



VISION CARE, INC.

**Johnson & Johnson Vision Care, Inc. Comments to
FTC's Review of the 2004 Final Rule Implementing
The Fairness to Contact Lens Consumers Act**

October 26, 2015

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VISION CARE, INC.

EXECUTIVE SUMMARY

Johnson & Johnson Vision Care, Inc. Comments to Contact Lens Rule, 16 CFR Part 315

Johnson & Johnson Vision Care, Inc. (“JJVCI”) is committed to creating life-long solutions to vision care needs and appreciates the opportunity to submit comments on the Federal Trade Commission’s (the “Commission” or “FTC”) review of its 2004 Final Rule (the “Contact Lens Rule”) implementing the Fairness to Contact Lens Consumers Act (the “Act”).

We thank the Commission for its long history of promoting consumer choice and competition at the manufacturer, prescriber, and retail levels. As FTC undergoes its scheduled ten-year review of the 2004 Contact Lens Rule, we hope the Commission will work to maintain patients’ access to a range of retail options, while looking for opportunities to strengthen consumer protections by:

Ensuring patients continue to see their eye care professionals for their annual check-up and prescription renewal by enforcing the one-year minimum contact lens prescription expiration date.

- According to a recent JJVCI consumer survey, among the large majority (87%) of those who had an eye exam in the last year, 94% indicated that their contact lens prescription had changed since their last visit.¹
- Annual check-ups allow doctors to work with their patients to find the most compatible, safe, and effective contact lenses to meet patient’s vision needs.
- Annual eye exams for contact lenses are also an important part of overall eye health, and it is during these exams that a clinician can screen for signs of serious vision problems and diseases.

Maintaining and enforcing the current requirement that prescribers include the specific brand and product name on patient prescriptions.

- Because each consumer’s set of eyes react differently to individual brands—with certain brands causing issues with inappropriate lens movement on the ocular surface due to the specific shape, materiality, or inflammation—eye care professionals work with patients to find the most compatible, safe, and effective contact lenses for their patients.
- Unlike prescription drugs, these medical devices cannot be substituted with a non-prescribed equivalent, as each brand is unique and proprietary to each manufacturer and designed to suit a different set of corresponding patient physiology and consumer needs.
- JJVCI supports preserving the brand name on the contact lens prescription, providing patients with the confidence that the contacts they buy outside their provider’s office will match the lenses prescribed and fitted by their eye care professional.

Strengthening the prescription verification process between third-party sellers and eye care professionals through the inclusion of quantity limits.

- Today’s passive verification process has created an environment in which prescribers do not have a reasonable opportunity to respond to verification requests and FTC should develop additional guidance around automated telephone communication.
- FTC should also use its authority to require quantity limits to ensure patients have access to the products they need, while preventing excessive orders that may harm patient eye health.
- We also support additional guidance regarding non-domestic sales and enforcement of domestic laws and regulations.

¹ APCO Insight August 2015 telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc. [available in appendix]



VISION CARE, INC.

Submitted electronically via Regulations.gov

October 26, 2015

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. R5119955

Dear Secretary Clark:

Johnson & Johnson Vision Care, Inc. (“JJVCI”) is committed to creating life-long solutions to vision care needs and appreciates the opportunity to submit comments on the Federal Trade Commission’s (the “Commission” or “FTC”) review of its 2004 Final Rule (the “Contact Lens Rule”) implementing the Fairness to Contact Lens Consumers Act (the “Act”).

I. Introduction

Over the past 50 years, manufacturers have made dramatic advancements in contact lens research, bringing innovative vision care products to today’s nearly 44 million U.S. contact lens consumers. Every day at JJVCI, we work to share our commitment to promoting healthy vision, safe use, and developing products that address a wide-range of consumers’ vision needs. Since JJVCI’s ACUVUE® Brand made its debut in 1987 as the world’s first disposable soft contact lens, the company has repeatedly brought innovation, quality, and scientific advancements designed to meet doctor’s needs of high quality lens performance for patients. In addition, patients rely on the ACUVUE® Brand for good vision, exceptional comfort, and a healthy lens wearing experience.

With more than 160 brands of contact lenses available, each with its own proprietary formula and unique combination of material and design technologies, eye care professionals can customize lens selection to identify the lens best suited for each patient’s unique combination of eye shape, vision diagnosis, physiological and lifestyle needs.

Today’s consumers have many choices of where to purchase lenses —whether directly from an eye doctor, a retail outlet, or online—and can select the vendor that best meets their needs for service, convenience and price when filling their prescription. This highly competitive market continues to foster innovation and technological advances, which means consumers and eye care professionals have access to a greater number—and a wider range—of contact brands and products than ever before.

II. Summary of JJVCI Key Recommendations

We appreciate the Commission’s long history of promoting consumer choice and competition at the manufacturer, prescriber, and retail levels. As FTC undergoes its scheduled ten-year review of the 2004

Contact Lens Final Rule, we hope the Commission will work to maintain patients' access to a range of retail options, while looking for opportunities to strengthen consumer protections by:

- Maintaining and enforcing the current standards requiring that contact lens prescribers include the specific brand and product name on patient prescriptions;
- Preserving and enforcing existing consumer safeguards prohibiting a seller from substituting a non-prescribed brand without consulting and verifying such substitution with the prescriber;
- Upholding and enforcing the one-year contact lens prescription expiration date;
- Aligning the contact lens market with the dispensing/fulfillment standards in the pharmaceutical industry by requiring the quantity of lenses to be included on every contact lens prescription; and
- Strengthening critical consumer guardrails—such as the current verification system—to ensure consumers receive the correct contact lenses for their prescription and to, as intended by the Commission, “prevent patients from ordering excessive contact lenses.”

III. Importance of Current Brand and Product Name Requirement on Contact Lens Prescription

When the Commission initially drafted the 2004 Contact Lens Rule, it noted that Section 11(3) of the Act defines a “contact lens prescription” as

a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following: (a) the name of the patient; (b) the date of examination; (c) the issue date and expiration date of prescription; (d) the name, postal address, telephone number, and facsimile telephone number of prescriber; (e) the power, material or manufacturer or both of the prescribed contact lens; (f) the base curve or appropriate designation of the prescribed contact lens; (g) the diameter, when appropriate, of the prescribed contact lens; and (h) in the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.²

Given this explicit direction from Congress and after a thorough review of stakeholder input, the Commission adopted this definition without changes. We believe this consistency between the rule and statute afforded by the Commission has been critical to ensuring that the contact lens market remains strong, particularly as the inclusion of all eight criteria—the name of patient, date of examination, the manufacturer of the prescribed contact lens, etc.—is important to ensuring the complete and accurate filling of a contact lens prescription as intended by the eye health provider.

With more than 160 different brands of contact lenses available, the inclusion of the manufacturer and brand in a prescription play an often underestimated, but vital role, in protecting patient vision health and ensuring consumer confidence in their lenses.

²15 U.S.C. 7610(3).

The Commission and the U.S. Food and Drug Administration—Coordinating Regulation to Ensure Consumer Confidence in the Market, as well as Safety and Efficacy of Contact Lenses

Since 1976, contact lenses have been recognized by the U.S. Food and Drug Administration (FDA) as Class II or Class III medical devices and, by law, consumers are required to have a valid prescription from an eye care professional to purchase corrective lenses. As the agency charged with monitoring and enforcing the safety and effectiveness of drugs and devices available to consumers, FDA has a clear and understandable interest in appropriately classifying devices to minimize risks and ensure these devices are properly regulated. Since contact lenses directly interact with the ocular surface, it is critical that any regulatory framework controlling access to their use factor in the inherent risks of a consumer not wearing the specific contact lens brand prescribed by their eye care professional.

As noted, all contact lenses require a prescription. With the number of vendors selling contact lenses and marketing efforts suggesting that the prescription is equal to the lens power alone, consumers may incorrectly believe that these devices are largely interchangeable or substitutable. Unlike prescription drugs, these medical devices cannot be substituted with a non-prescribed equivalent, as each brand is unique and proprietary to each manufacturer and designed to suit a different set of corresponding patient physiology and consumer needs,³ including:

- **Oxygen Transmissibility** – *[determines the that rate oxygen can flow through the lens]*
 - The oxygen transmissibility of a contact lens is critical in avoiding oxygen deprivation of the cornea and related physiological damage. Transmissibility is determined by the thickness and material type of the lens (including lens water content for soft hydrogel lenses or silicone content for silicone hydrogel materials). As such, manufacturers have continued to develop a range of innovative material compositions, enhancing the

