Supporting Statement for Information Collection Provisions of
the Contact Lens Rule, 16 CFR Part 315
(OMB Control # 3084-0127)

(1) & (2) Necessity for and Use of the Information Collected

The Fairness to Contact Lens Consumers Act (the "Act"), Pub. L. No. 108-164 (December 6, 2003), helps consumers by requiring the release and verification of contact lens prescriptions, among other things. The Act directed the Federal Trade Commission ("FTC" or "Commission") to prescribe rules implementing the Act not later than 180 days after the Act took effect on February 4, 2004.[1] Accordingly, the Commission issued the Contact Lens Rule ("Rule"), 16 C.F.R. Part 315, on July 2, 2004. As mandated by the Act, the Rule contains disclosure and recordkeeping requirements applying to prescribers and sellers of contact lenses. The extent to which these requirements are subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35 ("PRA"), is described below.

(a) Disclosures

The Rule requires that contact lens prescribers provide patients with a copy of their contact lens prescriptions upon completion of a contact lens fitting and provide prescriptions to, or verify prescriptions with, third parties authorized to act on behalf of patients. The primary purpose of the prescription release requirement is to enable consumers to purchase their contact lenses from the seller of their choice. Without their prescription, consumers may be forced to purchase lenses from their prescriber. By requiring prescribers to provide prescriptions to their patients, the Act enables consumers to compare prices and modes of delivery among competing sellers, and ultimately purchase their lenses from the seller of their choice.

(b) Recordkeeping

The Rule also implements recordkeeping requirements imposed by the Act. First, the Act sets a minimum expiration date of one year for contact lens prescriptions, with an exception based on the medical judgment of a prescriber with respect to a patient's eye health. In cases in which a prescriber sets an expiration date shorter than one year, the Rule requires the prescriber to document in the patient's record the medical reasons for the shorter period. The Rule further requires that such records be kept for three years.

Second, the Act provides that a contact lens seller may sell contact lenses only in accordance with a prescription that the seller either (a) has received from the patient or prescriber, or (b) has verified with the prescriber. The Act, and hence the Rule, requires contact lens sellers to maintain records of verification communications with prescribers. The records to be kept depend on the mode of communication – telephone, facsimile, or email. The Rule also requires sellers to keep the prescriptions they receive directly from the patient or prescriber. The Rule requires that sellers keep these records for three years and make them

[1] 15 U.S.C. § 7607.

available for inspection by the Commission, but does not otherwise require production of the records.

The required records will allow the Commission to determine compliance with the Rule and provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult to ensure that entities are complying with the Rule's requirements or to prove Rule violations.

(3) Consideration of the Use of Information Technology to Reduce Burden

The Rule contemplates that covered entities may use information technologies in complying with their recordkeeping obligations under the Act. Such technologies may help reduce the burden of information collection imposed by the Act. For example, contact lens sellers who seek to verify prescriptions via facsimile and/or email may use information technology to create and/or retain those records as required by the Rule, and thereby reduce the time it may take to produce and maintain verification requests. In addition, nothing in the Act or Rule prohibits regulated entities from using the least burdensome information technology available. Moreover, in its Notice of Proposed Rulemaking,[2] 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 Rule's disclosure and 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 Rule's disclosure and 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.

However, staff believes that the burdens imposed by the Rule on small businesses will be relatively low. Based on staff's knowledge of the eyewear industry, the small businesses

[2] 69 Fed. Reg. 5,440 (Feb. 4, 2004).

affected by the Rule primarily consist of contact lens prescribers in solo or small practices. Their burdens under the Rule primarily entail providing contact lens prescriptions to patients or their agents, documenting in exceptional cases the medical reasons for setting a contact lens prescription date of less than one year, and verifying prescriptions for some of their patients who seek to purchase their contact lenses from another seller. The Rule permits some limitation on prescription release and verification. For example, the Rule does not require prescribers to provide additional copies of prescriptions to patients after the initial release upon completion of a contact lens fitting, although the Rule does not prohibit this practice.

