



January 30, 2017

Donald Clark  
Federal Trade Commission  
Office of the Secretary  
600 Pennsylvania Avenue N.W.  
Suite CC-5610 (Annex C)  
Washington, DC 20580

Re: Contact Lens Rule, 16 CFR part 315, Project No. R511995

Dear Secretary Clark,

The American Optometric Association (AOA) represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation's family eye doctors and the leading authority on eye health, vision care, and patient safety issues. Doctors of optometry prescribe the majority of contact lenses for patients in the United States. Contact lenses are an effective, safe, and popular choice for vision correction. Because improper use can lead to injuries and infections, our member doctors are essential in mitigating this risk and ensuring that the use of contact lenses results in optimal vision. The AOA thanks the Federal Trade Commission (FTC or the Commission) for consideration of our comments on the FTC's proposed changes to the Contact Lens Rule (the Rule). [81 Fed. Reg. 88526](#) (Dec. 7, 2016).

For the reasons detailed below, the AOA urges the Federal Trade Commission not to adopt the proposed new requirements that (a) every eye doctor obtain written acknowledgement from every patient that the doctor has given the patient a copy of the patient's contact lens prescription, (b) that the doctor maintain each signed acknowledgement for at least three years, and (c) that the doctor be subject to inspection by the FTC of the records of the authorizations. These new proposed requirements do not address patient safety concerns in the contact lens marketplace. Additionally, they do not exist in the statute, are unnecessary, and would impose burdens on eye doctors that will result in higher costs to patients.

### **Contact Lens Rule Review**

Previously, the FTC requested public feedback in its decennial review [80 Fed. Reg. 53272 (Sept. 3, 2015)]<sup>1</sup> of the Contact Lens Rule. We are very concerned that the Commission now asserts in this proposed rule that it "does not find the evidence proffered in this Rule review sufficient to support a conclusion that the Rule inadequately protects consumer eye health."<sup>2</sup> In the AOA's October 2015<sup>3</sup>

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<sup>1</sup> [80 Fed. Reg. 53272](#) (Sept. 3, 2015).

<sup>2</sup> [81 Fed. Reg. 88530](#).

<sup>3</sup> See P. 5 of [AOA comment letter](#)

comments to the FTC on the Contact Lens Rule review<sup>4</sup>, the AOA named 41 retailers and provided evidence that they were illegally offering contact lenses without a prescription.<sup>5</sup> In 2017, the AOA verified most of these retailers were still operating and allowing individuals to purchase contact lenses without a prescription. In our review, 33 of 41 (more than 80 percent) are still operating inappropriately ([Appendix A](#)). In October 2016, the AOA also reached out to an additional 31 contact lens retailers who had been reported to AOA for selling contact lenses without a prescription ([Appendix B](#)). The continued proliferation of online and brick and mortar retailers who publicly announce they are willing to sell regulated medical devices without the required prescription is a clear indication that the Rule is not working effectively and protecting eye health. It is important to recognize the medical device status of contact lenses. Many patients use extended-wear contacts, which are in the highest risk category of the device classification system under the Federal Food, Drug, and Cosmetic Act (class III).<sup>6</sup> All other types of contact lenses are in class II.<sup>7</sup> The sale of contact lenses without a prescription is unlawful and puts the public at direct risk as the lenses can be misused and cause patient eye complications. Much more needs to be done to address retailers who blatantly violate the law, and AOA would welcome the opportunity to work with the Commission to identify retailers who are evading the Rule. Safety is a component of competition and one of the responsibilities of the FTC as a result of the Fairness to Contact Lens Consumers Act (FCLCA) [Pub. Law 108–164 (Dec. 6, 2003)<sup>8</sup>]. Here the FTC is responsible for regulating the sale of a complex medical device, which makes this authority unique and multi-factorial, so the Commission must not approach this oversight as it would with a consumer good. Allowing some sellers to openly violate the rule harms competition in the marketplace. The FTC could do more to help competition and patient safety by taking action against these specific retailers than any of the much more expensive and burdensome steps it has now proposed.