³ Walline J, Morrison A, Smith M, Widmer D. “Are Contact Lenses Interchangeable”—The Ohio State University Technical Report, 2015 on behalf of Johnson & Johnson Vision Care. Morgan PB, Efron N. Comparative clinical performance of two silicone hydrogel contact lenses for continuous wear. *Clin Exp Optom* 2002;85:183-92.; Nichols JJ, Mitchell GL, Zadnik K. Daily disposable vs. disposable extended wear: a contact lens clinical trial. *Optom Vis Sci* 2000;77:637-47.; Richdale K, Berntsen DA, Mack CJ, Merchea MM, Barr JT. Visual acuity with spherical and toric soft contact lenses in low- to moderate-astigmatic eyes. *Optom Vis Sci* 2007;84:969-75.; Guillon M, Maissa C. Use of silicone hydrogel material for daily wear. *Cont Lens Anterior Eye* 2007;30:5-10; quiz 71.; Malet F, Pagot R, Peyre C, Subirana X, Lejeune S, George-Vicariot MN, Bleshoj H, Long B. Subjective experience with high-oxygen and low-oxygen permeable soft contact lenses in France. *Eye Contact Lens* 2003;29:55-9.; Ozkan J, Papas E. Lubricant effects on low Dk and silicone hydrogel lens comfort. *Optom Vis Sci* 2008;85:773-7.; Santodomingo-Rubido J. The comparative clinical performance of a new polyhexamethylene biguanide- vs a polyquad-based contact lens care regime with two silicone hydrogel contact lenses. *Ophthalmic Physiol Opt* 2007;27:168-73.; Varikooty J, Keir N, Richter D, Jones LW, Woods C, Fonn D. Comfort response of three silicone hydrogel daily disposable contact lenses. *Optom Vis Sci* 2013;90:945-53.; Malet F, Pagot R, Peyre C, Subirana X, Lejeune S, George-Vicariot MN, Bleshoj H, Long B. Clinical results comparing high-oxygen and low-oxygen permeable soft contact lenses in France. *Eye Contact Lens* 2003;29:50-4.; Santodomingo-Rubido J, Barrado-Navascues E, Rubido-Crespo MJ, Sugimoto K, Sawano T. Compatibility of two new silicone hydrogel contact lenses with three soft contact lens multipurpose solutions*. *Ophthalmic Physiol Opt* 2008;28:373-81.; Varikooty J, Schulze MM, Dumbleton K, Keir N, Woods CA, Fonn D, Jones LW. Clinical performance of three silicone hydrogel daily disposable lenses. *Optom Vis Sci* 2015;92:301-11.; Wolffsohn JS, Mroczkowska S, Hunt OA, Bilkhu P, Drew T, Sheppard A. Crossover Evaluation of Silicone Hydrogel Daily Disposable Contact Lenses. *Optom Vis Sci* 2015.; Lebow KA, Schachet JL. Evaluation of corneal staining and patient preference with use of three multi-purpose solutions and two brands of soft contact lenses. *Eye Contact Lens* 2003;29:213-20.; Riley C, Chalmers RL, Pence N. The impact of lens choice in the relief of contact lens related symptoms and ocular surface findings. *Cont Lens Anterior Eye* 2005;28:13-9.; Tilia D, Lazon de la Jara P, Weng R, Naduvilath T, Willcox MD. Short-term clinical comparison of two dual-disinfection multipurpose disinfecting solutions. *Eye Contact Lens* 2014;40:7-11.; Green-Church KB, Nichols JJ. Mass spectrometry-based proteomic analyses of contact lens deposition. *Mol Vis* 2008;14:291-7.; Jones L, Mann A, Evans K, Franklin V, Tighe B. An in vivo comparison of the kinetics of protein and lipid deposition on group II and group IV frequent-replacement contact lenses. *Optom Vis Sci* 2000;77:503-10.; Brennan NA, Coles ML, Connor HR, McIlroy RG, Gavras S, Moody KJ, Henderson T. Short-term corneal endothelial response to wear of silicone-hydrogel contact lenses in East Asian eyes. *Eye Contact Lens* 2008;34:317-21.; Steffen RB, Schneider CM. The impact of silicone hydrogel materials on overnight corneal swelling. *Eye Contact Lens* 2007;33:115-20.’ Maissa C, Guillon M, Cockshott N, Garofalo RJ, Lemp JM, Boclair JW. Contact lens lipid spoliation of hydrogel and silicone hydrogel lenses. *Optom Vis Sci* 2014;91:1071-83.; Morgan PB, Efron N. Hydrogel contact lens ageing. *CLAO J* 2000;26:85-90.

efficacy of lens oxygen transmissibility and enabling doctors to fine tune prescriptions to better meet the physiological demands of each patient.

- **Water Content** – [*establishes the oxygen transmissibility, fragility, rigidity, and thickness of hydrogel lenses*]
 - In addition to determining classification, FDA also regulates soft hydrogel lenses under one of four groupings based on water content, which can impact a variety of contact lens material properties. High water content lenses provide increased oxygen flow and fragility, while lower water content contact lenses provide limited oxygen flow, but better durability. Prescribers have a variety of options to find the best design to balance physiologic response, durability preference and vision performance for patients.
- **Ionicity**—[*affects lens surface sensitivity to changes in pH and to what degree it attracts deposits from the tear film*]
 - Ionic lenses are classified by FDA as group III and group IV lenses, while non-ionic contact lenses are FDA groups I and II. Ionicity (or the charge) of the lens material affects the tendency of protein from the patient’s tear film to be attracted to the lens, which can help determine the type of lens that will perform best with their eyes.
- **Rigidity or Modulus**—[*aids in determining the flexibility of each lens*]
 - Rigidity is largely determined by water content in hydrogel lenses, and silicone content in silicone hydrogel lenses. As such, rigidity can vary widely across brands and is a primary determinant of patient comfort. Modulus affects how the lens sits on the patient’s eye and how it handles upon insertion – another determinant of patient comfort. Some brands offer more rigid lenses while others more flexible options, each serving a different patient preference.
- **Silicone and Fluorine Content** – [*influences the flexibility, oxygen permeability, and lipid/protein deposition*]
 - Lens polymers can include a combination of both silicone and fluorine, neither, or an alternative material altogether. Some lens polymers contain hydrophilic (water loving) silicones while others contain hydrophobic (water hating) silicones. How these polymers are integrated into the contact lens material is critical to the success of the device on the patient’s eye. A range of material options is critical to ensure doctors have appropriate options to provide patients with the safest contact lens experience.
- **Lipid Deposition**—[*impacts optical performance, wettability, and comfort*]
 - While most silicone-based lenses are prone to the appearance of fatty deposits in the lens, the degree of lipid deposition is greatly dependent on each patient’s eyes’ biological response. Even among silicone-based lenses, lipid deposition can vary greatly between brands. Adding greater complexity, there are ‘good’ lipids and ‘bad’ lipids that can deposit on lenses, similar to ‘good’ and ‘bad’ cholesterol in the blood. That’s why eye care professionals offer different contact lens materials based on individuals’ tear film composition.
- **Wettability/Wetting Agent**—[*affects the moisture retention of the contact lens*]

- Contact lens manufacturers have developed a range of proprietary, specially-formulated wetting agents that continually improve the wearing experience by interacting more seamlessly with the tear film and ocular surface. These advances provide options that allow doctors to meet the needs of their patients in changing environments where variations in humidity, temperature and airflow can impact a patient's success with contact lenses.
- **Thickness**—*[aids in ensuring wearer comfort and oxygen transmissibility]*
 - Contact lens thickness affects oxygen transmission, comfort and lens centration over the cornea. Poor oxygen transmission can reduce wearing time and potentially cause irreversible corneal damage. Edge thickness and design can greatly effect lens comfort for the patient. Poor centration can cause redness, irritation and general discomfort.
- **Diameter**—*[determines how the device centers on eye]*
 - Appropriate coverage of the cornea is important because a soft contact with too large or too small a diameter for the patient's cornea can move excessively, cause tearing or discomfort, may dislodge, or may not move sufficiently which is needed for soft contact lens success. Additionally, optimal centration is important to ensure optimal vision correction with the lens optics centered correctly over the pupil; this is of particular importance with toric and multifocal lens designs for the correction of astigmatism and presbyopia respectively.
- **Base Curve**—*[curvature of the back surface of the lens]*
 - Proper base curve selection is critical to ensuring proper alignment with the ocular surface. An appropriately aligned lens provides an optimal environment for tear exchange behind the lens to provide nutrients to the cornea and removal of toxins. A lens that fits too tightly to the eye does not allow for the proper tear exchange necessary for keeping the eye healthy during contact lens wear. If a lens fits too flat on the eye, the lenses may move too much, adversely affecting vision and will likely be uncomfortable to wear. Further, an ill-fitted lens may slide up under the lid or potentially fall out during wear. The combination of base curve and diameter, as well as base curve design is critical to lens fitting success.
- **Edge Design**—*[the shape of the peripheral (non-optical carrier portion) section of a contact lens and, in particular, the thickness profile and degree of lift-off at the very edge of a lens]*
 - The edge design plays a significant role in the fit and comfort of a contact lens. It directly affects tear exchange under a contact lens, which can impact the physiological performance of the lens. Edge design is generally unique to a contact lens brand. Thus two manufacturers may use the same material with the same diameter, base curve and power but, because of different edge designs, the lenses will perform very differently on the eye.
- **Surface characteristics/treatments**—*[the physico-chemical properties of a contact lens surface]*
 - The way that a contact lens interacts with the tear film on the eye is largely determined by the physico-chemical properties of the lens surface. This interaction ideally leads to a stable tear film which promotes good vision and comfort of the lens but can also lead to deposition and adverse outcomes in some individuals where the tear chemistry is

incompatible with a particular lens surface. Different mold materials and different polymerization rates can lead to vastly different outcomes in terms of surface properties. Thus two different brands of lens of ostensibly the same material can perform differently on eye as a direct result of the manufacturing process.

