

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2008N0488]

Medical Devices: Ophthalmic Devices; Laser-Assisted In Situ Keratomileusis (LASIK) Devices; Reopening of the Comment Period

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration (FDA) is announcing the reopening until [insert one (1) year from date of publication in the Federal Register] of a public docket to receive information and comments on laser-assisted in situ keratomileusis (LASIK) devices.

DATES:

The agency encourages interested parties to submit information and comments by [insert one (1) year from date of publication in the Federal Register].

ADDRESSES:

Submit electronic comments or information to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., WO66 Rm. 4422, Silver Spring, MD 20993, 3017965733, e-mail: [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 12, 2008 (73 FR 53028), FDA published a notice announcing the opening of a public docket to receive information and comments on the post market experience associated with the use of laser-assisted in situ keratomileusis (LASIK) devices, as well as information regarding potential barriers that may exist in providing the agency with feedback regarding LASIK procedures. Interested persons were invited to submit comments

by September 14, 2009. At this time, the agency is reopening the docket to continue to receive public comments. Information and comments submitted to the docket will assist us in identifying ways in which we can improve our public outreach efforts regarding the safety and effectiveness of LASIK devices.

## II. Submission of Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. All comments submitted to the public docket are public information and may be posted to the FDA's Web site at <http://www.fda.gov> for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 30, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. 09?????? Filed ?????09; 8:45 am]BILLING CODE 416001S

[FR Doc. 2009-27222 Filed 11/12/2009 at 8:45 am; Publication Date: 11/13/2009]