

April 4, 2018

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Suite CC-5610 (Annex F)
Washington, DC 20580

RE: FTC 16 CFR Part 315 Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes To The Contact Lens Rule

Dear Secretary Clark:

Johnson & Johnson Vision Care, Inc., appreciates the opportunity to submit comments on issues discussed at the Federal Trade Commission's (FTC) March 7, 2018, Contact Lens Workshop, including our perspective on its proposed changes to the Contact Lens Rule (Rule) as outlined in the 2016 Notice of Proposed Rule Making (NPRM).

We would like to thank the Commission for inviting Mr. Peter Menziuso and Dr. Carol Lakkis to participate as panelists, offering them a unique opportunity to share their perspectives and underscore Johnson & Johnson Vision's support for eye health and vision safety in the contact lens marketplace today, and in the future.

Mr. Menziuso's and Dr. Lakkis' official FTC Contact Lens Workshop testimonies as submitted to the record, are included as an addendum to our comment.

I. Introduction and Overview of Johnson & Johnson Vision's Recommendations

We appreciate the role of the Contact Lens Rule in promoting greater consumer choice and competition alongside patient eye health and vision safety, and importantly, its contribution to both retention and growth in the number of contact lens wearers today.

We recognize the Commission's challenging role in an evolving contact lens marketplace—and the importance of its leadership to facilitate future innovation and access to technologies. We remain committed to serving as a key partner to the Commission—working together to ensure that we continue to promote patients' eye health and vision safety, alongside choice, competition, access, and meaningful innovation to address still unmet patient needs.

As the global market leader in contact lenses, and as part of our commitment to broader eye health, Johnson & Johnson Vision would like to offer the following recommendations for the Commission's consideration as it works to finalize the Contact Lens Rule.

We believe the Commission should:

1. Clarify the intent of its proposal outlined in the NPRM to remove the term "private label" from the Rule by providing explicit direction that removal of this term does not allow for substitution;

2. Reiterate its commitment to enforce existing contact lens prescription requirements, and its prohibition of unauthorized alterations of prescriptions in its preamble discussion;
3. Reaffirm its commitment to the minimum one-year contact lens prescription expiration limit requirement; and
4. Outline its goals for the future of the contact lens marketplace with considerations around patient eye health and safety.

II. Review of Recommendations

Upholding the Prohibition on Contact Lens Substitution

At the March 7 workshop, we heard from key experts from the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) who highlighted that contact lens technologies are complex medical devices that are not interchangeable—and as noted by FDA’s Dr. Eydelman, “the current care paradigm does not support substitution of contact lens brands without clinical evaluation.”ⁱ

At Johnson & Johnson Vision, we prioritize patient eye health and agree that contact lenses are not interchangeable. We appreciate the Commission’s intention to promote patient access to their prescribed lenses at the retailer of their choice; however, we have raised concerns that removing the term “private label” from the Rule may be misinterpreted as allowing for greater flexibility around prescription substitution—potentially compromising patient eye health and safety in the future.

To ensure patients continue to receive the exact lenses prescribed by their eye doctor, we believe that the Commission should:

1. Clarify the current definition of a contact lens prescription so it is clear that a prescription must include both the brand and manufacturer;
2. Enforce the prohibition on unauthorized alteration of the prescription; and
3. Address potential issues with the removal of the term “private label” from the rule. This includes the Commission providing explicit direction that removal of this term does not allow for substitution now or in the future beyond the scope of private label lenses unless identical contact lenses are available from the same manufacturer and sold under different labels.

Upholding this regulatory framework ensures that as we bring new technologies to market, patients will receive the exact lenses as prescribed by their eye doctor to minimize their risk of adverse events and optimize their contact lens wearing experience, no matter where or how they choose to purchase them.

Minimum One-Year Prescription Expiration Limit for Contact Lenses

Johnson & Johnson Vision strongly agrees with the FTC’s rationale for maintaining the Rule’s minimum one-year contact lens expiration date in the NPRM. We believe the importance of this provision was

further underscored by several panelists, including FDA’s Dr. Michelle Tarver at the Workshopⁱⁱ, who noted that routine eye exams not only support optimal patient health and safety, but also access to the most appropriate technologies for patients’ evolving eye health needs.

