Supporting Statement
Proposed Amendments to the Contact Lens Rule
16 CFR § 315
(OMB Control # 3084-0127)

(1-2) Necessity for Collecting the Information/Use of the Information

The Federal Trade Commission promulgated the Contact Lens Rule ("Rule") pursuant to the Fairness to Contact Lens Consumers Act ("FCLCA"), Public Law 108-164 (December 6, 2003), which was enacted to enable consumers to purchase contact lenses from the seller of their choice. The Rule became effective on August 2, 2004. As mandated by the FCLCA, the Rule requires contact lens prescribers to provide prescriptions to their patients upon the completion of a contact lens fitting, and provide or verify such prescriptions to authorized third parties, such as contact lens sellers. Sellers may provide contact lenses only in accordance with a valid prescription that is presented directly to the seller or verified with the prescriber.

Section 315.3(a)(1) of the Rule requires a prescriber to provide a copy of the contact lens prescription to the patient after completing a contact lens fitting, regardless of whether it was requested by the patient. Section 315.3(a)(1) of the Rule tracks the language of the Act verbatim.[1] This provision, referred to as automatic prescription release, was intended to empower consumers to comparison shop for contact lenses. Based on twelve years of experience enforcing the Rule and after carefully considering the 660 comments that were submitted pursuant to the ongoing periodic review of the Rule,[2] the Commission believes that the overall weight of evidence indicates that compliance with the automatic prescription release provision could be substantially improved.

To further the goals of the FCLCA, the Commission proposes to amend the Rule to require that contact lens prescribers obtain a signed acknowledgment after releasing a contact lens prescription to a patient, and maintain each such acknowledgment for a period of not less than three years. Such signed acknowledgments shall be available for inspection by the Federal Trade Commission, its employees, and its representatives. The Commission believes this provision will help inform patients of their right to their prescriptions, increase the number of patients who receive their prescriptions, and, consequently, increase the number of purchases made with initial presentations of complete and valid prescriptions, thus reducing the number of verifications by third-party sellers. The Commission believes that requiring signed acknowledgments would also improve the Commission's verification and enforcement ability. The addition of a signed acknowledgment requirement would accomplish the desired objectives with little increased burden on prescribers.

[1] 15 U.S.C. 7601(a)(1).
[2] Contact Lens Rule, Request for Comment, 80 Fed. Reg. 53,272 (September 3, 2015).

The proposed requirement that the prescriber request the patient acknowledge receipt of the contact lens prescription would be triggered once the prescriber has presented the prescription to the patient. The patient would receive the prescription prior to being asked to sign the acknowledgment form, and signing the acknowledgment form is not a condition to obtaining the prescription. If the patient refuses to sign or cannot sign the acknowledgment form, the prescriber must note the refusal or inability on the acknowledgment form and must maintain the form.

The proposed acknowledgment form may be either paper or in electronic format. The acknowledgment form, whether paper or electronic, must be entitled "Patient Receipt of Contact Lens Prescription," and must state, "My eye care professional provided me with a copy of my contact lens prescription at the completion of my contact lens fitting. I understand that I am free to purchase contact lenses from the seller of my choice." The acknowledgment form shall be in a format that allows either conventional or electronic signatures. The covered firms (contact lens prescribers) may maintain copies of the acknowledgment forms in paper or electronically.

(3) Consideration of Using Improved Technology to Reduce Burden

The proposed amendments permit the covered firms to use paper or electronic format to reduce the burden of information collection. Moreover, in its Notice of Proposed Rulemaking, the Commission specifically sought comments on ways to minimize the burden of the Rule's collections of information through the use of information technology.

Consistent with the Government Paperwork Reduction Elimination Act, Pub L. No. 105-227, Title XVII, 112 Stat. 2681-749, nothing in the Rule prescribes that the disclosures be made, records be filed or kept, or signatures be executed, on paper or in any particular format that would preclude the use of electronic methods to comply with the Rule's requirements.

(4) Efforts to Identify Duplication

The proposed recordkeeping requirements do not duplicate any other information collection requirements imposed by the Commission. To the extent some state laws may already require prescription release, and/or recordkeeping, similar to that required by the Act, prescribers and sellers likely can comply with both requirements through a single release or record-keeping system, thereby avoiding duplication.

(5) Efforts to Minimize Burden on Small Organizations

The proposed recordkeeping requirements are designed to impose the minimum burden on all affected members of the industry, regardless of size. The Act itself does not allow the Commission any latitude to treat small businesses differently, such as by exempting a particular category of firm or setting forth a lesser standard of compliance for any category of firm.