(6) Consequences of Conducting the Collection Less Frequently

Less frequent "collection" would violate the express statutory language of the Fairness to Contact Lens Consumers Act, 15 U.S.C. §§ 7601 *et seq*. Specifically, the Act's requirements that prescribers release contact lens prescriptions to their patients upon completion of a contact lens fitting, and document the medical reasons for setting a contact lens prescription expiration date shorter than one year, do not permit less frequent disclosure.[3] Similarly, the Act's requirement that contact lens sellers retain records of all direct communications involved in obtaining prescription verification does not permit less frequent collection of information.[4]

The Commission's Rule requires that sellers retain the required records for a period of three years. Staff believes that a record retention period shorter than three years would hamper the Commission's ability to verify contact lens prescribers' and sellers' compliance with the Rule, because the statute of limitations applicable to Commission rule violations is three years.[5]

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The collection of information in the Rule is consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2).

(8) Public Comments/Consultation Outside the Agency

On May 20, 2016, the FTC sought public comment on the Rule's information collection requirements and on the associated estimates of PRA burden. 81 Fed. Reg. 31,938. The Commission received comments from the American Optometric Association ("AOA") and 1-800 CONTACTS, Inc. ("1-800"), a seller of contact lenses. The AOA states in its comment that the FTC should (1) increase the estimate of time required for a prescriber to respond to a verification request from 3 minutes to at least 5 minutes, (2) include in its estimate the time prescribers spend addressing issues that may arise as a result of the Rule, and (3) include wages for ophthalmologists in the estimate for labor cost. The AOA also states that the FTC's description of the time required to provide a copy of the prescription to the patient mischaracterizes the assessment, fitting, and prescription process.

[3] *See* 15 U.S.C. §§ 7601, 7604.
[4] *See* 15 U.S.C. § 7603(b).
[5] *See* Section 19(d) of the FTC Act, 15 U.S.C. 57b(d).

1-800 CONTACTS states in its comment its belief that the current information costs of the Rule are reasonable and justified. However, it states that the FTC has overestimated the number of hours that prescribers spend releasing prescriptions because certain states require that prescriptions be valid for two years and because some prescribers are not releasing prescriptions. The company also opined that increased compliance would lessen the Rule's burden, requested increased enforcement, and suggested a change to the Rule to improve compliance.

Data provided and requested by the AOA is reflected in updated burden estimates set out below and both the AOA's and 1-800's comments are addressed further in our response to Specification 12 (Estimated Annual Hours and Labor Cost Burden) below.

Pursuant to the OMB regulations that implement the PRA (5 C.F.R. Part 1320), the FTC is providing a second opportunity for public comment while seeking OMB approval to extend the existing paperwork clearance for the Rule.

(9) Payments and Gifts to Respondents

Not applicable.

(10) Assurances of Confidentiality

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]

(11) Matters of a Sensitive Nature

Not applicable. The Contact Lens Rule does not require the disclosure or production of sensitive or confidential information to the Commission. To the extent that confidential information covered by a recordkeeping requirement is collected by the Commission for law enforcement purposes, the confidentiality provisions of Section 21 of the FTC Act, 15 U.S.C. 57b-2, will apply.

[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).

(12) Estimated Annual Hours and Labor Cost Burden

Estimated total annual hours burden: Approximately 1,903,315 hours.

This figure is derived by adding 949,710 disclosure hours for contact lens prescribers to 953,605 recordkeeping hours for contact lens sellers, for a combined industry total of 1,903,315 hours. This is higher than estimates submitted to OMB in 2013 (the figure was 1,594,981 hours in July 2013). The higher estimate is due to an increase in the estimated number of contact lens wearers from 38 million (2012) to 41 million (2015), an increase in the estimated percentage of verification requests that require the prescribers to make an affirmative response, and an increase in the estimated amount of time prescribers spend responding to verification requests.

1. Prescribers

The Rule requires prescribers to make disclosures in two ways. Upon completing a contact lens fitting, the Rule requires that prescribers (1) provide a copy of the contact lens prescription to the patient, and (2) as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription. Prescribers can verify a prescription either by responding affirmatively to a request for verification, or by not responding at all, in which case the prescription will be "passively verified" after eight business hours. Prescribers are also required to correct an incorrect prescription submitted by a seller, and notify a seller if the prescription submitted for verification is expired or otherwise invalid. Staff believes that the burden of complying with these requirements is relatively low.

