

# LASIK ads must warn consumers of risks: FDA

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By Susan Heavey Fri May 22, 2:26 pm ET

WASHINGTON (Reuters) – Doctors, clinics and others promoting corrective eye surgery known as LASIK need to make sure their advertisements tell consumers about possible risks, U.S. regulators said in a letter released on Friday.

The Food and Drug Administration, which has been investigating patient complaints over the procedure, told healthcare providers that commercials and other promotions that do not convey necessary warnings, side-effects and other precautions are deceptive.

"Advertising and promotional materials for FDA-approved lasers used during LASIK procedures must be truthful, properly substantiated and not misleading," wrote Timothy Ulatowski, head of the Office of Compliance for the FDA's Center for Devices and Radiological Health.

The letter comes more than a year after the FDA held a public meeting that drew dozens of unhappy patients who complained of blurriness, double-vision, depression and other problems after undergoing LASIK, or laser-assisted in-situ keratomileusis.

Surgeons and other industry groups said the procedure is safe and effective when done properly and that most patients are satisfied with their vision afterward.

LASIK involves cutting a flap in the eye and then using a laser to reshape the cornea, aiming to improve patients' vision so they can avoid glasses or contact lenses. About 700,000 Americans have undergone the procedure since it was approved in 1998, industry estimates have shown.

The FDA's letter spares LASIK-related companies which could have been hurt by stricter action, including device makers Abbott Laboratories' unit Abbott Medical Optics Inc, Alcon Inc, and Bausch & Lomb as well as clinics such as TLC Vision Corp and LCA Vision Inc.

A weak U.S. economy has already dampened demand for the elective surgery, which can cost several thousand dollars per eye and is not covered by most health insurers.

The FDA splits oversight of LASIK advertising with the Federal Trade Commission, which could not be immediately reached for comment. If the FDA deems LASIK advertising misleading, it can issue warning letters as well as take stronger action such as imposing fines or making referrals for criminal investigation.

But Diana Zuckerman, president of National Research Center for Women & Families, said the FDA could have done more than send a "vague" letter that does not help "patients in any meaningful way.

"The problem is there are certain people who are unlikely to benefit (from LASIK) and they don't know who they are," she said. "At this point many people think LASIK is some kind of miracle ... and that's just not true."

The agency should instead require doctors and clinics to give potential patients a simple, easy-to-understand booklet that lays out all the possible risks, Zuckerman said.

FDA spokeswoman Mary Long said the agency has taken additional steps, including updating its website and making it easier for people to report problems to the FDA.

The American Academy of Ophthalmology physicians' group said it appreciated the "reminder" from the FDA and would give the letter to its members. Other industry groups either could not be immediately reached or had no comment.

(Reporting by Susan Heavey, editing by Dave Zimmerman)