### **Availability of Contact Lens Prescriptions to Patients**

The AOA supports full compliance with the FCLCA and the Contact Lens Rule. The FCLCA, while not perfect, attempted a careful balancing of interests in which Congress sought to promote competition in the sale of contact lenses and to protect the interests of eye care patients – while not imposing excessive burdens on eye care providers that would unduly raise costs and hurt competition. Congress imposed very specific requirements with respect to making contact lens prescriptions available to patients. At the same time, it excluded from the FCLCA any of the requirements that the FTC now proposes to impose. Thus, the AOA believes the FTC may not now attempt to upset that balance by adding requirements through rulemaking beyond what Congress included in the FCLCA.

Notably, when the Contact Lens Rule was first issued in 2004, the FTC was respectful of the balance that Congress had struck. The Commission was careful not to go beyond the explicit provisions of the FCLCA. Now, however, the Commission is proposing to alter the balance that was struck by adding requirements that are not found in the text of the Act. Where a federal statute carefully enumerates specific substantive requirements but not others, the agency charged with administering that statute should not add additional requirements that Congress did not enact. In this respect, the FCLCA is very different from a more general statute such as Section 5 of the Federal Trade Commission Act – with its sweeping authorization to the Commission to regulate unfair methods of competition and unfair or deceptive acts or practices.

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<sup>6</sup> 21 CFR 886.5916, 886.5925; see section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)).

<sup>7</sup> Id.

<sup>8</sup> <https://www.congress.gov/108/plaws/publ164/PLAW-108publ164.pdf>

The AOA is committed to continuing education of both prescribers and patients regarding the requirements of the FCLCA and the Rule and will work to develop information and guidance related to any areas of confusion. We believe that the FTC proposal to require patients to sign an acknowledgment of receipt of a contact lens prescription would be overly burdensome to physicians who are already struggling to keep pace with ever changing regulatory requirements. The requirement would also create a further imbalance in the contact lens market. According to FTC estimates, prescribers are already carrying the lion share of the costs associated with Contact Lens Rule compliance. Right now, it costs doctors of optometry approximately \$46,921,798 annually to comply with the Contact Lens Rule, out of the total estimated \$61,540,563 cost of compliance. The new requirement would only further burden this section of the market, forcing doctors and their patients to attempt to navigate an even more lopsided market which already favors one outlet over another. Additionally, it would needlessly interfere with the process for patients to get contact lenses, and harm competition in the long run. While the FTC seems to dismiss the potential burden on physicians for complying with this requirement, the proposal would undoubtedly add new costs for doctors and patients with minimal, if any, benefits in safety, consumer convenience, market efficiency or other aspects of competition. It would require an additional step in the patient engagement process, which would necessitate ongoing staff training to ensure that doctors are meeting this unprecedented requirement. It would also require that doctors maintain these patient-signed forms for a number of years for review at a later date.

The AOA engaged Avalon Health Economics (Avalon) to conduct a study examining the burden of implementing the FTC's proposal to require a signed patient acknowledgment form after providing a contact lens wearing patient a copy of their prescription. Avalon conducted an online survey of doctors of optometry to assess the total cost per optometric practice in the United States for staff engagement training, periodic assessments of the new policy, explanation of new FTC rules, answering questions concerning new FTC rules, and administrative time associated with adhering to rules. Based on this analysis, Avalon found that in the initial year of implementation, the economic burden of complying with this new FTC proposal could be as high as \$49,913 for optometric practices with three doctors of optometry. The cost burden for a practice with one doctor of optometry could be as high as \$18,795.<sup>9</sup> For practices that have a higher than average volume of contact lens patients and have more than one doctor of optometry, the total cost could be as high as \$74,667. Thousands of doctors of optometry are small business owners who run their practices on tight margins. A regulatory burden of this weight could lead these doctors to eliminate staff positions. Furthermore, these additional costs could likely lead to increased consolidation of practices in the optometric profession putting into greater jeopardy the long term viability of family eye doctors who operate small practices.

We are also concerned that the Commission's proposal to implement this additional burden on contact lens prescribers is disproportionate to the number of actual patient complaints the FTC has received related to prescribers. As best we can ascertain, eye doctors across this country are complying with the requirement to make contact lens prescriptions available to patients in the manner required by the FCLCA and by the Contact Lens Rule. We are not aware of any disregard of that requirement or any other requirement sufficiently substantial to justify the imposition of burdensome new requirements on every patient and eye doctor in America. Indeed, it is noteworthy in this connection that, to the best to AOA's knowledge, not a single state has sought to impose the requirements now proposed by the Commission. To be sure, there are, no doubt, instances in which individual practitioners have failed to comply with the Act or with the Rule. But the correct solution is not to impose burdensome new requirements on the vast majority of eye doctors who have acted in compliance with all legal requirements.