- **Modality**—*[refers to the length of time a contact is worn prior to scheduled removal and/or replacement]*
 - Modality is based on eye health and lifestyle. For example, patients with very busy and active lifestyles may be better suited to daily disposable lenses than reusable lenses. Patients who sleep in their lenses require lenses that have undergone rigorous safety testing and FDA approval to determine that the lens can be worn safely on an extended wear replacement schedule.

- **UV Blocking**—*[lens properties that protect against harmful UV rays]*
 - Some contact lens brands provide ‘always on’ UV blocking to the cornea and the structures inside the eye. Not all contact lens brands contain UV blocking properties, and there are multiple levels of UV blocking standards as determined by international standards organizations.

- **Interaction with care solutions**—*[the impact of care solutions on the physiological performance of a contact lens]*
 - Considerable attention has been paid in recent years to the unwanted interaction between certain contact lens care solutions and contact lenses. A principal unwanted effect of the interaction may be widespread corneal staining. Prediction of the likelihood of such an outcome cannot be made simply by considering the material used in a contact lens and the components of a care solution. Advice on the likelihood of an interaction and follow-up to ensure that this does not occur is only reasonably provided by an eye-care practitioner.

This list represents just some of the parameter considerations that are unique to each individual contact lens available in the marketplace. Each brand represents a unique combination of lens parameters and that uniqueness is the reason substitutions cannot be condoned.

In fact, a recent literature review of 21 contact lens product peer-reviewed, crossover studies—comparing 51 products (some products were used in multiple studies)—concluded

[E]ven when the same subjects wear various contact lenses, they experience different physiological reactions in relatively short periods of time. No single lens can provide a healthy ocular response for every single patient, and contact lenses are not freely interchangeable because each one reacts differently on the ocular surface. The fit of each particular contact lens and the ocular response must be evaluated over time in order to provide a healthy vision correction that minimizes the risk of potentially sight-threatening complications.⁴

⁴ Walline J, Morrison A, Smith M, Widmer D. “Are Contact Lenses Interchangeable”—The Ohio State University Technical Report, 2015 on behalf of Johnson & Johnson Vision Care.

Of note, several of the crossover studies evaluated a variety of outcomes when fitting subjects with a range of contact lenses concluded that the subjects' physiological reactions and the contact lens parameters differed, based on the brand of contact lens used.⁵ For example, significant differences in reactions to reduced oxygen to the eye, as well as in corneal and conjunctival staining, were found between hydrogel and silicone hydrogel contact lenses—even when the base curves and diameters were nearly identical.⁶ As such, to substitute brands negates the fitting assessment and puts patients at risk for complications far beyond discomfort.

In short: each consumer's set of eyes react differently to each individual brand. For some consumers, certain brands may cause issues with inappropriate lens movement on the ocular surface due to the specific design and material, potentially causing inflammation, discomfort, damage, as well as impairment of the patient's visual acuity. Therefore a trial or diagnostic period under the close supervision of an eye care professional is critical to achieve a successful, safe contact lens prescription. Any efforts to bypass this important step of the process to find the most appropriate lenses would not only have a considerable impact on the marketplace, but also on consumer choice and, ultimately, eye health.

Importantly, the current market and the inclusion of brand have continued to foster a race amongst manufacturers to develop increasingly innovative technologies for better vision options and promising disease management tools. As a result, doctors have access to a growing range of lens options to better address their patients' unique vision care needs.

Given the wide variation in contact lens materials available today, JJVCI supports the continued inclusion and enforcement of the brand requirement as part of a contact lens prescription. Any concerns that such requirements impede consumers from changing their contact lens brand during the life of their

⁵ Morgan PB, Efron N. Comparative clinical performance of two silicone hydrogel contact lenses for continuous wear. *Clin Exp Optom* 2002;85:183-92.; Nichols JJ, Mitchell GL, Zadnik K. Daily disposable vs. disposable extended wear: a contact lens clinical trial. *Optom Vis Sci* 2000;77:637-47.; Richdale K, Berntsen DA, Mack CJ, Merchea MM, Barr JT. Visual acuity with spherical and toric soft contact lenses in low- to moderate-astigmatic eyes. *Optom Vis Sci* 2007;84:969-75.; Guillon M, Maissa C. Use of silicone hydrogel material for daily wear. *Cont Lens Anterior Eye* 2007;30:5-10; quiz 71.; Malet F, Pagot R, Peyre C, Subirana X, Lejeune S, George-Vicariot MN, Bleshey H, Long B. Subjective experience with high-oxygen and low-oxygen permeable soft contact lenses in France. *Eye Contact Lens* 2003;29:55-9.; Ozkan J, Papas E. Lubricant effects on low Dk and silicone hydrogel lens comfort. *Optom Vis Sci* 2008;85:773-7.; Santodomingo-Rubido J. The comparative clinical performance of a new polyhexamethylene biguanide- vs a polyquad-based contact lens care regime with two silicone hydrogel contact lenses. *Ophthalmic Physiol Opt* 2007;27:168-73.; Varikooty J, Keir N, Richter D, Jones LW, Woods C, Fonn D. Comfort response of three silicone hydrogel daily disposable contact lenses. *Optom Vis Sci* 2013;90:945-53.; Malet F, Pagot R, Peyre C, Subirana X, Lejeune S, George-Vicariot MN, Bleshey H, Long B. Clinical results comparing high-oxygen and low-oxygen permeable soft contact lenses in France. *Eye Contact Lens* 2003;29:50-4.; Santodomingo-Rubido J, Barrado-Navascues E, Rubido-Crespo MJ, Sugimoto K, Sawano T. Compatibility of two new silicone hydrogel contact lenses with three soft contact lens multipurpose solutions*. *Ophthalmic Physiol Opt* 2008;28:373-81.; Varikooty J, Schulze MM, Dumbleton K, Keir N, Woods CA, Fonn D, Jones LW. Clinical performance of three silicone hydrogel daily disposable lenses. *Optom Vis Sci* 2015;92:301-11.; Wolffsohn JS, Mroczkowska S, Hunt OA, Bilkhu P, Drew T, Sheppard A. Crossover Evaluation of Silicone Hydrogel Daily Disposable Contact Lenses. *Optom Vis Sci* 2015.; Lebow KA, Schachet JL. Evaluation of corneal staining and patient preference with use of three multi-purpose solutions and two brands of soft contact lenses. *Eye Contact Lens* 2003;29:213-20.; Riley C, Chalmers RL, Pence N. The impact of lens choice in the relief of contact lens related symptoms and ocular surface findings. *Cont Lens Anterior Eye* 2005;28:13-9.; Tilia D, Lazon de la Jara P, Weng R, Naduvilath T, Willcox MD. Short-term clinical comparison of two dual-disinfection multipurpose disinfecting solutions. *Eye Contact Lens* 2014;40:7-11.; Green-Church KB, Nichols JJ. Mass spectrometry-based proteomic analyses of contact lens deposition. *Mol Vis* 2008;14:291-7.; Jones L, Mann A, Evans K, Franklin V, Tighe B. An in vivo comparison of the kinetics of protein and lipid deposition on group II and group IV frequent-replacement contact lenses. *Optom Vis Sci* 2000;77:503-10.; Brennan NA, Coles ML, Connor HR, McIlroy RG, Gavras S, Moody KJ, Henderson T. Short-term corneal endothelial response to wear of silicone-hydrogel contact lenses in East Asian eyes. *Eye Contact Lens* 2008;34:317-21.; Steffen RB, Schneider CM. The impact of silicone hydrogel materials on overnight corneal swelling. *Eye Contact Lens* 2007;33:115-20.; Maissa C, Guillon M, Cockshott N, Garofalo RJ, Lemp JM, Boclair JW. Contact lens lipid spooliation of hydrogel and silicone hydrogel lenses. *Optom Vis Sci* 2014;91:1071-83.; Morgan PB, Efron N. Hydrogel contact lens ageing. *CLAO J* 2000;26:85-90.

⁶ Ibid.

contact lens prescription are best mitigated knowing that prescribers have a medical obligation to ensure patients have the right lenses for their vision care needs and are safe and comfortable with the lenses prescribed.

Including the brand name in the contact lens prescription ensures that, regardless of where a patient chooses to purchase their lenses, they can be confident that the contacts they buy outside their provider's office will match the lenses prescribed and fitted by their eye care professional. Consumer confidence is imperative to ensuring a healthy marketplace, and reinforces the FTC's regulatory framework in cooperation with existing FDA oversight and surveillance, supporting the safety and efficacy of these medical devices.

IV. Importance of Restrictions on Substituting Non-Prescribed Brand Lenses

JJVC supports preserving and enforcing section 315.5(e) of the Final Rule, which expressly prohibits sellers from substituting contact lenses unless the substitution involves the replacement of private label lenses made by the same manufacturer, but sold under the labels of other sellers.⁷

We recognize the importance of ensuring convenient consumer access to our prescription lenses through a range of retail options, but never at the risk of eye health. As the Commission is aware from its preparation of the 2004 Contact Lens Rule, a number of prescribers raised concerns regarding instances where sellers provided patients with lenses that are substantially different from the ones prescribed by the prescriber, including reports of sellers altering patients' prescriptions and supplying them with non-prescribed, extended-wear, or tinted lenses. Not only does this run counter to Congressional and FTC intent, but it raises significant concerns around the safe use of contact lenses when contact lens resellers start making inappropriate and potentially harmful decisions for patients without the necessary oversight and input from eye care professionals.

