



VISION CARE, INC.

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January 30, 2017

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

RE: Contact Lens Rule, 16 CFR Part 315 Project No. R511995

Dear Secretary Clark:

Johnson & Johnson Vision Care, Inc. (JJVCI) appreciates the opportunity to submit comments to the Federal Trade Commission's (the Commission or FTC) Notice of Proposed Rulemaking (NPRM) following its scheduled 10-year review of the 2004 Contact Lens Rule (Rule) implementing the Fairness to Contact Lens Consumers Act (Act).

I. Introduction and Overview of JJVCI Response to FTC Positioning

At JJVCI, we are driven to creating life-long solutions to vision care needs and helping people to see better, connect better, and live better. Through our EYE-INSPIRED™ Design approach, our ACUVUE® Brand Contact Lenses offer clear vision, unbeaten comfort, and a healthy lens wearing experience for our consumers.

We appreciate the Commission's long history of promoting consumer choice and competition at the manufacturer, prescriber, and retail levels. This highly competitive marketplace has continued to foster innovation and technological advances—providing both consumers and eye care professionals with access to an increasing number—and a wider range—of contact brands than ever before, including through our portfolio of ACUVUE® Brand Contact Lenses.

As outlined in our October 2015 public comments¹, JJVCI is committed to improving access and consumer choice, while preserving the important patient eye health and vision safety protections in the marketplace today. We believe this balance provides critical assurance to manufacturers, like JJVCI, that as we bring new technologies to market, our products will continue to be used safely and appropriately.

We also thank the Commission for its recognition of JJVCI's perspective in its review of the current contact lens landscape—including its consideration of both our recent research and consumer-reported data, along with other key statistics.

In our review of the NPRM, JJVCI supports the Commission's positioning on several central provisions of the rule—especially with respect to private label lenses and unauthorized alterations of prescriptions, including substitution; the minimum one-year contact lens expiration limit; and continued consumer access to lenses from a range of vendor options—and has also highlighted opportunities that remain to ensure our regulatory framework meets the demands of the modern marketplace.

¹<https://www.jjvisioncareinfo.com/sites/default/files/2017-03/JJVCI%20Full%20FTC%20Comment%202016%20NPRM%20CLR.pdf>



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II. FTC’s Role in Creating Today’s Competitive Contact Lens Marketplace

For more than three decades, the Commission has served as a vital partner in laying the foundation of our vision care landscape—and through its efforts to balance consumer choice with eye health and safety, it has fostered more than 10 years of intense growth, helping to create robust and competitive contact lens marketplace that consumers continue to benefit from today.

As the Commission cites, the total U.S. market for contact lenses was approximately \$3.3 billion in 2006—with estimated online sales representing less than 13% of the market.² Now, a decade later, there are over 40 million contact lens wearers in the U.S. over the age of 18, accounting for more than 16 percent of the population.³

In fact, today’s marketplace is estimated to be between \$4 billion and \$5 billion annually.⁴ Of that, over half (60%) of sales are from vendors other than independent eye care professionals (optometrists and ophthalmologists)—including 19% by conventional retail chains (such as LensCrafters, etc.), 25% from mass merchants and wholesale clubs (such as Costco, Sam’s Club, etc.), and 18% by online sellers (16% of sales are by “pure play” online sellers, such as 1-800 CONTACTS).⁵ Thanks to our regulatory framework and broad consumer awareness about the options available to them, this diverse marketplace continues to grow—ensuring that consumers have choice in where and how they purchase their lenses.

The FTC’s contact lens regulatory framework has also helped to encourage manufacturer research and product innovation—creating a true “race to the top” in vision care technology. As the Commission cites, there are significantly more types of lenses in the U.S. now than there were 10 to 15 years ago, with more than 160 brands available today.⁶ Through our portfolio of ACUVUE® Brand Contact Lenses alone, we have a range of technologies to address a variety of challenging vision needs—including myopia, hyperopia, astigmatism, and presbyopia—as well as innovations that go beyond traditional vision correction and address the broader elements of eye health.

Moreover, due—in part—to the assurance provided by today’s regulatory framework, JJVCI has been able to increase its investment in research and development efforts to address still unmet patient needs. In the next few years, we anticipate introducing several new technologies ranging from lenses that enable the delivery of medication to the eye to adaptive technology for changing external environments to completely customized correction and fit.