As noted above, the number of contact lens wearers in the United States is estimated to be approximately 41 million. Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 41 million people would receive a copy of their prescription each year under the Rule.

At an estimated one minute per prescription, the annual time spent by prescribers complying with the requirement to release prescriptions to patients would be approximately 683,333 hours. [(41 million × 1 minute)/60 minutes = 683,333 hours]. This estimate likely overstates the actual burden because it includes the time spent by prescribers who already release prescriptions to patients in the ordinary course of business.[7]

[7] In its comment, the AOA stated that the FTC's description of the brief time required to provide a copy of the prescription to the patient mischaracterizes the assessment, fitting, and prescription process. However, the OMB regulation that implements the PRA defines the "burden" calculated for this purpose to exclude any effort that would be expended regardless of a regulatory requirement. Since the prescriber assesses and fits the patient, and creates the underlying prescription in the ordinary course of business, we do not include the time spent on these tasks as part of the PRA burden. This calculation only takes into account the extra effort by the prescriber or prescriber's office to create or print a copy of the prescription, sign it, and hand it to the patient as required by the Rule.

1-800 CONTACTS commented that staff's estimate of the prescription release burden on prescribers is too high because (1) certain state laws require that prescriptions be valid for two years – meaning that some patients may only receive a prescription once every two years, and (2) some prescribers are not releasing prescriptions as required by the Rule. While staff's estimate may overstate the burden for these reasons, we assume the annual release of a prescription for each contact lens wearer provides the best estimate because the Contact Lens Rule requires that most prescriptions be valid for at least one year and many patients may return to their doctor annually regardless of when their prescription expires. Additionally, staff believes a calculation that assumes compliance with the Rule will provide the best estimate of the Rule's contemplated burden.[8]

As stated above, prescribers may also be required to provide or verify contact lens prescriptions to sellers. According to recent survey data, approximately 35.6% of contact lens purchases are from a source other than the prescriber. Assuming that each of the 41 million contact lens wearers in the U.S. makes one purchase per year, this means that approximately 14,596,000 contact lens purchases (41 million x 35.6%) are made from sellers other than the prescriber.

Based on recent discussions with industry, approximately 73% of sales by non-prescriber sellers require verification, and prescribers affirmatively respond (by notifying the seller that the prescription is invalid or incorrect) to approximately 15% of those verification requests. Using a response rate of 15%, the FTC therefore estimates that prescribers' offices respond to approximately 1,598,262 verification requests annually. [(14,596,000 x 73%) x 15% = 1,598,262 responses]. Additionally, some prescribers may voluntarily respond to verification requests and confirm prescriptions (as opposed to simply letting the prescription passively verify). Because correcting or declining incorrect prescriptions is mandated by the Rule and occurs in response to approximately 15% of requests, staff assumes that prescribers voluntarily confirm prescriptions less often, and confirm no more than an additional 15% of prescriptions. Using a combined response rate of 30%, the FTC estimates that prescribers' offices respond to approximately 3,196,524 requests annually.

According to the AOA, responding to verification requests requires approximately five minutes per request.[9] Using that data, we estimate that these responses require an additional

[8] 1-800 CONTACTS also opined that increased compliance with the release requirements of the Rule would lessen the Rule's overall burden (by reducing the number of verifications required), requested additional enforcement of the Rule, and suggested a change to the Rule. Staff appreciates these comments and advises 1-800 CONTACTS to stay informed about the Commission's ongoing Rule review. See https://www.ftc.gov/news-events/press-releases

[9] Although a comment that AOA previously submitted in 2013 indicated that responding to a verification request requires approximately 3 minutes, the AOA now recommends in its 2016 comment that the Commission use 5 minutes for this estimate. The AOA states that the recent survey on which the estimate is based was of approximately 300 optometric practices. This survey may not be representative of all offices due to its small size and the characteristics of responding offices. However, absent other data upon which to rely, the staff elects to use~~s~~ this 5 minute estimate.

