

April 6, 2018

Re: Contact Lens Rule
16 CFR Part 315
Comment
Project No. R511995

Dear Federal Trade Commission:

We would like to offer the following comments regarding the recent *Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule* which was held on 7 March 2018.

Alcon is the global leader in eye care. As a division of Novartis, we discover new ways to enhance sight and improve people's lives. We have done this successfully for over 70 years, through the development of innovative products, partnerships with Eye Care Practitioners (ECPs) and programs that create greater access to quality eye care. Our portfolio of vision care and surgical products touch the lives of millions of people each year and help patients see, look and feel their best.

Modern day contact lens products are more advanced than ever and are worn by an estimated 41.4 million patients in the United States.¹ At Alcon, we have a strong desire to continue to grow the number of contact lens wearers; however we steadfastly believe that it must be done in an ethical and responsible manner to ensure the safe and effective use of these U.S. Food and Drug Administration (FDA) regulated products.

Since the Fairness to Contact Lens Consumer Act (FCLCA) was established in 2004, we have witnessed significant changes in the U.S. contact lens marketplace. Today, there are more contact lens choices than ever before and more avenues for consumers to purchase their lenses after receiving their contact lens prescription from their ECP. However, what hasn't changed is that contact lenses are regulated by the FDA as a Class II (moderate risk) or Class III (high risk) medical device. It is well established that contact lenses are a safe and effective vision correction option as long as they are prescribed by an ECP, worn and cared for properly and that the contact lens wearer receives ongoing professional care.

ECPs play a critical role in assessing patients for prospective contact lens wear, selecting contact lenses that are appropriate for each individual patient, evaluating the lens fit, training patients on proper lens wear and care practices, as well as regularly monitoring patients' eye health and evolving vision care needs. Medical supervision of contact lens prescribing and wear are essential to ensure a continued proper lens fit, ongoing health, comfort and overall satisfaction of patients wearing these medical devices. Since contact lenses are placed on the eye, the

¹ Steve Cody, Sr. Director of Industry Research Services, The Vision Council. FTC workshop "The Contact Lens Rule and the Evolving Contact lens Marketplace". Washington Dc, March 7, 2018.

physiological response of the cornea and other ocular tissues must be monitored to ensure safe wear. As indicated in our FDA regulated Patient Instruction Booklets and Package Inserts, serious conditions such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious adverse events such as abrasions, infiltrates, and conjunctivitis must be diagnosed, managed and treated early in order to avoid more serious complications. Clinical experience has also shown that there are a number of asymptomatic conditions that contact lens wearers can experience which, left unrecognized or untreated, can lead to more serious problems.

In addition, the medical and scientific literature is clear that contact lens-related complications can and do occur. The facts are clear that these complications can lead to the loss of vision or, in the worst cases, the loss of an eye. Multiple factors have been associated with the development of infectious and inflammatory events with contact lens wear, including age of the wearer; type of lenses worn; frequency of lens replacement; overnight wear; exposure of lenses to water; lens case contamination; and source of purchase.² However, there is no sure way to predict which individuals will or will not develop a problem. Current Standard of Care recommendations and guidelines in many contact lens package inserts state that contact lens wearing patients should see their optometrist or ophthalmologist once each year, or more often, as recommended by their ECP.

Experts from the Centers for Disease Control and Prevention (CDC) and FDA, have provided clear and definitive testimony on the clinical, public health and patient safety reasons as to why contact lenses are regulated by U.S. law as a medical device, as well as labelled “Federal law restricts these devices to the sale by or on the order of a licensed ECP”.³ Further, the FDA and CDC have acknowledged that eye health is of key importance in the following advice they provide for contact lens wearing patients:

*Wearing contact lenses puts you at risk of several serious conditions including eye infections and corneal ulcers. These conditions can develop very quickly and can be very serious. In rare cases, these conditions can cause blindness.*⁴

*You can not determine the seriousness of a problem that develops when you are wearing contact lenses. You have to get help from an eye care professional to determine your problem.*⁵

² Sorbara L, Zimmerman A, Mitchell G, Richdale K, Lam D, Kinoshita B, Chalmers R, Wagner H. Multicenter Testing of a Risk Assessment Survey for Soft Contact Lens Wearers With Adverse Events: A Contact Lens Assessment in Youth Study. *Eye Contact Lens*. 44(1):21-28, 2018.

³ Malvina Eydelman, MD – Director, Division of Ophthalmic and Ear, Nose and Throat Devices, Office of Device Evaluation, CDRH/FDA, Jennifer Cope, MD, MPH, Medical Epidemiologist, Division of Foodborne, Waterborne, and Environmental Diseases, Centers for Disease Control and Prevention and Michelle Tarver, MD, PhD, Medical Officer, Division of Ophthalmic and Ear, Nose and Throat Devices, Office of Device Evaluation, CDRH/FDA. FTC workshop “The Contact Lens Rule and the Evolving Contact lens Marketplace – Panel 2: Contact Lens Health and Safety Issues”. Washington DC, March 7, 2018.

⁴ FDA, ““Contact Lens Risk””; available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm062589.htm>. Updated 17 August 2017. Accessed 4 April 2018.

