



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

October 26, 2004

Thomas C. Green
Sidley Austin Brown & Wood LLP
1501 K Street, N.W.
Washington, DC 20005

Dear Mr. Green:

We received your letter of September 30, 2004 regarding Computerized Thermal Imaging, Inc.'s (TCI) Citizen Petition (Docket No. 2004P-0276). Thank you for clarifying that your request is for depositions of FDA staff reviewers.

Ordinarily, FDA considers written requests for testimony before any tribunal under 21 CFR § 20.1. Because there is no court proceeding underlying your request, 21 CFR § 20.1 does not apply. However, one of the principles that informs this regulation, balancing the need of the agency to protect the public health, against the needs of private parties, is relevant. Under these circumstances, granting your request would be virtually unprecedented and would divert FDA employees from their duties, including promotion of the public health through implementation of the various provisions of the Federal Food, Drug, and Cosmetic Act. Given that there is no court proceeding underlying your request and that it would divert FDA resources, we decline to grant the request.

If you have any questions about this letter, please contact Joseph M. Sheehan of the Regulations Staff of FDA's Center for Devices and Radiological Health at 301-827-2794.

Sincerely,

William K. Hubbard
Senior Associate Commissioner
for Policy and Planning