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<sup>9</sup> Avalon Health Economics "Economic Evaluation of FTC Ruling on Contact Lens Prescriptions."

Having had the opportunity to review the complaints that the Commission has received regarding compliance with the Contact Lens Rule over the past five years, the AOA believes that the Commission's patient acknowledgment proposal would not directly address the majority of complaints received. From AOA's review, we have found that less than half of the complaints were directly related to prescription release, and the majority of complaints were rooted in other issues. Approximately 18 percent of complaints were related to confusion regarding the contact lens evaluation and fitting process, 5 percent were related to issues with expired prescriptions, 4 percent were related to payment issues and 18 percent simply had insufficient information to assess. Out of the 41 million contact lens wearing individuals in the United States, approximately 0.0003 percent contacted the FTC in the last five years with a potentially valid complaint regarding contact lens prescription release. Again, while the AOA does not condone any violation of the law, we are very concerned that the FTC is making such a drastic regulatory proposal that adds unnecessary paperwork for 100 percent of contact lens consumers when the population of potential prescriber violators appears to be relatively low in numbers. It seems logical that there would be a far more efficient way forward to address any non-compliance that may exist.

In addition to our concerns with the disproportionate nature of the proposal, we also believe that having a signed acknowledgement form *after* the evaluation and fitting process is complete would not address the FTC's concern that some patients may misunderstand the Rule and may be confused about when or under what conditions they should receive their prescriptions. If there is patient confusion, greater patient education and outreach by FTC, consumer groups and physician organizations about patient rights under the Rule would be far more effective than requiring an acknowledgment at the time a prescription is presented to a patient. Additionally, while our doctors dedicate time and resources to ensuring their patients are well educated on appropriate contact lens use and their rights, these efforts are nullified when patients receive information from contact lens retailers that encourage patients to discount and disregard the requirements under the law.

Beyond the fact that the new requirements would upset the balance struck in the FCLCA and are not justified by any significant non-compliance with current law, the proposed new requirements will raise the price of eye care – a result which is the precise opposite of the objectives of the FCLCA and of what the Commission normally seeks to achieve. Here, it is worth noting that in its notice of proposed rulemaking on the original Contact Lens Rule, published February 4, 2004, the Commission estimated that it would take one minute per patient encounter to provide a copy of the patient's contact lens prescription.<sup>10</sup> At the time, the Commission estimated this would add an additional labor burden of 600,000 hours on prescribers (i.e. eye doctors).<sup>11</sup> Avalon Health Economics estimates that it will take an average of 3.12 minutes to explain the purpose of the acknowledgement to a patient and an additional 3.41 minutes to answer patient questions about the acknowledgement. Even if we assume that no patients would have questions regarding the acknowledgement, the current burden of complying with the law would add an additional 2,132,000 hours to compliance. And that additional burden does not take into account the costs of developing new forms, training office staff, and storage of the acknowledgements for three years – let alone of responding to requests for inspection by the Commission.

It should come as no surprise that compliance with the proposed new requirements will, therefore, result in higher costs to the eye doctor – costs that will, of course, be passed on to eye care patients. Those increased costs would be acceptable if they resulted in a significant patient benefit. But here, as explained above, any patient benefit would be marginal at best. Particularly, where, as here, it is at best questionable whether imposition of the new requirements would be consistent with Congressional intent, the Commission should not impose those costs on patients in the absence of a clear demonstration of a substantial need – a demonstration that is lacking in this matter.

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<sup>10</sup> Contact Lens Rule, 69 Fed. Reg. 5444 (February 4, 2004).

<sup>11</sup> Contact Lens Rule, 69 Fed. Reg. 5444 (February 4, 2004).

