October 9, 2008
LASIK Surgery Watch
PO Box 91381
Raleigh, NC 27675

Daniel Schultz, M.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville , MD 20850
Dear Dr Shultz,

LASIK Surgery Watch, a non-profit LASIK patient advocacy organization, approves the Food and Drug Administration's (FDA) collaboration with the American Academy of Ophthalmology to develop a card to preserve a LASIK patient's preoperative corneal measurements for the purpose of calculating IOL power should they require future cataract surgery.

Our concern is that preoperative measurements will not be available for all LASIK patients. Over the course of years, many patients will lose paper documents, and at present there is no organized effort to provide records to millions of Americans who have already had LASIK surgery. The concern that patients will be unable to locate their surgeons, or that surgeons may fail to retain medical records beyond state law requirements is legitimate.

All LASIK patients past and future must be informed of the need to preserve their LASIK medical records, and all surgeons should be required to provide this information for past and future patients. Additionally, patient information should be stored in a central database that is securely maintained.

In the years since initial FDA approval of LASIK we have seen the emergence of a number of unanticipated LASIK risks, including intractable dry eye, night vision disturbances, late flap dislocation, post-LASIK ectasia, and inaccurate IOP measurements. Lasik Surgery Watch encourages the FDA to seriously reconsider safety of the procedure in light of these real risks. Clearly, there are other organizations who do not share our opinion. There is, however, no difference of opinion concerning LASIK patients' need for their medical records.

The FDA must act swiftly before existing LASIK medical records are lost. The current financial condition of two large LASIK chains in the United States underscores this need. We call on the FDA to issue a public health advisory encouraging LASIK patients to contact their surgeons to request their medical records.

We further request a meeting with a representative of your office at your earliest convenience to discuss this matter. Our organization considers public dissemination of information on the risk of improper IOL power calculation after LASIK to be a public health issue that is best addressed by the FDA as part of your oversight of ophthalmic devices.

Sincerely,
Gerard J. Dorrian
Lauranell Burch
Matthew Kotsovolos
(Directors LASIK Surgery Watch)