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March 20, 2006

Via Facsimile 301 827 9434 and US Mail

Jesse Goldman, MD, MPH
Director, Center for Biologics Evaluation
and Research
Food and Drug Administration (HFM-1)
5630 Fischers Lane
Rockville, Maryland 20857

Re: Citizen Petition 2005-0182/CP1

Dear Dr. Goldman:

This is response to your letter dated March 13, 2006, for which I thank you, regarding the fact that the captioned Citizen's Petition submitted on May 11, 2005, has still not been decided.

We appreciate the fact that the agency has other priorities and that one reason a Citizen Petition may not be decided in 180 days from submission is the existence of other agency priorities. However, the existence of such priorities does not mean a Citizen Petition, any Citizen Petition, may go undecided for an unreasonable period of time or forever. This is so because a Citizen Petition that is not reasonably decided or never decided is a denial of the both the constitutional and statutory right to petition the government .

Your letter says you plan to give a final response in the near future. The term "near future" is an imprecise term that does not put any limit as to time in place. "Near future" could mean in a few days, a few weeks, or some longer undefined time. I do not see "near future" going out several months, especially since it has now been more than ten months since the Citizen Petition at issue here was submitted. One could argue with some force that more than a year with no answer is an unreasonable length of time and a denial of due process. This is especially true since the citizen petition here is neither complicated nor does it involve a large record.

Because the term "near future" is one you used, and the regulation provides that "The tentative response . . . may specify when a final response may be furnished." 21 CFR 10.30(e)(2)(iii), we request that the agency give a

2005P-0182

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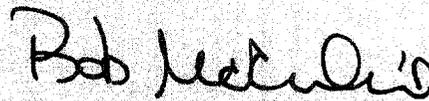
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specific time when the petition will be decided. I do not think defining "near future" with specificity is an unreasonable request or that it should take more than 30 days to do so. Of course, if a final decision is forthcoming in the next 30 days this request for specificity may be ignored

Sincerely,



Charles R. McConachie

CC: Antibody Systems
Division of Documents Management
(HFA-305)