May 19, 2008

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Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition to:
1) ban the use of all refractive surgery lasers for LASIK surgery due to substantial deception in the labeling and an unreasonable and substantial risk of injury, and
2) acknowledge and enforce remedy for the misbranding of lasers used for LASIK (false and misleading labeling) due to failure to properly report adverse events and complications. The authority for the first action is under U.S. Code Title 21, Section 516 [21 USC 360f] of the Federal Food, Drug, and Cosmetic Act, Banned Devices. Authority for the second action is under U.S. Code Title 21, Section 502 [21 USC 352a] of the Federal Food, Drug, and Cosmetic Act, Misbranded drugs and devices - False or misleading label.

Factual Grounds

In the FDA clinical trials of lasers for LASIK, the devices failed to meet the Agency's safety requirements. The guidance document dated 9/5/1997 titled *Discussion Points for Expansion of the "Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers" Draft Document* (exhibit A) states that less than one percent of eyes may experience adverse events. A meta-analysis of *Summaries of Safety and Effectiveness* for the twelve lasers approved from 1998 through 2004 (exhibit B) found that six months after LASIK, 17.5% of patients report halos, 19.7% report glare, 19.3% report night-driving problems and 21% report dry eyes. These complications were deceptively reported as "symptoms"; however, they should have been reported as adverse events. The risk of injury from the medical devices used to perform LASIK is unreasonable and substantial. The purported benefits of LASIK (reduced dependence on glasses or contact lenses) do not outweigh the risks. LASIK surgery does not meet any medical need that cannot be met with safer alternatives, such as glasses or contact lenses.

LASIK devices appear to meet the efficacy standards for approval; and most patients report satisfaction with the visual outcome even in the presence of complications such as dry eyes and night vision impairment. It should be noted, however, that of the 14 FDA approvals for LASIK, no study of safety and effectiveness of LASIK reported adverse events in less than one percent of eyes as required by FDA safety requirements for approval.

FDA-2008-P-0319-0001

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Environmental Impact

This petition qualifies for categorical exclusion under 25.30 - 34 of this chapter from the requirement of an environmental impact assessment.

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Name of petitioner: Lauranell H. Burch

Mailing Address:
[redacted]

Telephone Number:
[redacted]

Exhibit A: Checklist of information usually submitted in an Investigational Device Exemption (IDE) application for refractive surgery lasers.

Exhibit B: Bailey MD, Zadnik K. Outcomes of LASIK for myopia with FDA-approved lasers. Cornea. 2007 Apr;26(3):246-54.