



Division of  
Advertising Practices

United States of America  
FEDERAL TRADE COMMISSION  
Washington, D.C. 20580

**VIA FED EX**

**Notice of the Fairness to Contact Lens  
Consumers Act and the Contact Lens Rule**

Dear \_\_\_\_\_:

The staff of the Division of Advertising Practices of the Federal Trade Commission recently received (a) complaint(s) claiming that your company, \_\_\_\_\_, sold contact lenses to consumers without either obtaining a copy of a valid contact lens prescription or verifying the consumer's contact lens prescription with the eye care prescriber. We are writing to inform you that such practices would be in violation of the Fairness to Contact Lens Consumers Act ("the Act"), 15 U.S.C. § 7601 et seq., and the Contact Lens Rule ("the Rule"), 16 C.F.R. Part 315.

Contact lenses are restricted medical devices, 21 U.S.C. § 360j(n)(1), whose purchase requires a prescription from a medical professional. The Rule provides that contact lenses may be sold to consumers only in accordance with a valid prescription that is either presented to the seller or verified with the prescriber by the seller. To verify a prescription, the Rule requires a seller to send the prescription information it receives from its customer to the prescriber for verification. The sale of contact lenses without either obtaining a copy of a valid prescription or verifying his or her prescription information with the prescriber constitutes a violation of the Rule.

A valid and verified prescription helps ensure that consumers have been examined for overall eye health and proper fitting by a licensed eye care professional. Without guidance or supervision by a licensed eye care professional, consumers may develop serious injuries or complications from contact lenses, including:

- Pain and discomfort of the eyes;
- Red or swollen eyes;
- Blurred or decreased vision;
- Corneal abrasion (cut or scratch on top layer of eye);
- Allergic reactions (itchy, watery, red eyes);
- Infection; and
- Blindness

This letter places you on notice that violations of the Rule may result in legal action, including civil penalties of up to \$16,000 per violation.

You should review the Rule and revise your practices as necessary to ensure that they comply with the Rule's requirements. For your reference, enclosed is a copy of the Rule and two business guidance publications produced by the FTC, *The Contact Lens Rule: A Guide for Prescribers and Sellers* and *Complying with the Contact Lens Rule*, which contain information about how to comply with the Rule. These publications are also available on our web site at [www.ftc.gov](http://www.ftc.gov).

If you have any questions regarding this letter or the Contact Lens Rule generally, you may contact Beth Delaney at (202) 326-2903. Thank you for your prompt attention to this matter.

Very truly yours,

Mary K. Engle  
Associate Director