And thanks to this period of intense innovation, the increasing number of retail options and lens technologies available today, and the valued professional oversight of an eye care professional, consumers are also highly satisfied with the current marketplace. Eighty-five percent of contact lens wearers say it’s easy to find a brand they like and 97% of consumers report that their eye care professional has been helpful to them in finding contacts they like.⁷ Nearly all consumers (96%) express satisfaction with their contact lens-purchasing options.⁸

Today’s marketplace is working and, as a manufacturer, JJVCI believes it is vital to continue to support this growth and ensure that patients who are prescribed ACUVUE® Brand Contact Lenses have access to

² NPRM, Citation 32

³ NPRM, Citation 29

⁴ NPRM, Citation 30

⁵ NPRM, Citation 31

⁶ NPRM, Citation 33

⁷ Ibid

⁸ APCO Insight August 2015 telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc.



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our technologies through their choice of retailer—including their eye care professional, retail chains, wholesale clubs, and online.

III. JJVCI's Support of Key FTC Positioning

JJVCI thanks and continues to support the Commission's positioning on several central and guiding provisions of the Rule—chief among them, the Commission's reaffirmation of its intent and commitment to the current Rule's language for private label lenses and the unauthorized alterations of prescriptions, including substitutions.

Private Label Lenses and Unauthorized Alterations of Prescriptions

First, JJVCI appreciates the Commission's separate consideration and clarification of the current regulations regarding private label substitution and the alteration of prescriptions, including its specific response to reports of substitutions of non-prescribed brand.

As noted in our October 2015 comment, JJVCI supports preserving and enforcing the Rule's prohibition of sellers substituting contact lenses unless the substitution involves private label lenses made by the same manufacturer, but sold under the labels of other sellers.

This provision—which helps to ensure consumers receive the exact lenses prescribed by their eye care professional, regardless of where they choose to purchase—is vital to the sustainability of competition and innovation and is an aspect of the market highly valued by consumers. 94% of online contact lens purchasers say it's important that they receive the exact brand of contacts they order—with three-in-four (76%) noting that it is “very important.”⁹

JJVCI also strongly supports the Commission's underlying intention of ensuring consumers have safe and appropriate access to their lenses. However, as the marketplace evolves, it's also clear that the careful work of preserving choice, encouraging competition, and balancing the eye health and safety implications of a rapidly expanding marketplace have become increasingly challenging.

In the NPRM, the Commission points to reports of existing issues—from vendor accounts regarding their difficulties filling prescriptions for unpopular or private label lenses to prescriber and consumer concerns that the lenses sold to patients are not always consistent with the lenses prescribed.

In response, the Commission has taken the measured approach of clarifying its intent in the preamble and focusing on using existing reporting mechanisms and enforcement authority—rather than adding new regulatory language or making any amendments to the Rule itself. Not only does this approach provide vendors, manufacturers, consumers, and prescribers with expanded rationale and clarity regarding how the Commission interprets the Act and Rule in today's marketplace, but given all stakeholders' familiarity with the current Rule, we agree that preserving the existing regulatory language provides stability to the market and reduces future unintended consequences.

We also believe that this approach should be applied consistently to all issues raised with regard to private label and prescription alteration provisions—including as it relates to vendors who sell and wish to substitute their own private label lenses.

⁹ APCO Insight September 24 – October 2, 2015 online survey among adult contact lens consumers 18 years of age or older who have purchased contacts online in the last six months on behalf of Johnson & Johnson Vision Care, Inc.



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In its proposal to address this issue by removing the term “private label” from Section 315.5(e), the Commission notes that in its current form, the Rule’s language may be misinterpreted as unintentionally limiting vendors from selling their own private label and highlights its goal of better aligning the Rule’s language with that of the Act. While we understand this intent, we disagree that removing “private label” from Section 315.5(e) is the best approach.

First, we believe that the preamble of the Rule, rather than the regulatory language itself, is the most appropriate and effective place to clarify how the Commission interprets specific provisions of the Rule. Moreover, since there were not specific reports or accounts of vendors encountering issues with the current language, providing additional assurance in the preamble best meets the goal of ensuring the Rule is clear in its intent and non-limiting in its application.

In addition, although we understand the Commission’s rationale behind aligning the Rule language with the Act, the modifier of “private label” in fact provides the additional, clear guidance needed to illustrate that private label is the only specific instance in which the alteration of a prescription or substitution of lenses other than those expressly listed on a prescription is acceptable.

This inclusion is particularly important given the reports noted above from nearly every stakeholder in the contact lens landscape—from vendors to prescribers to consumers—regarding the ongoing issues with this provision. While we understand that the term would still remain preserved in the definitions section of the Rule and the Act, its omission from any command section of the Rule will result in the term becoming un-actionable and meaningless.

We believe that the removal of the term may be misinterpreted by both the current marketplace and future Commissions as this FTC adding new flexibility under the Rule, which, depending on the future market, could potentially lead to new and unforeseen instances of substitution that could ultimately cause undue, avoidable harm to patient eye health and vision safety.

