

As you know, 21 CFR 10.30(e)(2)(iii) states that "The Response<sup>1</sup> will provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished."

The October 24<sup>th</sup> letter fails to comply with the regulation in that it (1) neither approves nor denies the Petition and (2) fails to comply with Section 10.30(e)(2)(iii). The reason the letter does not comply with (iii) of the regulation is there is no reason given why the agency is unable to reach a decision. To say FDA is still considering the Petition does not comply with the regulation.

<sup>1</sup> Section 10.30(e)(2)(i) and (ii) provide for approval or denial.

2005P-0182

LET 2

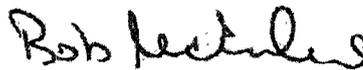
November 2, 2005  
Page 2

SIMPSON WOOLLEY McCONACHIE LLP

By this letter I request that FDA comply with its own regulations and grant or deny the petition on or before November 9, 2005, the 180<sup>th</sup> day by my count from the filing date of May 13, 2005, or otherwise provide a proper response under the regulations.

This Citizen's Petition is not complicated, the record is not great, and the relief sought is neither unreasonable nor difficult to do. Because of the continuing disclosure of the incorrect warning letter on the Internet and by way of the FOIA requests, the wrongful dissemination of the error continues with no end in sight.

Sincerely,



Charles R. McConachie

CRM/ss  
CC Terry Fredeking

ROUTING AND TRANSMITTAL SLIP

DATE: 1/18/06

0055 6 JAN 19 P2:06

TO:	INITIALS	DATE
1. Jenny Butler HFA-305		
2.		
3.		
4.		
5.		
6.		
CC:		
CC:		

<input checked="" type="checkbox"/> Action	<input type="checkbox"/> File	<input type="checkbox"/> Note and Return
<input type="checkbox"/> Approval	<input type="checkbox"/> For Clearance	<input type="checkbox"/> Per Conversation
<input type="checkbox"/> As Requested	<input type="checkbox"/> For Correction	<input type="checkbox"/> Prepare Reply
<input type="checkbox"/> Circulate	<input type="checkbox"/> For Your Info.	<input type="checkbox"/> See Me
<input type="checkbox"/> Comment	<input type="checkbox"/> Investigate	<input type="checkbox"/> Signature
<input type="checkbox"/> Coordination	<input type="checkbox"/> Justify	

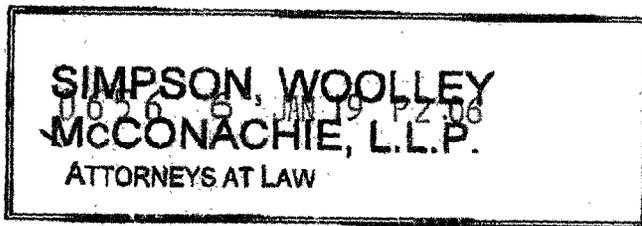
REMARKS: Docket No. 2005-0182/CP-1

Please post attached response to the above docket. This response was faxed to docket; however, the incorrect fax number for docket was used, and you did not receive. I am sending a copy to you for posting.

Thank you.

FROM:

Brenda R. Friend, Regulatory Counsel  
U.S. Food and Drug Administration  
Center for Biologics Evaluation and Research  
Regulations and Policy Staff (HFM-17)  
WOC I/Rm. 580N  
Phone#: 301-827-9440, FAX#: 827-9434



**TELECOPY TRANSMITTAL**

**PLEASE DELIVER THE FOLLOWING PAGES TO:**

**NAME:** Dr. Jesse Goodman  
Lyle Jaffe

**TELECOPY NUMBER:** 301 827 0440  
**TELECOPY NUMBER:** 301 927 6830

**FROM:** Bob McConachie

**TOTAL NUMBER OF PAGES:** 2 (PLUS THIS COVER PAGE)

**DATE:** November 2, 2005

**FILE NUMBER:** Citizen Petition of Terry Fredeking and Antibody Systems, Inc.

**IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 214-871-5080**

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**NOTE:**