



October 3, 2013

Tedford Marlow
Chief Executive Officer
Urban Outfitters Group
5000 South Broad St
Philadelphia, PA 19112-1495

Mr. Marlow,

The American Optometric Association (AOA) represents approximately 36,000 doctors of optometry, optometry students and paraoptometric assistants and technicians. 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. This letter is related to the sale of "Character Contacts"¹ that are available on your company's website. The AOA believes that the sale of these contact lenses is a violation of federal law and regulations. Furthermore, this illegal sale of contact lenses poses an urgent and immediate threat to the public's visual health. We urge Urban Outfitters to cease the illegal sale of these contacts.

As you may know, the Fairness to Contact Lens Consumer Act (FCLCA) (P.L. 108-164) was enacted to ensure patient safety related to the use of contact lenses. 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."² The "Character Contacts" available on the Urban Outfitters website are sold entirely without prescription, which appears to be a clear violation of the FCLCA.

The AOA would also like to note that the Food and Drug Administration (FDA) regulates contacts as medical devices. As such, it is irresponsible for your company and dangerous to consumers to sell such devices without appropriate physician supervision. With regard to decorative contact lenses 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

¹ <http://www.urbanoutfitters.com/urban/catalog/productdetail.jsp?id=29605029&parentid=SEARCH+RESULTS>

² <http://www.gpo.gov/fdsys/pkg/PLAW-108publ164/pdf/PLAW-108publ164.pdf>

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

As Urban Outfitters has chosen to become a vendor of contact lenses, we believe it is your responsibility to guarantee compliance with federal laws and regulations governing the sale, marketing, and distribution of these devices.

The AOA is also very concerned with the product detail for the “Character Contacts” included on your company’s website. The website misleadingly indicates that one size fits all and that the contact lenses can be wiped clean. Contact lenses of all kinds should only be worn after being fitted and prescribed by an eye doctor. Failure to follow all safety precautions can lead to serious infections in the eye. Urban Outfitters also urges consumers to “Go all-out with these creepy contacts in a fun, festive array of styles that will compliment almost any costume.” Improper contact lens wear and care can cause corneal ulcers, conjunctivitis, and even vision loss. It is neither fun nor festive to expose consumers to these serious risks. Again, we urge Urban Outfitters to cease the sale of the “Character Contacts” available on your company’s website.

If you have any questions or need additional information, please contact Kara Webb at kcwebb@aoa.org or 703-837-1018.

Sincerely,

A handwritten signature in black ink that reads "Mitchell T. Munson, O.D.".

Mitchell T. Munson, O.D.
President
American Optometric Association