Furthermore, we are concerned about the effect that this proposal would have on competition in the contact lens market. As the FTC has noted, the contact lens market has grown over the past several years since the implementation of the Rule and likewise online sales of contact lenses have increased. The FCLCA and the Rule have been effective in improving prescription portability. Currently, there is less difference in price between sellers today than there was prior to the FCLCA. The FTC estimates that currently approximately 40 percent of sales are made by family eye care professionals. While the majority of contact lens sales are not made by independent eye doctors, these doctors are the ones that are already bearing a majority of the burden of complying with the Contact Lens Rule. This new requirement would seem to utilize the federal bureaucracy to tip the scales further in the direction of one avenue for purchasing contact lenses. While most agencies seek to help all businesses compete, both large and small, the FTC proposal strongly favors mass retailers by adding costs only to the small businesses in the market.

Despite the relatively low number of complaints related to prescription release, we understand that the Commission believes it would be beneficial to increase compliance with automatic prescription release requirement of the Rule. If the Commission feels that some action must be taken, we believe that the Commission could require that prescribers post in a clear and visible place a notice informing patients that prescribers are required to provide patients with a copy of their contact lens prescription after the contact lens evaluation and fitting. The Commission discussed, but did not propose, this type of requirement. It is a common approach in the health care arena to use signs to notify patients of their rights related to health care. For example, the federal government requires patients to be notified of the obligation of certain hospitals to provide free care to those who are unable to pay.<sup>12</sup> The Emergency Medical Treatment and Labor Act also has signage requirements.<sup>13</sup> A requirement to post a notice of patient rights would also be far less burdensome for patients and prescribers yet still achieve the Commission's objectives to address any prescriber confusion related to requirements of the Rule, make patients aware of their rights, and improve the Commission's enforcement ability. This type of notice would also better address the patient confusion made apparent by consumer complaints to the FTC.

The FTC noted in the Proposed Rule that the Commission did not have good evidence about the effects of California's requirement for contact lens prescribers to post clear and visible signage informing patients of their right to their prescriptions. To address this data gap, the AOA commissioned a survey of 1,000 18- to 40-year-old contact lens wearers in California to better assess the impact of the California law and to get more information on consumer perspectives of the requirement. The survey found that California contact lens wearers support the law and believe it is the best way to ensure contact lens wearers are well informed of their rights.

- The majority (96 percent) of California contact wearers support the law.
- California contact wearers overwhelmingly (97 percent) think the law makes patients more aware of their rights.
- Patients view the requirement as a positive for competition, as 93 percent think the law helps enable patients to find the best prices for contact lenses.
- Survey respondents were in favor of this type of communication method, as 88 percent believe the law is the best way to make sure contact lens wearers are as informed as possible about their contact lens purchasing options.

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<sup>12</sup> <https://www.hrsa.gov/gethealthcare/affordable/hillburton/signenglish.pdf>

<sup>13</sup> <https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/>

The Commission noted that the requirement to post clear and visible signage informing consumers of their right to their prescription could be expanded via the Rule to apply nationwide. This feedback from patients provides positive support for this less burdensome alternative to requiring a patient acknowledgment following the provision of a contact lens prescription.

### **Compliance with the Automatic Prescription Release Requirement**

The Commission has asserted that the number of verifications conducted by third-party sellers suggests that many consumers are not automatically receiving their prescriptions from prescribers, or are not receiving complete prescriptions. The AOA believes that this assumption is inaccurate. It is important to note that many online retailers work to simplify the contact lens ordering process by relying on the verification system. For example, 1-800-CONTACTS advertises that contact lenses can be ordered in just two steps by having patients select from their order history to purchase lenses ([Appendix C](#)). Through the 1-800-CONTACTS mobile app, new customers are prompted to scan their box of contact lenses, rather than asking for a copy of the patient's prescription initially ([Appendix D](#)). In these cases, the methods by which online retailers engage patients may lead to increased verification calls. Additionally, patients often lose paper copies of prescriptions and for many patients it is simply easier to allow the retailer to verify the prescription than to upload the prescription themselves. This happens with all types of health care prescriptions. Many doctors have specific office policies related to replacing lost prescriptions because of the frequency by which this occurs. Overall, the number of verifications that are occurring could be related to a number of factors. The AOA does not believe that it is a reasonable, safe, or logical assumption for the Commission to link the number of verifications to possible physician non-compliance.

