FDA drafts guidance on patient labeling information for LASIK devices

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In a draft guidance document issued July 28 by the U.S. Food and Drug

Administration, content and formatting recommendations are presented for patient labeling information for laser-assisted in situ keratomileusis (LASIK) devices.

Owing to concerns that some patients are not receiving and/or understanding information regarding the risks and benefits of LASIK devices, the authors offer content and formatting suggestions for patient labeling information. The labeling recommendations are intended to enhance the physician-patient discussion of the benefits and risks of LASIK.

The suggested format and content of patient labeling should include a description of the eye and the surgery and explanation of what LASIK is and what the laser does. Indications for use should be presented, and there should be discussion of the benefits, alternatives, contraindications, warnings, and precautions, as well as a description of patient risks. In addition, the labeling should include a description of what the patient should expect before, during, and after surgery, as well as relevant clinical study information, while providing specific context about the LASIK device to be used in the procedure.

"The FDA recommends that a copy of the patient decision checklist be provided to the patient so that the patient can refer back to this important information," the authors write. "The FDA also encourages device manufacturers to develop a plan to ensure that patients are adequately informed of the risks of LASIK."

More information: More Information

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