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September 30, 2004

**VIA FAX AND POST**

William K. Hubbard  
Senior Associate Commissioner  
for Policy and Planning  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Docket No. 2004P-0276

Dear Mr. Hubbard:

We received the tentative response of the Food and Drug Administration ("FDA"), dated September 15, 2004, to the Citizen Petition filed by Computerized Thermal Imaging, Inc. ("CTI"). It is difficult to comprehend how the FDA's tentative response could in good faith state that "FDA is unable to issue a final response to your petition at this time because it is not clear to us exactly what action you are asking us to take." CTI's petition was written in English and is not inscrutable.

As explained in the Citizen Petition, CTI seeks extra-record discovery, and in particular, depositions of the FDA staff reviewers involved with CTI's premarket approval application, P010035, because of their improper and pervasive bias and bad faith towards CTI and its application. As CTI stated, it is entitled to an investigation into the bias of the FDA staff reviewers in order to supplement the administrative record, *see* Citizen Petition at 1 & 19, and this includes "extra-record discovery and examination of" key FDA staff reviewers involved in CTI's application. Citizen Petition at 19 (emphasis added).

Moreover, CTI cited numerous cases in the Citizen Petition supporting its position that upon a strong showing of bias and bad faith, extra-record discovery, including depositions, is appropriate. *See Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971) (holding that strong showing of bad faith may necessitate examination of "decisionmakers themselves"); *Sokaogon Chippewa Community v. Babbitt*, 961 F. Supp. 1276, 1279 (W.D. Wis. 1997) (showing of bad faith allows party to take discovery and "depose relevant individuals"); *Pension Benefit Guaranty Corp. v. LTV Steel Corp.*, 119 F.R.D. 339, 344 (S.D.N.Y. 1988)

2004P-0276

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William K. Hubbard  
September 30, 2004  
Page 2

(holding that allegation of bad faith sufficient to allow examination of agency decisionmaker). These cases demonstrate that depositions of agency personnel are permissible when there has been a strong showing of bias or bad faith. CTI has more than satisfied this burden and is therefore entitled to take the depositions of key FDA staff reviewers immediately.

The citation to 21 C.F.R. § 12.1, *et seq.*, was included to demonstrate one of the mechanisms that "the Commissioner may use," 21 C.F.R. § 10.30(h), in order to provide CTI with the extra-record discovery and depositions of FDA staffers involved in the review of CTI's premarket approval application. However, CTI's Citizen Petition is not limited to the type of action specified in 21 C.F.R. Part 12. Rather, as stated previously and supported by the authority cited in the Citizen Petition, CTI seeks to depose key FDA staff reviewers who undoubtedly possess information that will substantiate CTI's claim of bad faith or bias.

Finally, as CTI explained in the Citizen Petition, the actions of the FDA staff reviewers have pushed CTI to the brink of extinction. *See* Citizen Petition at 27-28. CTI has thus requested expedited consideration of the Citizen Petition in order to begin conducting extra-record discovery and depositions of FDA staff reviewers immediately. It is therefore distressing and unconscionable that FDA has allowed almost three months to elapse before notifying CTI that, in the view of the FDA, the relief sought by CTI is "not clear." In fact, the Citizen Petition quite clearly stated that CTI sought "extra-record discovery and examination of those [FDA] personnel" involved in considering CTI's premarket approval application. Citizen Petition at 19. Accordingly, CTI requests that it be allowed to immediately depose the key FDA staff reviewers involved in the premarket approval application P010035.

In light of all of the attendant circumstances, it is imperative that we receive a prompt response. If such response is not forthcoming, we will seek judicial relief.

Regards,

  
Thomas C. Green

cc: Daniel E. Troy,  
Chief Counsel, FDA

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