Dear Mr. Zapolsky,

The American Optometric Association (AOA) represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation’s doctors of optometry, and a leading authority on eye health, vision care, and patient safety issues. The AOA is aware that sellers are using the Amazon platform to sell contact lenses without requiring a prescription (see Appendix A). While the AOA is not a regulatory enforcement entity, a central mission of the AOA is to serve as a resource to the public for reliable and current information related to eye care and health care policy.¹

Amazon’s own policy on “Medical devices and Accessories” indicates to sellers, “If you supply products for sale on Amazon, you must comply with all federal, state, and local laws and Amazon policies applicable to those products and product listings.”² Contact lenses sales are regulated by both the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA). All contact lenses, even those that are only intended to change the appearance of the eye, require a prescription. Contact lenses are FDA regulated medical devices. The FDA has indicated:

As FDA-regulated devices, all contact lenses, including non-corrective and decorative contact lenses that are intended only to change the perceived appearance of the eye, are required to have in effect an approved premarket approval application (PMA) or a cleared premarket notification (510(k)) before they may be legally marketed. The sale, marketing, and distribution of any contact lenses in the absence of the appropriate FDA approval or clearance renders the products adulterated and/or misbranded. 21 U.S.C. §§ 331, 351, 352. All currently approved or cleared decorative contact lenses are prescription devices and, therefore, may be sold only to or on the prescription of a licensed practitioner. 21 CFR 801.109.³

The Fairness to Contact Lens Consumer Act (FCLCA) (P.L. 108-164) also includes certain patient protection provisions. The law indicates that a contact lens seller “may sell contact lenses only in accordance with a contact lens prescription for the patient that is (1) presented to the seller by the patient or prescriber directly or by facsimile; or (2) verified by direct communication.”⁴ The contact lenses available for sale on Amazon are sold entirely without a prescription which we believe is a FCLCA violation.

¹ The U.S. Food and Drug Administration, the Federal Trade Commission, and various state agencies have enforcement authority over regulations governing the prescribing and sale of contact lenses.
³ http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm341507.htm
Contact lenses prescribed by a licensed physician are worn safely and comfortably by millions of people worldwide and contact lenses have a long history of providing wearers with a safe and effective form of vision correction. While contact lenses provide many vision benefits, they are not risk-free. Serious eye infections that can lead to blindness affect up to 1 out of every 500 contact lens users per year.\(^5\) Additionally, the Centers for Disease Control and Prevention has indicated, keratitis, an eye infection often linked to improper contact lens use, leads to 1 million doctor and hospital visits annually, at a cost of $175 million to the US healthcare system.\(^6\)

In addition to the sales via your platform raising legal questions related to the FCLCA, the guidance provided by sellers regarding these FDA regulated medical devices is very concerning. One seller indicates the following in the product information, “The right hand index finger gently press the contact lens opposite clockwise or counterclockwise turn 30 times, and put it in a box for a new care solution. Note: Before use and after the use of it, please soak it with care solution, if you do not use for a long time, please put it in the box soak with care solution, replace the care solution every three days.”\(^7\) This type of guidance is wholly inappropriate and dangerous. Proper physician oversight is needed for the use of regulated medical devices that require a physician prescription.

We urge Amazon to take immediate steps to stop the sale of contact lenses without a prescription through your platform. If you have any questions or concerns, please contact Kara Webb at kcwebb@aoa.org.

Sincerely,

Samuel Pierce, OD
President, American Optometric Association

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\(^7\)https://www.amazon.com/Oanono-Multi-Color-Contact-Cosplay-Cosmetic/dp/B07NKYY8NN/ref=sr_1_8_s_it?k=beauty&ie=UTF8&qid=1551155042&s=beauty&sr=1-8&keywords=contact%2Blenses&th=1
Appendix A

https://www.amazon.com/Oanono-Multi-Color-Contact-Cosplay-Cosmetic-Eyes-Contact/dp/B07NKYV8NN/ref=sr_1_8_s_it?s=beauty&ie=UTF8&qid=1551115042&sr=1-8&keywords=contact%2Blenses&th=1

https://www.amazon.com/Colors-Contacts-Cosmetic-Makeup-Shadow/dp/B07MPSRMHY/ref=sr_1_4_s_it?s=beauty&ie=UTF8&qid=1551115042&sr=1-4&keywords=contact%2Blenses&th=1
https://www.amazon.com/Colors-Contacts-Cosmetic-Makeup-Shadow/dp/B07N6GKLGG/ref=sr_1_6_s_it?ie=UTF8&qid=1551115042&sr=1-6&keywords=contact+lenses&th=1

https://www.amazon.com/Multi-Color-Contact-Cosplay-Attractive-Cosmetic/dp/B07NSL7KYM/ref=sr_1_7_s_it?ie=UTF8&qid=1551115042&sr=1-7&keywords=contact+lenses&th=1