⁵ Ibid.

Make sure your prescription is current. Don't order with an expired prescription, and don't stock up on lenses right before the prescription is about to expire. If you haven't had your eyes checked within the last year or two, you may have eye problems that you are not aware of, or your lenses may not correct your vision well.⁶

Make sure that you get the exact brand, lens name, power, sphere, cylinder (if any), axis (if any), diameter, base curve, and peripheral curves (if any) noted on the prescription. If you think you've received an incorrect lens or brand, check with your eye care professional. (The correct brand is important because there are differences in the water content and shape among the brands.) Don't accept any substitution unless your eye care professional approves it.⁷

Failure to wear, clean, and store your lenses as directed by your eye doctor raises the risk of developing serious infections. Your habits, supplies, and eye doctor are all essential to keeping your eyes healthy.⁸

Visit your eye doctor yearly or as often as he or she recommends.⁹

Therefore, in light of the medical evidence and the recommendations of federal health agencies, Alcon is opposed to any policy or rule change that would authorize or encourage the sale or use of contact lenses without proper evaluation, ongoing consultation and a valid contact lens prescription from a licensed ECP. Additionally, we believe patients should receive an annual comprehensive eye exam.

At the same time, we fully respect the right of all consumers to receive a copy of their contact lens prescription and to comparison shop for their contact lenses. To that end, we supply our contact lenses to a variety of resellers including licensed eye care practitioners, eye care retailers, pharmacies, as well as authorized distributors and mail order companies / internet providers. Further, we invest millions of dollars on annual basis to educate and inform consumers about the multitude of contact lens technological advances and options available today.

As a member of the Coalition for Patient Vision Care Safety (CPVCS), we previously voiced recommendations to address marketplace concerns with the current Contact Lens Rule.¹⁰

⁶ FDA, "Focusing on Contact Lens Safety – Tips for Buying" available at <https://www.fda.gov/forconsumers/consumerupdates/ucm048893.htm>. Updated: 17 August 2017. Accessed: 4 April 2018.

⁷ Ibid.

⁸ CDC, "Healthy Contact Lens Wear and Care – Protect Your Eyes"; available at <https://www.cdc.gov/contactlenses/protect-your-eyes.html>. Updated 11 December 2015. Accessed 4 April 2018

⁹ Ibid.

¹⁰ Letter submitted to FTC by the *Coalition for Patient Vision Care Safety*. Dated 30 January 2017 in response to the 7 December 2016 proposed amendments to the CLR at 81 Fed. Reg. 88526.

The enhancements that could positively affect contact lens health and safety included the following:

- Strengthening enforcement to protect consumers against deceptive claims (e.g., no prescription needed, being able to obtain lenses after the prescription is expired).
- Addressing non-permissible substitution or switching the brand of lenses prescribed by the patients ECP.
- Creating better channels for reporting issues affecting and/or involving either prescribers or sellers.
- Modernizing the Passive Verification Process by discontinuing use of Robocalls and replacing with email communication which is a more effective and reliable method of verification.
- Establishing reasonable quantities of lenses sold and tied to the contact lens Rx expiration date. Selling excessive numbers of lenses has the effect of discouraging patients from seeing their ECP regularly in accordance with public health recommendations.
- Encouraging better communications between prescribers and sellers all while emphasizing the importance of ongoing professional care.

Recently, questions have been raised about the existence and availability of “generic” soft contact lenses. Due to differences in contact lens polymers, manufacturing techniques, lens design, optical properties, lens packaging solutions and other variables - generic soft contact lenses do not exist. Unlike a pharmaceutical, there are simply too many variables to control making generic contact lenses extremely difficult, if not impossible to achieve.¹¹ In addition, in our experience, the power profile (the optical power of the contact lens that affects the correction of vision) varies with brand. Subsequently, the implication is that all -3.00 D or +3.00 D lenses (or any other power) lenses are not the same. As a result, it is not uncommon for a given patient to need one power for a given lens brand and a different power for another brand. This can even occur with two brands from the same manufacturer. Finally, from a regulatory standpoint, Malvina Eydelman, MD – Director, Division of Ophthalmic and Ear, Nose and Throat Devices, Office of Device Evaluation, CDRH/FDA has stated there are no generic medical devices and there is currently no regulatory pathway for marketing of generic contact lenses¹²

In conclusion, it is Alcon’s firm belief that any changes to the Contact Lens Rule should aim to achieve a proper balance between what is best for patient health and safety, while at the same time preserving and protecting consumer choice & competition in the evolving U.S. contact lens marketplace.

¹¹ Barr, Joseph. “Contact Lenses Must be Dispensed as Written and Cannot be Generic or Sold by Substitution”. Course 405 – Contact Lens Roundtable. EastWest Eye Conference. Cleveland, OH, November 2, 2017.

¹² Malvina Eydelman, MD – Director, Division of Ophthalmic and Ear, Nose and Throat Devices, Office of Device Evaluation, CDRH/FDA. FTC workshop “The Contact Lens Rule and the Evolving Contact lens Marketplace – Panel 2: Contact Lens Health and Safety Issues”. Washington DC, March 7, 2018.

Thank you for your consideration of our comments.

Regards,

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