If the FTC elects to maintain its removal of the term “private label” from Section 315.5(e), the Commission should explicitly clarify that such removal is not intended to allow for substitution now or in the future beyond the scope of private label lenses or identical contact lenses that the same company manufactures and sells under different labels.

Minimum One-Year Prescription Expiration Limit

We also thank the Commission for its recognition regarding the important role that its minimum one-year contact lens prescription expiration plays as “a safeguard against the improper dispensing of contact lenses.”¹⁰ As the Commission notes, the use of contact lenses involves significant health issues, and as such, the Act requires that contact lenses only be sold to consumers with valid prescriptions.¹¹

JJVC strongly agrees with the Commission’s rationale for maintaining the Rule’s minimum one-year contact lens expiration date. As we noted in our October 2015 comment, the current minimum one-year expiration date ensures that patients continue to receive the vital professional oversight necessary to decrease certain avoidable risks associated with contact lenses and increases patient access to the latest technologies to best meet their vision care needs. Today, a majority of consumers (97%) also agree that it

¹⁰ NPRM, C. Section 315.3(a)(2)—Provide or Verify the Contact Lens Prescription, I. Sellers Designated to Act on Behalf of Patients
¹¹ NPRM, Citation 19



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is important to regularly visit the eye doctor to ensure they have the right lenses to meet specific vision needs.¹²

Consumer Access to Lenses

Finally, JJVCI also supports the Commission's ongoing efforts to promote consumer access to their prescribed lenses from a range of vendor options, from online to chain retailers to independent eye care professionals. Nearly all consumers (96%) express satisfaction with the diverse options available to them today in where and how they can purchase their lenses.¹³

IV. The Path Forward: Meeting the Demands of the Modern Marketplace

As the Commission knows from more than 30 years of work with the broader vision care community, the contact lens marketplace is constantly evolving. While its scheduled ten-year review of the Contact Lens Rule marks a significant opportunity to ensure our regulatory framework meets the demands of the modern marketplace, a number of important steps remain—including updating the way prescribers and vendors communicate regarding the validity of prescriptions and providing continued assurance that the Commission will take an equitable approach in its application of the rule to the current and future marketplace.

First, JJVCI appreciates the Commission's acknowledgment of commenters' suggestions and concerns around direct communications for the purpose of contact lens prescription verification—including prescribers' selection of their preferred method of verification, the use of automatic telephone calls (robo-calls) as a method of direct communication, and vendor contact information.

However, we also believe that updates to the permissible communications between prescribers and vendors in verifying the validity of a contact lens prescription will only become more necessary to ensure the validation process works as intended as the marketplace continues to grow and modernize. As such, we will continue to work with the Commission and Congress to develop and codify solutions to improve prescriber-vendor communications such as allowing a prescriber to select their preferred method for verification request, and requiring that vendors provide a toll-free telephone number and email address that prescribers may use to ask questions about the seller's prescription verification request.

It is also essential for the Commission to ensure that the Rule responds to the needs of today's contact lens wearers by taking an equitable approach to improving access, choice, and patient safety across all parts of our marketplace. As we continue to promote choice, more work is necessary to provide patients with the assurance that they will receive the exact lenses prescribed to them—regardless of where they purchase them—and can continue to wear their prescribed lenses with low risk to their eye health and safety.

We believe that manufacturers, prescribers, and sellers have a shared responsibility to promote patient eye health and vision safety, which must be consistently considered in concert with our goals around increased competition and choice in the marketplace. As such, we will continue to work with the Commission, the Food and Drug Administration (FDA), and Congress to ensure that steps may be taken to better enforce current requirements in the Rule, including those related to the unauthorized alteration of contact lens prescriptions and sales of contact lenses based on an expired or invalid prescription.

¹² APCO Insight August 2015 telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc.

¹³ *Ibid*



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V. JJVCI's Commitment to Contact Lens Consumers

To reiterate, JJVCI appreciates the opportunity to provide these comments to the FTC's NPRM following its 10-year review of the Rule. We thank the FTC for its ongoing efforts to balance consumer choice and competition in the contact lens marketplace with patient eye health safety—including in its recent response to its scheduled 10-year review of the Rule.

As we look ahead, JJVCI remains committed to continuing our work with the FTC, the FDA, Congress, and a range of stakeholders to support policies like those outlined above that encourage consumer choice and competition, reinforce the value of patient eye health and vision safety, and promote product innovation.

Sincerely,

Peter Menziuso
President, North America
Johnson & Johnson Vision Care, Inc.