### **Additional Mechanisms for Improving Prescription Portability**

The AOA agrees with the Commission that the use of patient portals to provide patients with access to electronic copies of their prescriptions could benefit prescribers, sellers, and patients. While thousands of doctors of optometry use electronic health records and may have a patient portal component of their EHR, there have been significant barriers to implementation and actual use of portals by doctors and their patients over the past decade. Studies have also found that there are disparities in patient population with regard to use of portals.<sup>14</sup> For those doctors who have functioning patient portals and for patients who would like to use them, it would be beneficial for the Commission to clarify that providing access to a contact lens prescription through the patient portal would meet the prescriber requirements of automatic prescription release.

### **Sellers Designated to Act on Behalf of Patients**

The AOA supports the Commission's decision not to modify the Rule by requiring a prescriber to respond to a request for a copy of a prescription within eight business hours. 1-800 CONTACTS has a history of using deceptive techniques to act as a patient's agent, so the company can obtain a patient's contact lens prescription.<sup>15</sup> The AOA is concerned that other retailers will use similar tactics and again put doctors of optometry in a difficult position to meet retailers demands when the physician is uncertain whether the retailer's request is legitimate or not.

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<sup>14</sup> <http://healthaffairs.org/blog/2016/04/07/lessons-from-more-than-a-decade-in-patient-portals/>

<sup>15</sup> See [AOA Complaints lead to changes in 1-800 Contacts Business Practice](#)

## **Prescribers' Selection of Communication Mechanism**

The Commission has suggested that sellers evaluate whether honoring prescriber preferences with regard to communication method would increase the speed and efficiency of the verification process. Although the AOA believes this is a step in the right direction, we urge the Commission to provide more instruction to retailers. Issuing guidance that outlines the complaints that the Commission has received related to verifications will allow retailers to work together with prescribers and provide the best possible approach to ensuring that patients receive the contact lenses that were prescribed.

## **Length of Contact Lens Prescriptions**

We appreciate that the Commission is maintaining the provisions outlined in statute related to contact lens prescription length and is not proposing any changes to the Rule's prescription length provisions. As the Commission noted, doing otherwise would run afoul of certain state laws.

## **Private Label Lenses and Contact Lens Substitution**

We oppose the Commission's proposal to remove "private label" from Section 315.5(e). This language is useful in providing the necessary clarity to ensure that inappropriate substitutions do not occur. We recommend that the Commission develop sub-regulatory guidance related to "private label" contact lenses, if the Commission believes that additional information would be useful to patients, prescribers, and retailers.

## **Enforcement Efforts**

The Commission indicated it will explore whether a dedicated email address would be beneficial to complement the Complaint Assistant for receiving complaints related to the Contact Lens Rule. We strongly recommend that the Commission move forward with this type of additional option for reporting Contact Lens Rule potential violations. Each week, the AOA receives reports from our member doctors regarding retailers that are selling contact lenses without a prescription. Having a more direct method by which to report these retailers would be beneficial. Although 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. We often reach out to retailers who are improperly selling contact lenses without a prescription to inform them of the regulatory and legal requirements that relate to the sale of contact lenses in the United States. In our outreach, we have received responses from a number of companies who have committed to changing their policies in response to our concerns. We believe that the FTC is in a far more authoritative position to do this type of outreach, and we are willing to work with the FTC to stop the proliferation of contact lens retailers who openly violate the Contact Lens Rule and FCLCA. The AOA stands ready to work with the FTC to leverage its enforcement, consumer education, and business guidance efforts related to the Contact Lens Rule.

## **Regulatory Freeze Pending Review**

On January 20, 2017, Reince Priebus, Assistant to the President and Chief of Staff, issued a memorandum<sup>16</sup> for the heads of Executive Departments and Agencies that applies to "any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking." Since the memorandum is to ensure that the President's appointees or designees have the opportunity to review any new or pending regulations, we urge the FTC to withdraw this proposed rule as written. In addition, by proposing new legal requirements beyond the terms of the FCLCA, the proposed rule raises questions of law and policy, issues that the memorandum clearly intends for agencies to withhold pending further review by the President's appointees and designees. Thank you for the opportunity to provide these comments.

Please contact Kara Webb, Associate Director of Coding and Regulatory Policy, at \_\_\_\_\_ if you need additional information.