While some contact lens prescribers subject to the Rule's requirements are small businesses, staff believes that everything consistent with the requirements of Rule has been done to minimize compliance burden. Although the Act requires the Rule to apply to all covered firms whether they are small entities or not, the Commission is seeking comment about minimizing impact on small businesses.

(6) Consequences of Conducting the Collection Less Frequently

The proposed recordkeeping requirement would require that sellers retain the required records for a period of not less than three years. Staff believes that a record retention period shorter than this would hamper the Commission's ability to verify contact lens prescribers' compliance with the Rule, because the statute of limitations applicable to Commission rule violations is three years.[3]

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The proposed amendment's information collection requirements are consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2). Under the proposed rule amendments, the Commission's Rule would only require that covered entities maintain the form for three years. Instances where records are required to be maintained longer than three years are mandated by individual state laws.[4]

(8) Consultation Outside the Agency

In developing the proposed requirements, the Commission considered 660 comments from individuals and entities representing a wide range of viewpoints, including prescribing eye care practitioners (ophthalmologists and optometrists), opticians and other eye wear industry members, sellers of contact lenses (both online and brick-and-mortar), contact lens manufacturers, and consumer and competition advocates.[5] Virtually all commenters agreed that there is a continuing need for the Rule and that it benefits consumers and competition. The majority of commenters recommended some modifications to the Rule in order to maximize the benefits to consumers and competition, decrease the burden on businesses, protect consumers' eye health, or improve overall compliance with the Rule's existing requirements.

[3] *See* Section 19(d) of the FTC Act, 15 U.S.C. 57b(d).
[4] *See, e.g.*, 246 Mass. Code Regs. § 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code § 246-851-290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645-182.2(2) (requiring optometrists to maintain patient records for at least five years); Fla. Admin. Code r. 64B13-3.003(6) (requiring optometrists to maintain patient records for at least five years).
[5] *See supra* note 2.

(9) Payments and Gifts to Respondents

Not applicable.

(10-11) Assurances of Confidentiality/Matters of a Sensitive Nature

Not applicable. No assurance of confidentiality is necessary because although the Contact Lens Rule requires regulated entities to disclose and/or maintain records, it does not require the submission of any such records to the agency. Thus, to the extent, if any, that the agency may require production of such records for law enforcement purposes in specific proceedings, such production would not constitute an information collection activity within the meaning of the Paperwork Reduction Act. In any event, in such proceedings, records would be protected by law from mandatory public disclosure.[6]

(12) Estimated Annual Hours Burden and Associated Labor Cost

Estimated Additional Annual Hours Burden: 683,333 hours.

Commission staff estimates the paperwork burden of the proposed modifications based on its knowledge of the eye care industry. The staff believes there will be an additional burden on individual prescribers' offices to maintain the signed acknowledgment forms for a period of not less than three years.

The number of contact lens wearers in the United States is currently estimated to be approximately 41 million.[7] Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 41 million people would read and sign an acknowledgment form every year.[8]

Maintaining the form for a period of not less than three years does also not impose a substantial new burden on individual prescribers and their office staff. The majority of states already require that optometrists maintain records of eye examinations for at least three years,[9] and adding a one-page acknowledgment form per patient per year should not take more than a few seconds of time, and an inconsequential, or *de minimis*, amount of record space. The

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[6] *See, e.g.*, Section 21 of the FTC Act, 15 U.S.C. 57b-2; Exemption 6 of the Freedom of Information Act, 5 U.S.C. 552(b)(6).

[7] Jennifer R. Cope et al., "Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections—United States, 2014," Morb. Mortal. Wkly. Rep. 64(32):865-70, 866 (Aug. 21, 2015). *See also* Vision Council, "Consumer Barometer," Sept. 2015 (estimating that 16.2% of American adults wear contact lenses).

[8] In the past, some commenters have suggested that typical contact lens wearers obtain annual exams every 18 months or so, rather than one every year. However, because most prescriptions are valid for a minimum of one year under the Rule, and use of a longer exam cycle would lead to an estimate of a lower number of signed acknowledgment forms and a reduced burden, we continue to estimate that patients seek exams every 12 months.

[9] *See supra* note 4.