Importantly, consumers agree. In fact, 94% of online contact lens purchasers say it is important that they receive the exact brand of contacts they order—with three-in-four (76%) noting that it is *very* important.⁸ Unfortunately, in the current marketplace, one-in-four online consumers report having received a different brand of contact lenses than they had ordered without being given advance warning they were getting another brand.⁹

As manufacturers, we strongly support any regulatory efforts that help to ensure that our medical device products are sold and used as prescribed by an eye care professional and in a manner that adheres to FTC and FDA regulations. If consumers aren't receiving the exact contact lenses that they were prescribed by their eye care professional, they may not only lose confidence in their ability to purchase lenses outside of their prescriber's office, but also experience potentially permanent eye damage from wearing a non-prescribed brand.¹⁰ Maintaining and enforcing existing safeguards mitigates

⁷ Section 315.5(e) of the proposed Rule prohibits the alteration of prescriptions by stating that a "seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, a seller may substitute for private label contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels." See *69 FR at 5449*

⁸ 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. [available in appendix]

⁹ *Ibid.*

¹⁰ <http://www.ncbi.nlm.nih.gov/pubmed/?term=contact+lenses%2C+soft%2C+fit%2C+internet>

risk, as well as helps to prevent serious consumer injury and ocular complications such as, corneal neovascularization, corneal infection, or even permanent vision loss.

V. Strengthening Consumer Safeguards via Prescription Expiration Requirements, Quantity Limits and Verification

Finally, both the authorizing statute and the 2004 Contact Lens Rule included a requirement that sellers verify a consumer's prescription with the prescriber prior to furnishing the requested lenses to the consumer. As the Commission noted while outlining its objective within the Rule, this verification process was not only included as a way to offer consumers flexibility and choice in purchasing, but also to serve as a critical safeguard to ensure consumers receive the correct lenses for their prescription and to prevent patients from ordering excessive quantities of contact lenses.

Importantly, a high percentage consumers who visited their eye care professional regularly also noted that their prescription often changes from annual exam to annual exam.¹¹ Among the large majority (87%) of those who had an eye exam in the last year, 94% indicated that their contact lens prescription had changed since their last visit.

Today's patients place a tremendous value on the relationship with and advice of their eye health professional, with nearly all (97%) consumers agreeing that it is important to regularly visit the eye doctor to ensure they have the right lenses to meet specific vision needs and most (90%) having purchased lenses from their eye doctor.¹² In fact, 85% of those surveyed say it is easy to find contact lenses they like, while 97% indicate that their doctor has been helpful in finding contact they like.¹³

Eye care professionals work with patients to find the most compatible, safe, and effective contact lenses for their eyes. They examine a range of factors, including those related to the material and design properties outlined above, as well as any other vision diagnoses, such as myopia or astigmatism. In addition, eye care professionals consider risk factors and other health issues that may impact long-term eye health, such as diabetes, hypertension, or hepatitis.

That's why it's critical to ensure patients continue to see their eye care professionals for their annual check-up and prescription renewal by upholding and enforcing the one-year contact lens prescription expiration date. Annual check-ups not only allow doctors to work with their patients to find the most compatible, safe, and effective contact lenses to meet patient's vision needs, but are also an important part of overall eye health, and it is during these exams that a clinician has the opportunity to screen for signs of serious vision problems and diseases. Moreover, with evolving patient vision care needs, an overwhelming majority (94%) of consumers place significant importance on having a contact lens prescription that is not expired.¹⁴

However, the landscape of contact lens resale has changed in a range of ways since 2004—including an increasing and more diversified use of modern technology, as well as a growing number of contact lens

¹¹ APCO Insight August 2015 telephone survey among adult contact lens consumers 18 years and older on behalf of Johnson & Johnson Vision Care, Inc. [available in appendix]

¹² Ibid.

¹³ Ibid.

¹⁴ Ibid.

sellers flooding the marketplace. As such, despite consumers’ remarks regarding the importance of maintaining an up-to-date prescription given their changing vision needs, roughly one-in-three online contact lens purchasers admit to ordering lenses using an *already expired* prescription.¹⁵ Moreover, nearly six-in-ten online consumers say they have received an email or letter from their retailer reminding them their Rx was expiring soon (58%) and the vast majority who received this notice (86%) ordered more contact lenses as a result—unfortunately, one-in-five did so *after* their prescription had expired.¹⁶

Not only does this raise concerns around patient health, but it also means that the safeguards that Congress and FTC put in place aren’t protecting consumers as intended and the current verification process must be adjusted.

The Passive Verification Process—The Commission’s and Congress’ Intent Versus Reality

Many of these patient, provider, and seller concerns stem from the current passive verification system. As FTC is aware, under the FCLCA and current rule, contact lens sellers are required to verify each patient’s prescription with the prescriber prior to furnishing the lenses to the requesting patient. After receiving the request for verification, the seller has an eight business hour window in which to verify the prescription or address inaccuracies. If the eye care professional fails to confirm the prescription within this allotted timeframe, the sale is automatically authorized.

In outlining its original interpretation of the Act and its review of submitted comments, the Commission highlighted two key ideas that, among others, provide important guardrails to the verification process:

- First, the Commission noted that the Act “clearly contemplates that prescribers should have a reasonable opportunity when they are open to respond to verification requests;” and
- Second, that it is “incumbent upon the party initiating the communication to use a method that enables the recipient to receive all the information being communicated” in order for that communication to be seen as “completed.”

As manufacturers, we understand and recognize both the Commission’s and Congress’ intention of ensuring consumers have uninhibited access to purchasing lenses through retailer of their choice. These two tenets—that the party initiating communication is responsible for communicating in a method that allows the intended recipient to fully and completely receive all the required information and that the recipient should have a reasonable opportunity to respond—aim to provide consumers with the assurance that regardless of where they purchase their lenses, they should receive the exact lenses prescribed and verified by their eye care provider. Unfortunately, given the health implications stemming from the aforementioned reports, as well as continued concerns regarding patient privacy, challenges remain under the current system.

The Act¹⁷ and existing 2004 Contact Lens Rule expressly authorizes a seller to send verification by facsimile, electronic mail, and telephone. During the drafting of its Final Rule, the Commission determined that it would, at that time, permit automated telephone system requests and voice

¹⁵ 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. [available in appendix]

¹⁶ Ibid.

¹⁷ 15 U.S.C. 7603(a)(2)(permitting prescription verification by “direct communication”) , 7603(g)(defining “direct communication” to include communication by telephone)

messages to remain valid means of communication in order to allow for the broadest interpretation of Congress' inclusion of seller verification via "telephone."

However, in doing so, it also recognized that "automated telephone systems may create problems" and confirmed that the Commission would continue to monitor whether full, valid requests for verification of a prescription are being made through the use of automated telephone systems and that it would revisit this issue "if evidence demonstrates that sellers are not making valid verification requests but are providing consumers with contact lenses despite deficient requests."

A review of the passive verification process of the past 10 years shows a process that varies substantially in practice. In fact, many of the concerns recognized by the Commission in its drafting of the 2004 Final Rule are now a reality—with sellers using one-way and outdated communication methods to contact prescribers, ranging from faxing to machines that are out of use or non-existent to seller-initiated robo-callers leaving voice messages on prescriber's office phone lines, often after hours.¹⁸

As a result, prescribers are often unable to verify the patient's prescription information. Not only does this undermine the aforementioned principles outlined in the Act by Congress and recognized by the Commission, but it has also caused numerous issues for consumers, including sellers contacting the wrong prescriber,¹⁹ automatically verifying outdated or incorrect prescriptions, auto-sending consumers lenses that result in duplication, or—in cases of purchases from non-domestic sellers—no prescription verification at all. Moreover, with the majority (65%) of consumers relying on the existing verification process to validate their prescription prior to sale, it's clear that the issues under the existing process ultimately undermine consumer trust and value in the marketplace.²⁰

While we recognize that the Act does not permit prescribers to limit which of the communications mechanisms allowed under the statute sellers may use to submit verification requests, it's clear that today's passive verification process has created an environment in which prescribers not only do not have a reasonable opportunity to respond, but that, in some instances, the party initiating communication selects methods that make it unnecessarily and inappropriately difficult for the recipient to fully receive, review, and respond to all the information in order for consumers to purchase contact lenses in a safe and convenient manner.

As such, we respectfully request that the Commission consider modernizing its guidance by updating its allowable forms communication and providing additional requirements around automated telephone communication and voice mail, such as: allowing for additional time to respond; requiring affirmative prescriber confirmation of receipt prior to triggering the verification period; allowing prescribers to provide written notification that they will not accept verification requests via robo-calls; providing a dedicated toll-free phone number and email address for sellers to prescriber questions and concerns; and requiring follow-up by live telephone operator. In addition, given the growing number of retail options for consumers, including many which are based outside of the United States and thus do not

¹⁸ According to the American Optometric Association, the Association has often received complaints from doctors of optometry that robocalls from some sellers were difficult to understand or did not include all of the necessary information to confirm a prescription.