Sincerely,

Andrea Thau, OD  
President, American Optometric Association

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<sup>16</sup> <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>

## **Appendix A**

### **Retailers Selling Lenses without Prescriptions**

[www.9mmsfx.com](http://www.9mmsfx.com)

<http://www.aalens.com/>

<http://www.boulonguise.com>

<https://www.buyingforbeauty.com>

<http://candylens.com/>

<http://circlelens2u.com/>

<http://colorcontacts.silkfair.com/>

<http://www.colorlens4less.com>

<http://www.contactlenshouse.com/index.asp>

<http://e-circlelens.com/shop/main/index.php>

[www.eyecandys.com](http://www.eyecandys.com)

<http://www.geocolouredlenses.com/>

<http://www.hollywoodcolorcontacts.com/index.php>

<http://honeycolor.com>

<http://www.iszocirclelens.com/>

<http://klenspop.com/en/>

<http://www.kawaiilovebeauty.com>

<http://www.lensvillage.com/>

<http://loveshoppingholics.com/>

<http://magicangeeyes.com/>

<http://maplelens.com/>

<http://myeyecolors.com/>

<http://ohmykitty.com/>

<http://www.thedollyeye.com/store/circle-lenses/>

[www.pinkyparadise.com](http://www.pinkyparadise.com)

<http://www.pricemartcontacts.com/>

<http://rainbowcomplete.com/>

<http://www.shellysdanceandcostume.com/accessory-products/color-contacts/>

<http://shopcoloredcontacts.com/>

<http://uniqso.com/>

<http://www.whatlenses.com/>

[http://www.yesstyle.com/en/beauty-circle-contact-lenses/list.html/bcc.11966\\_bpt.46](http://www.yesstyle.com/en/beauty-circle-contact-lenses/list.html/bcc.11966_bpt.46)

[Saveonlens.com](http://Saveonlens.com)

## **Appendix B**

<https://www.sclera-lenses.com/>

<http://www.spookyeyes.com/>

<http://extremesfx.com/>

<http://www.fashion-contactlenses.com/>

<http://www.foureyez.com/types-of-contact-lens/non-prescription-contact-lenses.html>

<https://circlelensesusa.com/>

[www.goodeyeglasses.com](http://www.goodeyeglasses.com)