Commission notes, however, that for optometrists who maintain all records in an electronic format, the new recordkeeping requirement would likely require that office staff electronically scan the signed acknowledgment form and save it as an electronic document. The Commission estimates this scanning and saving would take approximately one minute. Other prescribers might present the acknowledgment form electronically, and such format would allow the signed acknowledgment to be preserved without any additional burden.

The Commission does not possess any information regarding the percentage of prescribers' offices that use paper forms, electronic forms, or that scan paper files and maintain them electronically. Therefore, for purposes of this notice, staff will assume that *all* prescriber offices require a full one minute per form per year for record maintenance purposes arising from the proposed modifications.

As noted above, the number of contact lens wearers in the United States is currently estimated to be approximately 41 million. Therefore, assuming one signed acknowledgment form for each contact lens wearer per year, prescribers' offices, collectively, would have to spend approximately 41 million minutes, or 683,333 hours, per year maintaining records of eye examinations (recordkeeping requirement).

In all likelihood, the actual overall increased burden on prescribers may be less than 683,333 hours, because increasing the number of patients in possession of their prescriptions should correspondingly increase the number of consumers who provide their prescriptions to third-party sellers when purchasing contact lenses. This, in turn, should reduce the number of verification requests that third-party sellers would otherwise make to prescribers. Based on current estimates, responding to verification requests requires that prescribers spend approximately five minutes per request.[10] The Commission, however, does not presently have enough information to devise a reliable estimate for how many more consumers are likely to present third-party sellers with a complete copy of their prescription following the proposed Rule modification. Therefore, for purposes of calculating the burden, the Commission, at this time, will not credit the expected reduction in verification burden.

Estimated Additional Annual Labor Cost Burden: $10,475,495.

Commission staff derives labor costs by applying appropriate hourly cost figures to the burden hours described above. The Commission assumes that office clerks will perform most of the labor when it comes to printing, disseminating, and storing the acknowledgment forms for prescribers' offices. According to Bureau of Labor Statistics, general office clerks earn an average wage of $15.33 per hour.[11] Based on this data, the estimated total additional labor cost

[10] *See* American Optometric Association, Comment in response to the Agency Information Collection Activities; Proposed Collection; Comment Request, 81 FR 31938 (May 20, 2016), https://www.ftc.gov/policy/public-comments/initiative-665.

[11] Press Release, U.S. Dep't of Labor, Bureau of Labor Statistics, "Occupational Employment Statistics—May 2015," http://www.bls.gov/news.release/ocwage.t01.htm.

attributable to the proposed modifications to the Rule would amount to approximately $10,475,495.

While not insubstantial, this amount constitutes just under one-fourth of one percent of the estimated overall retail market for contact lens sales in the United States.[12] Furthermore, the burden is likely to be less, since many prescribers' offices will not require a full three minutes to present, receive back, and store the acknowledgment forms. And, as noted above, increasing the number of patients in possession of their prescriptions should correspondingly increase the number of consumers who provide their prescriptions to third-party sellers when purchasing contact lenses. This, in turn, could potentially reduce the number of verification requests made to prescribers, and the time prescribers spend responding.

(13) Estimated Annual Capital or Other Non-labor Costs

Staff believes that the Rule's recordkeeping requirements impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (e.g., prescription pads, patients' medical charts, facsimile machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

(14) Estimated Cost to Federal Government

Staff believes that the cost to the FTC for administering the proposed Rule changes will be *de minimis*. Accordingly, Commission staff retains the previous estimate of $52,000 per year as the cost to the Government for implementing the Rule. This estimate is based on the assumption that 15-20% of one Attorney work year, 2.5% of one Economist work year, 15% of one Investigator work year, and 15% of one Paralegal work year will be expended to enforce the Rule's requirements.

(15) Program Changes/Adjustments

The proposed amendments will result in an estimated additional 683,333 hours burden hours, annualized, and cumulative of all affected manufacturers, $10,475,495 in associated labor costs, and negligible capital/non-labor costs.

(16) Plans for Tabulation and Publication

Not applicable. There are no plans to publish for statistical use any information required by the Rule.

[12] According to The Vision Council, the contact lens sales market in the United States in 2015 totaled $4,664,200,000 at the retail level. *See* The Vision Council, "U.S. Optical Industry Report Card," Dec. 2015. The estimated additional burden of $10,475,495 thus amounts to approximately 0.22% of the total market.

(17) Requested Permission Not to Display the Expiration Date for OMB Approval

This is not applicable, since the Commission will display the expiration date of the clearance.

(18) Exceptions to the "Certification for Paperwork Reduction Act Submissions"

Not applicable.