¹⁹ This practice has continued to occur, despite the Commission's confirmation during its drafting of its 2004 Final Rule and as outlined under the Act that "a verification request sent to the wrong prescriber does not conform with the requirements of the Act and section 315.5(b) of the Rule," and thus does not officially trigger a verification period.

²⁰ 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. [available in appendix]

adhere to verification rules outlined in the Statute or Final Rule, we ask that the Commission provide guidance regarding non-domestic sales and the Commission's enforcement of domestic laws and regulation.

In addition, under the current system, there are reports of consumers inadvertently receiving duplicate orders of lenses. Online sellers often auto-purchase lenses or, as nearly 60% of online purchasers report, send renewal reminders—similar to a subscription service—close to a consumer's yearly prescription expiration date that can result in unintended purchases.²¹

The Commission and Quantity Limits

One important way to improve the current verification process would be a change that mimics the dispensing and fulfillment standards in the pharmaceutical industry within our healthcare system. For example, when considering drugs that require a prescription, limits are placed on the length of time the prescription is valid, and the quantity available to the patient over that period of time. Such quantity limits serve as a critical guardrail to ensure patients have access to the health products they need, while preventing excessive orders that may ultimately harm patient health.

During the drafting of the 2004 Contact Lens Rule, FTC noted that, at that time, it was unnecessary to modify the definition of contact lens prescription to require the inclusion of quantity of lenses or refills allowed because "Section 315.5(b) requires verification requests to contain the quantity of lenses ordered and...the quantity ordered may be a legitimate basis for a prescriber to treat a request for verification as 'inaccurate.'" The Commission then concluded that this "verification process itself thus generally allows prescribers to prevent patients from ordering excessive contact lenses."

However, given this changing landscape and the availability of new information about how this process works in practice, it is clear that verification is not enough to effectively protect consumers and maintain the medical integrity of the marketplace.

The Act provides the Commission latitude to adjust the language around quantity limits and recognizes that quantity limits are an appropriate consumer safeguard given its requirement that sellers include the quantity limits in their verification request.

As manufacturers, we believe that quantity limits impose important safeguards and also strengthen the prescriber-patient relationship. For example, if a patient's lenses become torn or their supply runs short, this offers yet another opportunity for consumers to ask questions, share health and other issues they may be encountering with their lenses, or adjust their prescription under the supervision of an eye care professional.

Instituting quantity limits and maintaining the current annual expiration requirements would provide meaningful and improved protection for the safety and healthcare of consumers.

²¹ 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. [available in appendix]



VISION CARE, INC.

VI. Johnson & Johnson Vision Care, Inc. – Review of Recommendations and Contact

We appreciate the opportunity to provide these comments and provide recommendations to strengthen consumer protections, including:

- Maintaining and enforcing the current standards requiring that contact lens prescribers include the specific brand and product name on patient prescriptions;
- Preserving and enforcing existing consumer safeguards prohibiting a seller to substitute a non-prescribed brand without consulting and verifying such substitution with the prescriber;
- Upholding and enforcing the one-year contact lens prescription expiration date;
- Aligning the contact lens market with the dispensing/fulfillment standards in the pharmaceutical industry by requiring the quantity of lenses to be included on every contact lens prescription; and
- Strengthening critical consumer guardrails—such as the current verification system—to ensure consumers receive the correct contact lenses for their prescription and to, as intended by the Commission, “prevent patients from ordering excessive contact lenses.”

If you have any questions, you may reach me at 904-443-1012.

Sincerely,

Laura Angelini

President, Johnson & Johnson Vision Care, Inc.



VISION CARE, INC.

[APPENDIX]

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Johnson & Johnson Vision Care, Inc.

U.S. Contact Lens Consumers Telephone Survey

n= 867 adult contact lens consumers 18 years + (decision-makers who have purchased contacts in the last year)

Survey conducted over the phone

Fielded: July 27 – August 16, 2015

Question 1

How long have you been wearing contact lenses?

LESS THAN A YEAR	4%
1 - 2 YEARS	3%
3 - 5 YEARS	18%
6 - 10 YEARS	20%
11 - 20 YEARS	25%
21 - 30 YEARS	18%
31 - 40 YEARS	7%
MORE THAN 40 YEARS	5%
DON'T KNOW/REFUSED	-

Question 2

Where do you TYPICALLY purchase contacts lenses? Do you buy them through...

AN EYE DOCTOR SUCH AS AN OPHTHALMOLOGIST OR OPTOMETRIST	60%
A DISCOUNT RETAILER SUCH AS WALMART OR TARGET	12%
AN INTERNET, ONLINE OR MAIL ORDER RETAILER SUCH AS 1-800 CONTACTS	12%
A WHOLESALE CLUB SUCH AS SAM OR COSTCO	8%
AN OPTICAL RETAIL CHAIN SUCH AS LENS CRAFTERS OR PEARLE VISION	7%
SOMEWHERE ELSE	1%
DON'T KNOW	-

Question 3

If Q2=1-6

n=867

The LAST time you purchased contacts, did you buy them through [INSERT ANSWER FROM Q2] or somewhere else?

YES, [Q2 ANSWER]	93%
SOMEWHERE ELSE	7%
DON'T KNOW	-

Question 4

If Q3=somewhere else

n=49

And from where did you buy your contact lenses the LAST time you purchased them?

AN EYE DOCTOR SUCH AS AN OPHTHALMOLOGIST OR OPTOMETRIST	39%
AN OPTICAL RETAIL CHAIN SUCH AS LENS CRAFTERS OR PEARLE VISION	28%
AN INTERNET, ONLINE OR MAIL ORDER RETAILER SUCH AS 1-800 CONTACTS	17%
A DISCOUNT RETAILER SUCH AS WALMART OR TARGET	9%
A WHOLESALE CLUB SUCH AS SAM OR COSTCO	2%
SOMEWHERE ELSE	5%
DON'T REMEMBER	-

Table 5
Summary of Contact Purchases: % Yes

THROUGH EYE DOCTOR	73%
INTERNET, ONLINE OR MAIL ORDER RETAILER	18%

Question 5A

If Q2 OR Q4 does not equal eye doctor

n=323

Have you ever purchased your contacts through an eye doctor?

YES	72%
NO	28%
DON'T KNOW/REFUSED	-

Question 5B

If Q2 OR Q4 does not equal internet, online, or mail order

n=751

Have you ever purchased your contacts through an internet, online or mail order retailer?

YES	17%
NO	83%
DON'T KNOW/REFUSED	-

Question 6

If Q2 equals eye doctor and Q3= eye doctor

n=514

Have you always purchased contacts through your eye doctors?

YES	89%
NO	10%
DON'T KNOW/REFUSED	1%

Question 7

Thinking about all of the different ways you can buy contact lenses - through your doctor, internet/online, by mail, at a store, etc. - how satisfied are you with your options? Would you say you are very, somewhat, not very or not at all satisfied?

TOTAL SATISFIED	96%
TOTAL NOT SATISFIED	3%
VERY SATISFIED	80%
SOMEWHAT SATISFIED	17%
NOT VERY SATISFIED	1%
NOT AT ALL SATISFIED	1%
DON'T KNOW/REFUSED	1%

Question 8

In your opinion, is it very, somewhat, not very or not at all important, to be able to purchase your contacts through your eye doctor?

TOTAL IMPORTANT	78%
TOTAL NOT IMPORTANT	21%
VERY IMPORTANT	53%
SOMEWHAT IMPORTANT	25%
NOT VERY IMPORTANT	16%
NOT AT ALL IMPORTANT	5%
DON'T KNOW	*

Question 9

I am going to read through some reasons people have said that they like purchasing their contacts through their eye doctor. As I read each one, please tell me if it is a reason you might purchase your contacts through an eye doctor.

I TRUST MY EYE DOCTOR	81%
I KNOW I GETTING THE CORRECT CONTACTS AS PRESCRIBED BY MY DOCTOR	77%
I CAN GET MY QUESTIONS ANSWERED IN-PERSON	77%
IT IS CONVENIENT	77%
IT IS EASY	77%
I KNOW I GETTING THE BEST FITTING CONTACTS	72%
I CAN TRY OUT DIFFERENT PAIRS OF CONTACTS UNTIL I FIND A TYPE THAT WORK FOR ME	67%
I CAN GET MY EYEGLASSES AT THE SAME TIME	65%
THEY WORK WITH ME TO FIND THE BEST CONTACTS AT THE LOWEST PRICE	60%
I CAN GET A DISCOUNT THROUGH INSURANCE	56%
I CAN PICK CONTACTS UP THE SAME DAY AS I VISIT MY EYE DOCTOR	46%
I CAN TURN IN UNUSED CONTACTS FOR A REBATE OR REFUND	24%
ANOTHER REASON NOT YET MENTIONED	1%
NONE OF THE ABOVE	3%

Question 10

When was the last time you had an eye exam?

WITHIN THE LAST YEAR	87%
MORE THAN A YEAR	13%
WITHIN THE LAST SIX MONTHS	53%
MORE THAN SIX MONTHS AGO, BUT WITHIN THE LAST YEAR	34%
MORE THAN A YEAR AGO, BUT WITHIN THE LAST TWO YEARS	11%
MORE THAN TWO YEARS AGO, BUT WITHIN THE LAST THREE YEARS	1%
MORE THAN THREE YEARS AGO	1%
DON'T KNOW/REFUSED	-

Question 11

When was the last time your prescription for contact lenses changed?