<https://www.contactlensclub.us>

Mercari

Ily

Eye Candy

Chevron Gas Station

Jacksonville Beauty Supply

Fancy Beauty Cosmetics

8 Mile Beauty Supply

Corner Cupboard #7

<http://www.beautylens.us/>

SuperSexyEyes.Com

Angel Beauty Supply III

King Dollar 16

Pinky Paradise

<http://www.lensflavors.com/>

Blimpie Rivercenter Mall, 849E

A Dollar

<http://bscloseout.com/product/freshlook-colorblends-color-contact-lenses/>

<http://www.swapeyes.com/>

Dickies BBQ

<http://store.flashyandbroke.com>

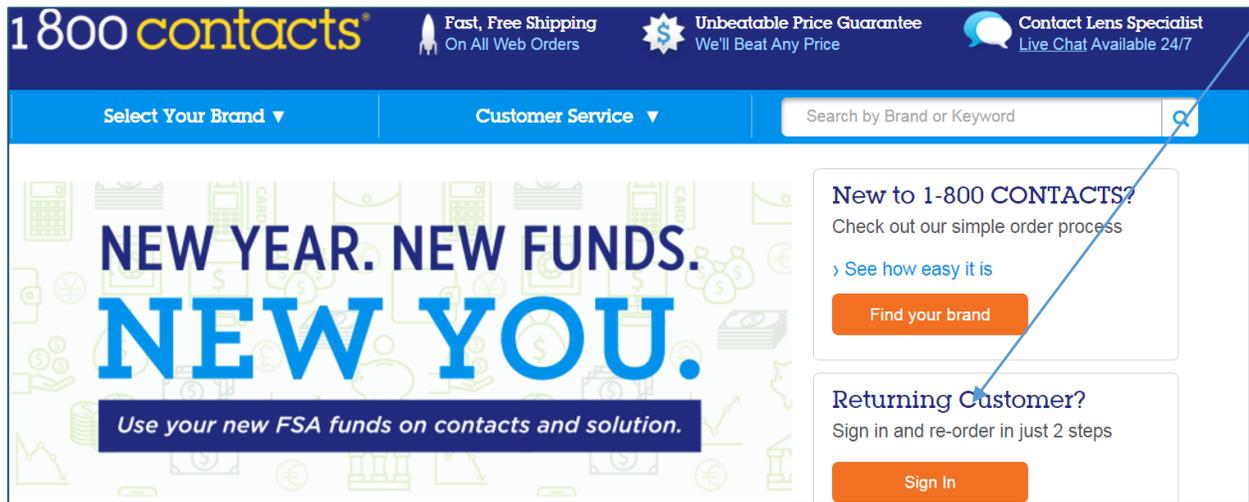
<http://hailfashion.net>

Empire Chinese Buffet

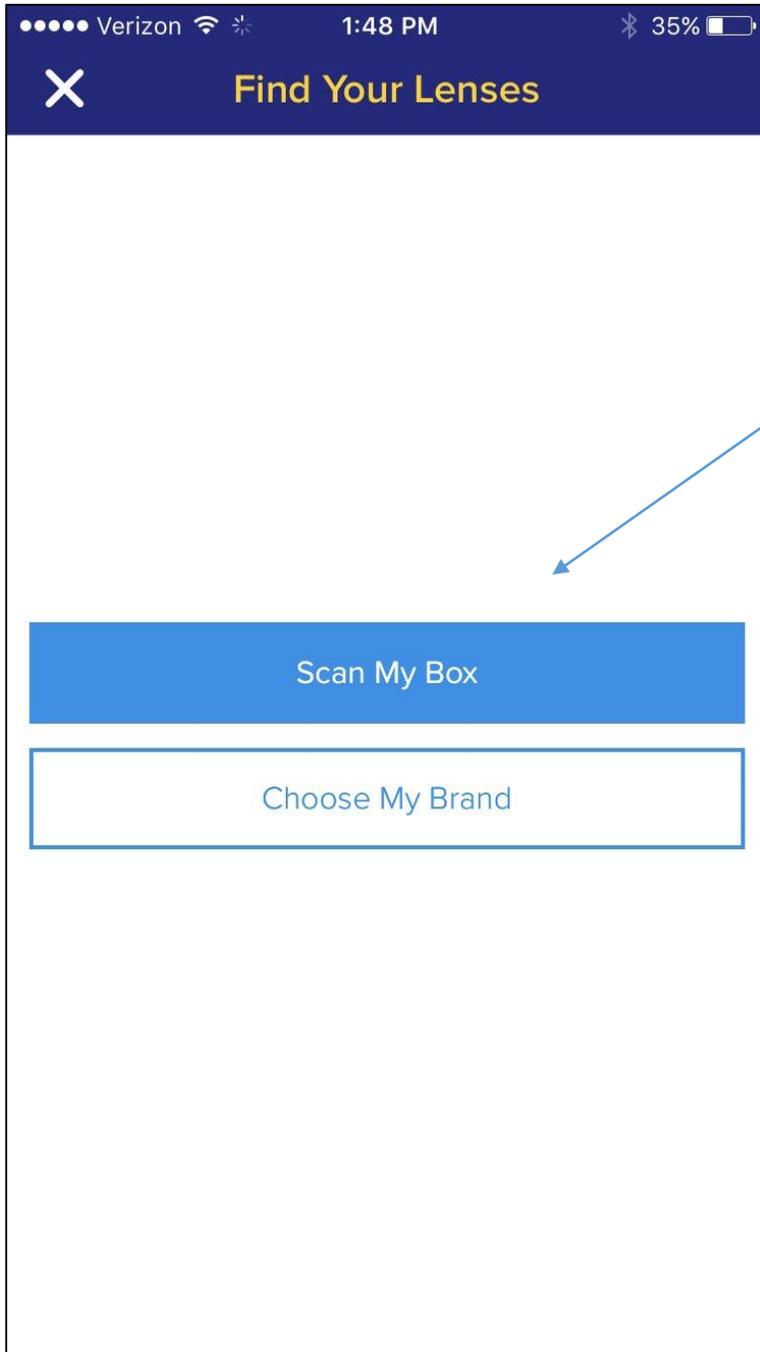
<http://www.cosplaycolorcontacts.com>

Appendix C

**Patients are encouraged to re-order in 2 steps which relies on the verification process.**



**Appendix D**



**This is a screenshot of the initial step in the 1-800-CONTACTS Mobile Application which instructs patients to first scan their contact lens box to obtain the specifications of the patients' prescription. The company does not initially prompt patients to provide a copy of their contact lens prescription.**