MAY 1 8 2010

Mr. Scott Tolchin

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Re: Citizen Petition No. FDA-2009-P-0253
Filed May 25, 2009

Dear Mr. Tolchin:

This letter responds to the above referenced citizen petition requesting that the Food and Drug Administration (FDA) enforce compliance with medical device reporting (MDR) regulations by LASIK device user facilities and Ambulatory Surgical Facilities or LASIK clinics. Your petition also requests the agency to impose sanctions on those LASIK clinics that are deemed non-compliant. In accordance with 21 CFR 10.30(e)(3), this letter is advising you that FDA is denying your petition.

In accordance with 21 CFR 10.30(k), the citizen petition process "does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action." Rather, such matters are with the exclusive discretion of the Commissioner. A denial of a request to take enforcement action does not constitute final agency action. (See 21 CFR 10.45.) Further, FDA takes enforcement action on a case-by-case basis based upon agency priorities and available resources. We do not advise the public in advance of our intentions to take enforcement action against particular products.

At the same time, we appreciate you sharing your concerns regarding the safety of LASIK. The agency is currently working on improving its outreach initiatives for consumers who are considering this procedure, as well as developing a guidance document to improve the labeling of LASIK devices. In addition, FDA recently reopened a docket to receive public comment from patients regarding their post-LASIK experience and on ways the agency might improve patient safety. That docket may be accessed at the www.regulations.gov website, under docket no. FDA-2008-N-0488.

Sincerely,

Leslie Kux, J.D.
Acting Assistant Commissioner for Policy
Office of Policy, Planning, and Budget
Office of the Commissioner