DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 22 2008

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Dear Dr. Patterson:

This is in response to your letters and recent e-mails to the Secretary of Health and Human Services, and to staff in FDA's Office the Commissioner and the Center for Devices and Radiological Health (CDRH) concerning the safety of LASIK procedures.

I appreciate the time and effort you took to share your concerns about the safety of LASIK. I am sorry that you experienced problems with this procedure and that you feel FDA has not been responsive to the issues you have raised. It is my understanding that in direct response to four citizen petitions you submitted, CDRH convened the Ophthalmic Devices Panel to consider quality of life and outcome issues associated with LASIK devices. The meeting was held on April 25, 2008. You made a presentation during the open public hearing session of that meeting as did many others who had similar concerns regarding the safety of LASIK. I can assure you that these presentations made us keenly aware of the problems you and others have experienced.

As an immediate result of this advisory panel meeting, the Agency added additional links and information to our website regarding reporting LASIK problems. We are studying ways to make these links even easier to use. The LASIK web site will continue to be updated periodically or as needed. In addition, all suggestions we have received for LASIK labeling and for our LASIK web site are being seriously considered, and we are working with several FDA groups to implement those changes as soon as possible.

In addition, we are planning to conduct a study to look at how symptoms affect a patient's quality of life after LASIK. We are also strengthening our post-market surveillance in order to better understand how LASIK is conducted in real world situations within the general surgical and optometric community.

We agree that there is concern about potential under-reporting of adverse events and serious complications from ambulatory surgical facilities, and we are considering various methods to address this very important issue. Our decision to issue an inspection is based upon the information we receive from MDRs and MedWatch reports. Since 2000, FDA has inspected three LASIK user facilities. These inspection reports may be obtained under the Freedom of Information Act (FOIA) once a record of an inspection is closed. (An inspection report is considered closed when FDA has concluded its review of the facility's activities and decides that no additional administrative or regulatory action is warranted.)

FDA believes it is important for members of the public like you to have the opportunity to further comment on issues associated with the safety of LASIK procedures. Accordingly, we are considering establishing a docket so that interested persons may submit to the Division of Dockets Management written or electronic comments regarding LASIK. If a public docket is established, the comments we have received from you and others thus far and any future communications will be included in the docket for our further consideration.

We appreciate your interest in this important public health issue.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Center for Devices and
Radiological Health

cc: Larry Pilot