

June 30, 2003

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FDA Contact Lens Issue  
Docket #03D-0118  
Fax: 301 8276870

Dear FDA:

Contact lenses (both dioptric prescription and cosmetic) must absolutely be maintained as a prescription medical device. As an eye practitioner, I observe first-hand the consequences of misinformed contact lens wear and non-compliance. The sequelae of ill-fitting lenses, overwear, and non-compliance to proper hygiene and wear schedules has been well documented. This list includes corneal complications of edema, warpage, chronic infections, ulcerations, neovascularization leading to PERMANENT SCARRING and VISION LOSS; not to mention patient discomfort and suffering. Further mismanagement can lead to all sorts of problematic ocular health situations such as allergy development, permanent lid and conjunctival irritation as well as tear gland dysfunction.

The public cannot and should not be responsible for monitoring these aspects of contact lens wear. These medical devices can be used safely and beneficially only if monitored properly by licensed practitioners. The public will surely be at high risk if not required to be routinely monitored by optometric doctors who can educate and extend the highest quality of product and product safety to their patients.

Sincerely,



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