



AMERICAN OPTOMETRIC ASSOCIATION

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February 27, 2019

David Zapolsky
Senior Vice President, General Counsel & Secretary
410 Terry Avenue North
Seattle, Washington 98109

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.

² https://sellercentral.amazon.com/gp/help/external/200164650?language=en-US&ref=mpbc_200277400_cont_200164650

³ <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm341507.htm>

⁴ <http://www.gpo.gov/fdsys/pkg/PLAW-108publ164/pdf/PLAW-108publ164.pdf>

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,

A handwritten signature in black ink, appearing to read "Samuel Pierce". The signature is fluid and cursive, with a long horizontal line extending to the right.

Samuel Pierce, OD
President, American Optometric Association

⁵Dart JK, Radford CF, Minassian D, Verma S, Stapleton F. [Risk factors for microbial keratitis with contemporary contact lenses: a case-control study.External](#) Ophthalmology. 2008;115(10):1647-54, 1654 e1-3.

⁶ Collier SA, Gronostaj MP, MacGurn AK, Cope JR, Awsumb KL, Yoder JS, Beach MJ. [Estimated burden of keratitis — United States, 2010](#). MMWR Morb Mortal Wkly Rep. 2014;63(45):1027-30.

⁷ https://www.amazon.com/Oanono-Multi-Color-Contact-Cosplay-Cosmetic/dp/B07NKYV8NN/ref=sr_1_8_s_it?s=beauty&ie=UTF8&qid=1551115042&sr=1-8&keywords=contact%2Blenses&th=1

Appendix A

The screenshot shows the Amazon product page for 'Oanono Multi-Color Cute Contact Lenses Color Blends Cosplay Eyes Cosmetic Makeup Eye Shadow With a Case (A Pair) (1 pair, Red)'. The product is priced at \$12.99 with Prime. It features a 5-star rating from 5 customer reviews. The main image shows a close-up of a person's eye wearing a red contact lens, with a separate image of the red contact lens below it. The product is available in 4 colors, with the 'Red' option selected. The 'Add to Cart' and 'Buy Now' buttons are visible. The 'About the product' section includes details about the material (HEMA), occasion, and usage instructions.

Oanono Multi-Color Cute Contact Lenses Color Blends Cosplay Eyes Cosmetic Makeup Eye Shadow With a Case (A Pair) (1 pair, Red) by Oanono

★★★★★ 5 customer reviews | 5 answered questions

Price: **\$12.99** ✓prime
Get \$40 off instantly. Pay \$0.00 upon approval for the Amazon Prime Store Card.

Note: Available at a lower price from other sellers, potentially without free Prime shipping.

FREE Delivery by **Thursday** Details

In Stock. Sold by Mgsia Hfyaa and Fulfilled by Amazon. Gift-wrap available.
This item is returnable.

4 Colors: Red

Deliver to Kara - Arlington 22204
Qty: 1 Turn on 1-click ordering

Add to Cart Buy Now

Add to your Dash Buttons
Learn more about Dash Buttons

Add to List

Other Sellers on Amazon 2 new from \$6.98
\$6.98 + \$4.99 shipping
Sold by Nikkas Add to Cart

About the product

- Material: HEMA, Colored contact lens, 0 degree, Soft and easy to wear.
- Occasion: Different colors for your choosing, different colors, different feel and charm.
- Wash your hands and dry, left hand flat, palms up, gently bend up to bowl-like, and then put the contact lenses on the palm, put 5-8 drops of care solution.
- 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.

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

The screenshot shows the Amazon product page for '5 Colors Eyes Color Contacts Lens Eyes Cosmetic Makeup Eye Shadow (Milk powder green) by LUDFF'. The product is priced at \$4 with Prime. It features a 5-star rating from 10 customer reviews. The main image shows a close-up of a person's eye wearing a green contact lens, with a separate image of the green contact lens below it. The product is available in 5 colors. The 'Add to Cart' and 'Buy Now' buttons are visible. The 'About the product' section includes details about the occasion and usage instructions.

5 Colors Eyes Color Contacts Lens Eyes Cosmetic Makeup Eye Shadow (Milk powder green) by LUDFF

★★★★★ 10 customer reviews

Price: **\$4** Prime!

FREE D

In St available
This it

5 Color

\$15.1

About the product

- Occasion: Different colors for your choosing, different colors, different feel and charm.
- Wash your hands and dry, left hand flat, palms up, gently bend up to bowl-like, and then put the contact lenses on the palm, put 5-10 drops of care solution.
- The right hand index finger gently press the contact lens opposite clockwise or counterclockwise turn 32 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.

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

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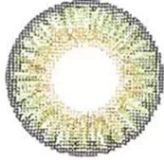
act lenses *

5 Colors Eyes Color Contacts Lens Eyes Cosmetic Makeup Eye Shadow (honey) by LIDFF

★★★★☆ - 4 customer reviews



Green



About the product

- they are made from high quality materials in the most advanced contact lens manufacturing facilities, you can be confident that this contact lenses are safe for your eyes.
- Multi-functional - Party, Cosplay, Fashion Show, Halloween Makeup, Eyes Cosmetics and Make Your Eyes Bigger.
- Colored contact lens, 0 degree: Soft and easy to wear.
- Notice: Decrease contacting high temperatures, keep it clean no matter when use it before or end
- Package Content: 1 Pair Contact Lenses (The Validity of This Contact Lens is One Year)

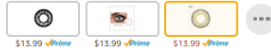
Price: **\$13.99** ✓prime
Your cost could be \$3.99. Eligible customers get a \$10 bonus wh reloading \$100.

FREE Delivery by **Friday** Details

In Stock. Sold by LIDFF and Fulfilled by Amazon. Gift-wrap available.

This item is returnable -

4 Colors: honey



Deliver to Kara - Arlington 22204
Qty: 1 Turn on 1-click ordering

Add to Cart
Buy Now
Add to your Dash Buttons
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https://www.amazon.com/Colors-Contacts-Cosmetic-Makeup-Shadow/dp/B07N6GKLGG/ref=sr_1_6_s_it?s=beauty&ie=UTF8&qid=1551115042&sr=1-6&keywords=contact%2Blenses&th=1

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act lenses *

Women Multi-Color Contact Lenses Cosplay Eyes Cute Colored Charm and Attractive Cosmetic Makeup Eye Shadow (pink) by uzqxix

Be the first to review this item

About the product

- Colored contact lens, 0 degree: Soft and easy to wear.
- Made from high quality materials in the most advanced contact lens manufacturing facilities.
- Perfect fit for party, Cosplay, Fashion Show, Halloween Makeup, Eyes Cosmetics and Make Your Eyes Bigger.
- Package Content: 2 Pcs Contact Lenses(The Validity of This Contact Lens is One Year)
- Notice: Decrease contacting high temperatures, keep it clean no matter when use it before or end


Price: **\$14.99** ✓prime | FREE One-Day
Get \$40 off instantly. Pay \$0.00 upon approval for the Amazon Prime Store Card.

Get FREE delivery **Tomorrow** if you order \$35 of qualifying items within 3 hrs and 52 mins and choose this date at checkout. Details

In Stock. Sold by uzqxix and Fulfilled by Amazon. Gift-wrap available.

This item is returnable -

7 Colors: pink



Deliver to Kara - Arlington 22204
Qty: 1 Turn on 1-click ordering

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https://www.amazon.com/Multi-Color-Contact-Cosplay-Attractive-Cosmetic/dp/B07NSL7KYM/ref=sr_1_7_s_it?s=beauty&ie=UTF8&qid=1551115042&sr=1-7&keywords=contact%2Blenses&th=1