LESS THAN A YEAR	46%
1 - 2 YEARS	27%
3 - 5 YEARS	14%
6 - 10 YEARS	5%
MORE THAN 10 YEARS	3%
DON'T KNOW/REFUSED	5%

Table 14

Summary Table: % Very Important

HAVING CONTACTS THAT FIT YOUR EYES COMFORTABLY	95%
REGULARLY VISITING YOUR EYE DOCTOR TO ENSURE YOU HAVE THE RIGHT LENSES TO MEET SPECIFIC VISION NEEDS	77%
REGULARLY VISITING YOUR EYE DOCTOR TO MAINTAIN EYE HEALTH	76%
UNDERSTANDING HOW TO SAFELY WEAR YOUR CONTACTS	76%
UNDERSTANDING HOW TO SAFELY CLEAN YOUR CONTACTS	73%
HAVING A CURRENT CONTACT LENS PRESCRIPTION THAT IS NOT EXPIRED	71%
REGULARLY VISITING YOUR EYE DOCTOR AS A PART OF YOUR OVERALL HEALTH	67%

Table 15
Summary Table: % Total Important

HAVING CONTACTS THAT FIT YOUR EYES COMFORTABLY	100%
REGULARLY VISITING YOUR EYE DOCTOR TO ENSURE YOU HAVE THE RIGHT LENSES TO MEET SPECIFIC VISION NEEDS	97%
REGULARLY VISITING YOUR EYE DOCTOR TO MAINTAIN EYE HEALTH	96%
REGULARLY VISITING YOUR EYE DOCTOR AS A PART OF YOUR OVERALL HEALTH	96%
HAVING A CURRENT CONTACT LENS PRESCRIPTION THAT IS NOT EXPIRED	94%
UNDERSTANDING HOW TO SAFELY WEAR YOUR CONTACTS	93%
UNDERSTANDING HOW TO SAFELY CLEAN YOUR CONTACTS	91%

Question 12_1

Now I am going to read through a list and I want you to tell me how important you believe each item is. Please tell me if each is very, somewhat, not very or not at all important.

Regularly visiting your eye doctor as a part of your overall health

TOTAL IMPORTANT	96%
TOTAL NOT IMPORTANT	4%
VERY IMPORTANT	67%
SOMEWHAT IMPORTANT	29%
NOT VERY IMPORTANT	3%
NOT AT ALL IMPORTANT	1%
DON'T KNOW	*

Question 12_2

Now I am going to read through a list and I want you to tell me how important you believe each item is. Please tell me if each is very, somewhat, not very or not at all important.

Regularly visiting your eye doctor to maintain eye health

TOTAL IMPORTANT	96%
TOTAL NOT IMPORTANT	4%
VERY IMPORTANT	76%
SOMEWHAT IMPORTANT	20%
NOT VERY IMPORTANT	3%
NOT AT ALL IMPORTANT	*
DON'T KNOW	*

Question 12_3

Now I am going to read through a list and I want you to tell me how important you believe each item is. Please tell me if each is very, somewhat, not very or not at all important.

Regularly visiting your eye doctor to ensure you have the right lenses to meet specific vision needs

TOTAL IMPORTANT	97%
TOTAL NOT IMPORTANT	3%
VERY IMPORTANT	77%
SOMEWHAT IMPORTANT	20%
NOT VERY IMPORTANT	3%
NOT AT ALL IMPORTANT	*
DON'T KNOW	*

Question 12_4

Now I am going to read through a list and I want you to tell me how important you believe each item is. Please tell me if each is very, somewhat, not very or not at all important.

Having a current contact lens prescription that is not expired

TOTAL IMPORTANT	94%
TOTAL NOT IMPORTANT	5%
VERY IMPORTANT	71%
SOMEWHAT IMPORTANT	23%
NOT VERY IMPORTANT	4%
NOT AT ALL IMPORTANT	1%
DON'T KNOW	1%

Question 12_5

Now I am going to read through a list and I want you to tell me how important you believe each item is. Please tell me if each is very, somewhat, not very or not at all important.

Having contacts that fit your eyes comfortably

TOTAL IMPORTANT	100%
TOTAL NOT IMPORTANT	-
VERY IMPORTANT	95%
SOMEWHAT IMPORTANT	5%
NOT VERY IMPORTANT	-
NOT AT ALL IMPORTANT	-
DON'T KNOW	*

Question 12_6

Now I am going to read through a list and I want you to tell me how important you believe each item is. Please tell me if each is very, somewhat, not very or not at all important.

Understanding how to safely wear your contacts

TOTAL IMPORTANT	93%
TOTAL NOT IMPORTANT	7%
VERY IMPORTANT	76%
SOMEWHAT IMPORTANT	17%
NOT VERY IMPORTANT	5%
NOT AT ALL IMPORTANT	2%
DON'T KNOW	*

Question 12_7

Now I am going to read through a list and I want you to tell me how important you believe each item is. Please tell me if each is very, somewhat, not very or not at all important.

Understanding how to safely clean your contacts

TOTAL IMPORTANT	91%
TOTAL NOT IMPORTANT	8%
VERY IMPORTANT	73%
SOMEWHAT IMPORTANT	19%
NOT VERY IMPORTANT	6%
NOT AT ALL IMPORTANT	2%
DON'T KNOW	*

Question 13

Who taught you to safely use your contacts?

YOUR EYE DOCTOR	60%
A STAFF MEMBER OR TECHNICIAN IN YOUR EYE DOCTOR OFFICE	42%
A FAMILY MEMBER	7%
A FRIEND	2%
SOMEONE ELSE	-
NO ONE	*
DON'T KNOW/REMEMBER	*

Question 14

Were you aware that part of your eye exam with your doctor includes checking for symptoms of diseases such as diabetes, arthritis, hypertension and even some cancers?

YES	79%
NO	21%

Question 15

In your opinion, have contacts improved in recent years?

YES	83%
NO	9%
DON'T KNOW	8%

Question 16A

Have you ever asked your eye doctor for a new brand or type of contact lenses?

YES	52%
NO	47%
DON'T KNOW	1%

Question 16B

If Q16A equals yes

n=435

Why did you ask for a new brand or type of contact lenses? Was it because of

COMFORT	65%
EFFECTIVENESS	19%
AN ADVERTISEMENT YOU SAW FOR ANOTHER BRAND OR TYPE OF CONTACT LENSES	17%
COST	16%
A RECOMMENDATION FROM A FAMILY MEMBER OR FRIEND	5%
RECOMMENDATION FROM EYE DOCTOR	3%
EYE COLOR/CHANGE OF EYE COLOR	3%
ANOTHER REASON	3%
DON'T KNOW	1%

Question 17

Do you agree or disagree that only certain manufacturers or brands of contacts work better for your eyes?

TOTAL AGREE	69%
TOTAL DISAGREE	19%
STRONGLY AGREE	44%
SOMEWHAT AGREE	24%
SOMEWHAT DISAGREE	14%
STRONGLY DISAGREE	5%
NEITHER AGREE NOR DISAGREE	8%
DON'T KNOW/REFUSED	4%

Question 18

Would you say it was or has been easy or difficult to find contacts that you like?

TOTAL EASY	85%
TOTAL DIFFICULT	13%
VERY EASY	57%
SOMEWHAT EASY	28%
SOMEWHAT DIFFICULT	8%
VERY DIFFICULT	5%
NEITHER EASY NOR DIFFICULT	1%
DON'T KNOW/REFUSED	1%

Question 19

And has your eye doctor been very, somewhat, not very or not at all helpful in finding contacts you liked?

TOTAL HELPFUL	97%
TOTAL NOT HELPFUL	3%
VERY HELPFUL	84%
SOMEWHAT HELPFUL	12%
NOT VERY HELPFUL	1%
NOT AT ALL HELPFUL	2%
DON'T KNOW	1%

Question 19_2

And has your eye doctor been very, somewhat, not very or not at all helpful in finding contacts you liked?

TOTAL HELPFUL	97%
TOTAL NOT HELPFUL	2%
VERY HELPFUL	86%
SOMEWHAT HELPFUL	11%
NOT VERY HELPFUL	1%
NOT AT ALL HELPFUL	1%
DON'T KNOW	1%

Question 19_3

And has your eye doctor been very, somewhat, not very or not at all helpful in finding contacts you liked?

TOTAL HELPFUL	92%
TOTAL NOT HELPFUL	8%
VERY HELPFUL	70%
SOMEWHAT HELPFUL	22%
NOT VERY HELPFUL	4%
NOT AT ALL HELPFUL	4%
DON'T KNOW	-

Table 33

Summary Table: % Agree

IMPROVED YOUR QUALITY OF LIFE	89%
HELPED YOU TO BE MORE PHYSICALLY ACTIVE	80%
GIVEN YOU GREATER CONFIDENCE	77%

Question 20_1

Do you agree or disagree that contact lenses have:
Improved your quality of life

AGREE	89%
DISAGREE	6%
NEITHER AGREE NOR DISAGREE	5%
DON'T KNOW/REFUSED	*

Question 20_2

Do you agree or disagree that contact lenses have:
Helped you to be more physically active

AGREE	80%
DISAGREE	14%
NEITHER AGREE NOR DISAGREE	5%
DON'T KNOW/REFUSED	1%

Question 20_3

Do you agree or disagree that contact lenses have:
Given you greater confidence

AGREE	77%
DISAGREE	14%
NEITHER AGREE NOR DISAGREE	8%
DON'T KNOW/REFUSED	1%

Question 21

The LAST time you purchased contacts, would you say it was easy or difficult to find a good price?