We recommend that the FTC reaffirm its commitment to the current one-year contact lens prescription expiration requirements and work more closely with the CDC and FDA to better understand the health and safety benefits of both an initial comprehensive eye exam and regular follow-up exams for contact lens patients, as recommended by the American Optometric Association and the American Academy of Ophthalmology^{iii iv}.

Strengthening the Future of the Contact Lens and Eye Health Landscape

When considering the future eye health landscape, we know that today’s regulatory framework promotes optimal patient eye health and safety through support for the doctor-patient relationship. Here in the U.S., patients receive ongoing care and education from their doctor, which promotes eye health and higher patient satisfaction wearing their lenses over time.

As a leader in delivering innovative technologies to patients, Johnson & Johnson Vision recognizes the value of incremental and broader improvements to the patient’s contact lens experience, as well as the importance of providing eye doctors with lenses that better meet their patients’ eye health needs today and tomorrow.

We know that technology plays a critical role in the future of our marketplace as consumers are increasingly looking for more convenient access to eye health information, products, and services. This reality of today’s marketplace inspires us to pursue technologies that improve patient access to their lenses, while keeping the doctor patient relationship at the core. Sightbox, our recent acquisition discussed at the Workshop, is an online membership service for contact lens wearers in the U.S. that makes it easier for patients to connect with eye doctors for a comprehensive eye exam and contact lens evaluation, while also addressing a growing consumer preference for online purchasing options.

As the Commission considers the future of the contact lens landscape, including disruptive technologies and how to promote competition and access while preserving eye health and patient safety, we recommend that the FTC give consideration and outline its goals as they relate to:

1. Working with partner agencies at the federal level—including the FDA and CDC—to engage in broader data collection, including a contact lens registry on adverse events, and to identify how existing U.S. and ex-U.S. regulatory frameworks impact contact lens patient eye health and safety;
2. Encouraging future contact lens and eye health innovation so that eye doctors and patients have access to a wider range of options to better meet their health needs; and
3. Identifying the ways technology can be appropriately integrated in eye care through models that continue to ensure that patients’ health is prioritized over convenience, and that those

employing new technologies are held to the same high and consistent standard of care as doctors who deliver in-person care.

As the Commission considers proposed changes to today's regulatory framework, we look forward to our role and partnership in ensuring a robust marketplace that prioritizes patient eye health and safety.

III. Conclusion: Our Commitment to Contact Lens Patients

Johnson & Johnson Vision would like to thank the FTC for its ongoing efforts to promote patient eye health and vision safety alongside choice and competition in the contact lens marketplace as it looks to finalize the Contact Lens Rule.

We remain committed to continuing our work with the FTC, the FDA, the CDC, Congress, and a range of vision care stakeholders to support policies that foster growth in the contact lens category, benefiting patients while prioritizing safe use of contact lenses to ensure optimal eye health and a consistently exceptional patient experience.

ⁱ The Contact Lens Rule and the Evolving Contact Lens Marketplace. Dr. Malvina Eydelman, ODE/CDRH/FDA, US Regulation for Safe Use of Contact Lenses. https://www.ftc.gov/sites/default/files/filefield_paths/dr_eydelman_powerpoint_presentation.pdf. Accessed March 28, 2018.

ⁱⁱ Sauer A, et al. Risk Factors for Contact Lens–Related Microbial Keratitis: A Case–Control Multicenter Study. *Eye and Contact Lens*. May 2016. Volume 42, Number 3.

ⁱⁱⁱ American Optometric Association. Contact Lenses. <https://www.aoa.org/patients-and-public/caring-for-your-vision/contact-lenses>. Accessed March 29, 2018.

^{iv} American Academy of Ophthalmology. How to Take Care of Contact of Contact Lenses. <https://www.aoa.org/eye-health/glasses-contacts/contact-lens-care>. Accessed March 29, 2018.