# FDA to study negative effects of Lasik eye surgery

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(AP) -- The Food and Drug Administration announced plans Thursday to study the scope of problems connected with laser eye-correcting surgery, which include blurred vision and dry eyes.

The FDA says it will work with the National Eye Institute and the Department of Defense to determine the percentage of patients who experience negative side effects following surgery.

The first phase of the project is already under way, with plans for an online questionnaire to help patients gauge their quality of life following surgery, according to an FDA statement.

The project will also include a clinical trial tracking patients who undergo the procedure, which is expected to conclude by 2012.

"This study will enhance our understanding of the risks of Lasik and could lead to a reduction in patients who experience adverse effects," said Dr. Jeffrey Shuren, the acting head of FDA's medical device division.

An estimated 6 million Americans have undergone Lasik surgery, which permanently reshapes the cornea, a clear layer covering the eye. There are no guarantees of 20/20 vision and the long-term safety of the procedure is still unknown.

Ophthalmology societies report that about 95 percent of patients are

satisfied with their new vision.

But a small number of patients have reported permanent damage to their eyes following the surgery, including double vision, dry eye and halos around objects at night.

The FDA agreed to look into the problems in 2008 after years of complaints. The agency said last summer it received 140 reports of Lasik-related problems between 1998 and 2006.

Lasik procedures have fallen off in the past year as consumers cut back on the pricey surgeries, which can cost between $1,500 and $5,000

Makers of Lasik lasers include Advanced Medical Optics Inc., Alcon Inc., and Bausch and Lomb.

Also on Thursday, the FDA announced warning letters sent to 17 Lasik surgery centers for inadequate adverse event reporting procedures. Regulators periodically send letters to facilities that don't follow federal guidelines for reporting patient complaints.

"The inspections did not identify problems with the use of the Lasik devices at these facilities," the FDA stated.

More inspections of Lasik centers are planned in coming months, according to the FDA release.