TOTAL EASY	81%
TOTAL DIFFICULT	9%
VERY EASY	51%
SOMEWHAT EASY	30%
SOMEWHAT DIFFICULT	6%
VERY DIFFICULT	3%
NEITHER EASY NOR DIFFICULT	8%
DON'T KNOW/REFUSED	2%

Question 22

Sometimes retailers and eye doctors supply rebates for contacts so that the amount paid at the time of purchase, is not actually the final price. Thinking back to the last time you bought a new brand or type of contacts, how clear was the final price?

TOTAL CLEAR	92%
TOTAL NOT CLEAR	5%
VERY CLEAR	77%
SOMEWHAT CLEAR	15%
NOT VERY CLEAR	4%
NOT AT ALL CLEAR	1%
DON'T KNOW	2%

Question S1

In the past year, have you purchased any of the following prescription eyewear for your personal use?

CONTACT LENSES	100%
PRESCRIPTION EYEGLASSES	44%
PRESCRIPTION SUNGLASSES	10%
NONE OF THE ABOVE	-
DON'T KNOW/REFUSED	-

Question D1

Gender.

MALE	40%
FEMALE	60%

Question D2

Age.

18 - 24	20%
25 - 34	25%
35 - 44	30%
45 - 54	8%
55 - 64	10%
65 AND ABOVE	7%
REFUSED	-
18 - 34	45%
35 - 49	33%
50 - 64	15%
65+	7%

Question D3
State.

AT RISK STATE	14%
CALIFORNIA	5%
FLORIDA	8%
UTAH	1%
NOT AT RISK STATE	86%
ALABAMA	3%
ALASKA	*
ARIZONA	3%
ARKANSAS	1%
COLORADO	5%
CONNECTICUT	1%
DELAWARE	-
DISTRICT OF COLUMBIA	*
GEORGIA	1%
HAWAII	-
IDAHO	*
ILLINOIS	7%
INDIANA	3%
IOWA	1%
KANSAS	2%
KENTUCKY	3%
LOUISIANA	2%
MAINE	1%
MARYLAND	2%
MASSACHUSETTS	1%
MICHIGAN	1%
MINNESOTA	4%
MISSISSIPPI	1%
MISSOURI	2%
MONTANA	*
NEBRASKA	2%
NEVADA	*
NEW HAMPSHIRE	*
NEW JERSEY	3%
NEW MEXICO	*
NEW YORK	4%
NORTH CAROLINA	5%
NORTH DAKOTA	1%
OHIO	6%
OKLAHOMA	1%
OREGON	1%
PENNSYLVANIA	7%
RHODE ISLAND	1%
SOUTH CAROLINA	1%
SOUTH DAKOTA	1%
TENNESSEE	1%
TEXAS	3%
VERMONT	1%
VIRGINIA	1%
WASHINGTON	1%
WEST VIRGINIA	1%
WISCONSIN	2%
WYOMING	-

Question D3A

Region.

NORTHEAST	17%
MIDWEST	30%
SOUTH	34%
WEST	19%

Question D4

Which of the following best describes your ethnic background?

CAUCASIAN OR WHITE	77%
AFRICAN AMERICAN OR BLACK	8%
HISPANIC OR LATINO	7%
ASIAN AMERICAN	2%
INDIAN AMERICAN	1%
NATIVE AMERICAN	1%
OTHER/SEVERAL BACKGROUNDS	2%
DON'T KNOW/REFUSED	1%

Question D5

Please stop me when I reach the highest education level you have completed.

HIGH SCHOOL OR LESS	19%
COLLEGE+	74%
GRADE SCHOOL OR LESS	1%
SOME HIGH SCHOOL	*
HIGH SCHOOL GRADUATE	18%
SOME COLLEGE OR TRADE SCHOOL	37%
COLLEGE GRADUATE	37%
POST-GRADUATE WORK	7%
PREFER NOT TO ANSWER	*

Question D6

What is your household income before taxes?

LESS THAN \$50K	30%
\$50K - \$75K	20%
\$75K - \$100K	16%
\$100K+	23%
LESS THAN \$25,000 A YEAR	10%
\$25,000 - \$50,000	20%
\$50,000 - \$75,000	20%
\$75,000 - \$100,000	16%
\$100,000 - \$125,000	10%
\$125,000 - \$150,000	5%
\$150,000 - \$175,000	2%
\$175,000 - \$200,000	2%
\$200,000 OR MORE	4%
PREFER NOT TO ANSWER	12%

Question D7

Which of the following best describes the community in which you live?

URBAN - LARGE CITY	16%
SUBURBS OF A LARGE CITY	32%
SMALL OR MEDIUM-SIZED TOWN	33%
RURAL AREA	17%
PREFER NOT TO ANSWER	1%

Johnson & Johnson Vision Care, Inc.
U.S. Contact Lens Online Purchasers Survey
500 adult consumers who purchase their contacts online
Field dates: September 24 – October 2, 2015

Question 1

From where, specifically, did you last purchase contact lenses for your personal use?

1-800 CONTACTS / 1800CONTACTS.COM	53%
VISIONDIRECT.COM	12%
COSTAL.COM	5%
LENS.COM	5%
VISIONPROS.COM	4%
LENSDISCOUNTERS.COM	3%
DISCOUNTCONTACTLENSES.COM	3%
LENSCRAFTERSCONTACTS.COM	2%
WALGREENS	1%
OPTICCONTACTS.COM	1%
SAVEONLENS.COM	1%
ALLABOUTVISION.COM	*
FRAMESDIRECT.COM	*
DAYSOFCONTACTLENSES.COM	*
PRICESMARTCONTACTS.COM	*
OTHER	5%
I DON'T KNOW/I DON'T REMEMBER	4%

Question 2

How long have you been wearing contact lenses?

LESS THAN A YEAR	2%
1-5 YEARS	22%
6-20 YEARS	47%
21+ YEARS	29%
1-2 YEARS	4%
3-5 YEARS	18%
6-10 YEARS	20%
11-20 YEARS	27%
21-30 YEARS	19%
31-40 YEARS	6%
MORE THAN 40 YEARS	4%

Question 3

What are some reasons you purchase contact lenses online or over the phone? Please select as many options as applicable.

PRICE	80%
CONVENIENCE OF DELIVERY	70%
EASE OF ORDERING	70%
TIME SAVINGS	54%
DON'T HAVE TO VISIT THE DOCTOR	28%
CONFIDENCE IN SELLER	25%
RECOMMENDATION FROM DOCTOR	15%
OTHER	1%

Question 4

Thinking about all the times you have ordered contacts online or over the phone, have you ever:

Summary Table: % Yes

ORDERED CONTACTS USING A CONTACT LENS PRESCRIPTION THAT WAS LESS THAN A MONTH FROM ITS EXPIRATION DATE?	62%
RECEIVED AN EMAIL OR LETTER FROM YOUR RETAILER REMINDING YOU THAT YOUR CONTACT LENS PRESCRIPTION WAS EXPIRING SOON?	58%
ORDERED CONTACTS USING A CONTACT LENS PRESCRIPTION THAT WAS ALREADY EXPIRED?	32%

Question 4_1

Thinking about all the times you have ordered contacts online or over the phone, have you ever:

Ordered contacts using a contact lens prescription that was less than a month from its expiration date?

YES	62%
NO	31%
I DON'T KNOW OR REMEMBER	7%

Question 4_2

Thinking about all the times you have ordered contacts online or over the phone, have you ever:

Ordered contacts using a contact lens prescription that was already expired?

YES	32%
NO	64%
I DON'T KNOW OR REMEMBER	4%

Question 4_3

Thinking about all the times you have ordered contacts online or over the phone, have you ever:

Received an email or letter from your retailer reminding you that your contact lens prescription was expiring soon?

YES	58%
NO	34%
I DON'T KNOW OR REMEMBER	8%

Question 5

Have you ever ordered contact lenses online or over the phone as a result of this reminder?

n=288

TOTAL YES	86%
I ORDERED MORE CONTACT LENSES BEFORE MY PRESCRIPTION EXPIRED	61%
I ORDERED MORE CONTACT LENSES AFTER MY PRESCRIPTION EXPIRED	19%
I ORDERED MORE CONTACT LENSES, BUT I DON'T REMEMBER WHETHER IT WAS BEFORE OR AFTER MY PRESCRIPTION EXPIRED	6%
NO	12%
I DON'T KNOW OR REMEMBER	2%

Question 6

How important is it to you that you receive the exact brand of contacts you order as opposed to a similar product under a different branding?

