



Division of
Advertising Practices

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

October , 2019

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 claiming that your store, , is selling contact lenses to consumers without a prescription. 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.

Both cosmetic contact lenses and corrective contact lenses are restricted medical devices, 21 U.S.C. § 360j(n)(1), whose purchase requires a prescription from a medical professional. Accordingly, cosmetic contact lenses are covered by the Rule.

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 cosmetic 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 decorative 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 \$42,530 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.

We request that you contact Alysa Bernstein at (202) 326-3289 immediately upon receipt of this letter and explain how you plan to address the reported violations. Thank you for your prompt attention to this matter.

Very truly yours,

Mary K. Engle
Associate Director