TOTAL IMPORTANT	94%
TOTAL UNIMPORTANT	6%
VERY IMPORTANT	76%
SOMEWHAT IMPORTANT	18%
NOT VERY IMPORTANT	5%
NOT AT ALL IMPORTANT	1%
I DON'T KNOW OR REMEMBER	0%

Question 7A

When buying contact lenses online or over the phone in the past, has the company you were ordering from ever informed you that they do not carry or do not currently have stocked, the brand of contact lenses on your prescription, and advised you to get another brand of contact lenses instead?

YES	31%
NO	66%
I DON'T KNOW OR REMEMBER	2%

Question 7B

Did you then order that other brand of contact lenses?
n=156

YES	80%
NO	18%
I DON'T KNOW OR REMEMBER	2%

Question 8A

Have you ever received, in the mail, a different brand of contact lenses than you thought you had ordered, without being given advance warning that you were getting another brand of contacts?

YES	24%
NO	76%
I DON'T KNOW OR REMEMBER	*

Question 8B

How satisfied were you with this different brand of contact lenses you received?
n=136

TOTAL SATISFIED	96%
TOTAL DISSATISFIED	4%
VERY SATISFIED	71%
SOMEWHAT SATISFIED	24%
SOMEWHAT DISSATISFIED	2%
VERY DISSATISFIED	1%
I DON'T KNOW OR REMEMBER	1%

Question 9

Thinking about the last time you purchased contact lenses through an online or telephone retailer, how much time, if any, did you spend comparing prices?

I DID NOT COMPARE PRICES OF CONTACT LENSES	8%
UNDER 30 MIN	58%
30 MIN OR LONGER	32%
LESS THAN TEN MINUTES	18%
TEN MINUTES TO A HALF HOUR	40%
A HALF HOUR TO AN HOUR	21%
MORE THAN AN HOUR	11%
I DON'T KNOW OR REMEMBER	2%

Question 9A

Thinking about the last time you purchased contact lenses through an online or telephone retailer with a new prescription, how did that retailer get your contact lens prescription?

I PROVIDED THE RETAILER WITH MY PRESCRIPTION	61%
THE RETAILER CONTACTED THE DOCTOR DIRECTLY TO GET MY PRESCRIPTION	35%
THE RETAILER GOT MY PRESCRIPTION ANOTHER WAY	1%
I DON'T KNOW OR REMEMBER	2%

Question 9B

Here are some reasons contact lens retailers may contact eye doctors directly to get patients' prescriptions. Which of the following are reasons your online or telephone contact lens retailer contacted your eye doctor directly for your prescriptions the last time you purchased contact lenses with a new prescription?

n=177

IT IS EASIER FOR ME FOR MY ONLINE OR TELEPHONE RETAILER TO CONTACT MY EYE DOCTOR DIRECTLY	51%
THIS IS THE WAY I HAVE ALWAYS DONE IT	49%
I COULD NOT FIND MY PRESCRIPTION	25%
I COULD NOT REMEMBER MY PRESCRIPTION	18%
OTHER	7%
I DON'T KNOW OR REMEMBER	3%

Question 10

The last time you purchased contacts over the internet or by phone, did that retailer ask for your permission for them to contact your eye doctor to verify your prescription?

n=184

YES	76%
NO	13%
I DON'T KNOW OR REMEMBER	11%

Question 11

Overall, do you think that online or phone contact lens retailers should be required to verify that your contact lens prescription is valid by contacting your eye care professional prior to the sale?

YES, ONLINE OR PHONE RETAILERS SHOULD BE REQUIRED TO VERIFY PRESCRIPTIONS WITH DOCTORS	65%
NO, ONLINE OR PHONE RETAILERS SHOULD NOT BE REQUIRED TO VERIFY PRESCRIPTIONS WITH DOCTORS	28%
I DON'T KNOW	7%

Question 13

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Summary of Attributes: % Very Important

PRICE	80%
REPUTABLE RETAILER	66%
TYPE	65%
BRAND	60%
DELIVERY TIME	52%
QUANTITY DELIVERED AT ONCE	47%

Question 13

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Summary of Attributes: % Total Important

PRICE	99%
REPUTABLE RETAILER	97%
TYPE	95%
BRAND	93%
DELIVERY TIME	92%
QUANTITY DELIVERED AT ONCE	88%

Question 13_1

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Brand

TOTAL IMPORTANT	93%
TOTAL NOT IMPORTANT	7%
VERY IMPORTANT	60%
SOMEWHAT IMPORTANT	33%
NOT VERY IMPORTANT	6%
NOT AT ALL IMPORTANT	1%
I DON'T KNOW	*

Question 13_2

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Type

TOTAL IMPORTANT	95%
TOTAL NOT IMPORTANT	5%
VERY IMPORTANT	65%
SOMEWHAT IMPORTANT	29%
NOT VERY IMPORTANT	4%
NOT AT ALL IMPORTANT	1%
I DON'T KNOW	*

Question 13_3

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Delivery time

TOTAL IMPORTANT	92%
TOTAL NOT IMPORTANT	8%
VERY IMPORTANT	52%
SOMEWHAT IMPORTANT	40%
NOT VERY IMPORTANT	7%
NOT AT ALL IMPORTANT	1%
I DON'T KNOW	0%

Question 13_4

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Quantity delivered at once

TOTAL IMPORTANT	88%
TOTAL NOT IMPORTANT	12%
VERY IMPORTANT	47%
SOMEWHAT IMPORTANT	41%
NOT VERY IMPORTANT	11%
NOT AT ALL IMPORTANT	1%
I DON'T KNOW	*

Question 13_5

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Price

TOTAL IMPORTANT	99%
TOTAL NOT IMPORTANT	1%
VERY IMPORTANT	80%
SOMEWHAT IMPORTANT	19%
NOT VERY IMPORTANT	1%
NOT AT ALL IMPORTANT	0%
I DON'T KNOW	0%

Question 13_6

Please tell us how important you find each of these attributes when purchasing contact lenses online or over the telephone.

Reputable retailer

TOTAL IMPORTANT	97%
TOTAL NOT IMPORTANT	3%
VERY IMPORTANT	66%
SOMEWHAT IMPORTANT	30%
NOT VERY IMPORTANT	3%
NOT AT ALL IMPORTANT	*
I DON'T KNOW	*

Question 14

Below are some reasons people schedule eye doctor visits. Which of the following are reasons you scheduled your most recent eye exam?
Please select as many as appropriate.

I RAN OUT OF CONTACTS OR WAS ABOUT TO RUN OUT OF CONTACTS, SO I NEEDED A NEW PRESCRIPTION	48%
I WAS OVERDUE FOR AN APPOINTMENT	43%
MY VISION CHANGED OR I NEEDED A NEW PRESCRIPTION FOR SOME OTHER REASON	34%
I NEEDED A NEW PAIR OF EYE GLASSES	34%
I RECEIVED AN EMAIL OR MAIL REMINDER FROM MY EYE DOCTOR THAT I WAS DUE FOR AN APPOINTMENT	24%
I TRIED TO REORDER CONTACT LENSES FROM MY ONLINE VENDOR AND WAS UNABLE TO DO SO	20%
I HAD AN EYE ISSUE, EYE PAIN OR EMERGENCY	18%
ANOTHER REASON	3%
I DON'T KNOW OR REMEMBER	2%

Question D1

Gender.

MALE	37%
FEMALE	63%

Question D2

Age.

18-24	12%
25-34	31%
35-44	30%
45-64	24%
65+	3%

Question D3

Region.

NORTHEAST	20%
MIDWEST	18%
SOUTH	31%
WEST	32%

Question D4

Are you of Hispanic, Latino, or Spanish origin?

YES	23%
NO	77%

Question D5

Which of the following best describes your ethnic background?

CAUCASIAN OR WHITE	83%
AFRICAN AMERICAN OR BLACK	9%
ASIAN AMERICAN	4%
NATIVE AMERICAN	1%
OTHER/SEVERAL BACKGROUNDS	3%
PREFER NOT TO ANSWER	0%

Question D6

What is the highest education level you have completed?

HIGH SCHOOL OR LESS	10%
SOME COLLEGE	35%
COLLEGE+	55%
GRADE SCHOOL OR LESS	0%
SOME HIGH SCHOOL	1%
HIGH SCHOOL GRADUATE	10%
SOME COLLEGE OR TRADE SCHOOL	35%
COLLEGE GRADUATE	34%
POST-GRADUATE WORK	21%
PREFER NOT TO ANSWER	0%

Question D7

What is your household income before taxes?

LESS THAN \$25,000 A YEAR	9%
MORE THAN \$25,000 BUT LESS THAN \$50,000	20%
MORE THAN \$50,000 BUT LESS THAN \$75,000	21%
MORE THAN \$75,000 BUT LESS THAN \$100,000	15%
MORE THAN \$100,000 BUT LESS THAN \$125,000	7%
MORE THAN \$125,000 BUT LESS THAN \$150,000	4%
MORE THAN \$150,000 BUT LESS THAN \$175,000	5%
MORE THAN \$175,000 BUT LESS THAN \$200,000	8%
\$200,000 OR MORE	6%
PREFER NOT TO ANSWER	3%

Question D8

Which of the following best describes the community in which you live?

URBAN - LARGE CITY	38%
SUBURBS OF A LARGE CITY	33%
SMALL OR MEDIUM-SIZED TOWN	18%
RURAL AREA	11%
PREFER NOT TO ANSWER	0%