266,377 hours annually. [(3,196,524 × 5 minutes)/60 minutes = 266,377 hours]. Combining these hours with the hours spent disclosing prescriptions to consumers, we estimate a total of 949,710 hours for contact lens prescribers. [683,333 + 266,377 hours = 949,710 hours].[10]

Lastly, as required by the FCLCA, the Rule also imposes a recordkeeping requirement on prescribers. They must document the specific medical reasons for setting a contact lens prescription expiration date shorter than the one-year minimum established by the FCLCA. This burden is likely to be nil because the requirement applies only in cases when the prescriber invokes the medical judgment exception, which is expected to occur infrequently, and prescribers are likely to record this information in the ordinary course of business as part of their patients' medical records. As mentioned previously, the OMB regulation that implements the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement.

2. Sellers

As noted above, a seller may sell contact lenses only in accordance with a valid prescription that the seller (a) has received from the patient or prescriber, or (b) has verified through direct communication with the prescriber. The FCLCA also requires sellers to retain prescriptions and records of communications with prescribers relating to prescription verification for three years. Staff believes that the burden of complying with these requirements is relatively low.

As stated previously, there are approximately 14,596,000 sales by non-prescriber sellers annually and approximately 73% of those sales require verification. Therefore, sellers verify approximately 10,655,080 orders annually and retain two records for such sales: the verification request and any response from the prescriber. Staff estimates that sellers' verification and recordkeeping for those orders will entail a maximum of five minutes per sale. At an estimated five minutes per sale to each of the approximately 10,655,080 orders, contact lens sellers will spend a total of 887,923 burden hours complying with this portion of the requirement. [(10,655,080 orders × 5 minutes)/60 minutes = 887,923 hours].

This means that approximately 27% of the remaining sales to non-prescriber sellers do not require verification and require the seller to keep only the prescription provided. Staff estimates that this recordkeeping burden requires at most one minute per order for 3,940,920 orders, resulting in 65,682 burden hours. [(3,940,920 orders × 1 minute)/60 minutes = 65,682 hours].

[10] In its comment, the AOA also asked that the FTC include in its estimate the time that prescribers spend addressing issues that may arise with retailers. Staff declines to do so as staff cannot predict or estimate times for sporadic issues that may arise. In fact, we may already account for such issues in our estimate to the extent the 5 minutes discussed above includes them.

Combining burden hours for all orders, staff estimates a total of 953,605 hours for contact lens sellers. This estimate likely overstates the actual burden because it includes the time spent by sellers who already keep records pertaining to contact lens sales in the ordinary course of business. In addition, the estimate may overstate the time spent by sellers to the extent that records (e.g., verification requests) are generated and stored automatically and electronically, which staff understands is the case for some online sellers.

Estimated total labor cost burden: Approximately $73,082,912.

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. In its comment, the AOA requested that the estimate use salary figures for ophthalmologists as well as opticians. Based on information from the industry, staff estimates that optometrists account for approximately 85% of prescribers. We assume that the other 15% of prescribers are ophthalmologists. According to Bureau of Labor Statistics, salaried optometrists earn an average wage of $55.65 per hour, other physicians and surgeons, such as ophthalmologists, earn an average wage of $95.05 per hour, and general office clerks earn an average wage of $15.33 per hour.[11]

Assuming that optometrists are performing 85% of the labor hours and ophthalmologists are performing 15% the labor hours for prescribers, and office clerks are performing the labor for non-prescriber sellers, estimated total labor cost attributable to the Rule would be approximately $73,082,912. [$58,464,147.60 for prescriber hours (($55.65 x 807,253.5 optometrist hours) + ($95.05 x 142,456.5 ophthalmologist hours)) + $14,618,765 for seller hours ($15.33 x 953,605 office clerk hours)].

The contact lens market is a multibillion-dollar market. One survey estimates that contact lens sales in the U.S. in 2015 totaled $4,664,200,000 at the retail level. The total labor cost burden estimate of $73,082,912 represents approximately 1.6% of the overall retail market.

(13) Capital and Other Non-Labor Costs

Estimated annual non-labor cost burden: $0 or minimal.

Staff believes that the Rule's disclosure and 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).

[11] *See* Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics – May 2015, available at http://www.bls.gov/news.release/ocwage.t01.htm.

(14) Estimated Cost to the Federal Government

Staff estimates that the fiscal year cost to the FTC of enforcing the Rule's requirements will be approximately $52,000 per year. 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 or Adjustments

There are no program changes since the FTC's prior clearance renewal in 2013. The increased estimates for burden hours are largely due to an upward adjustment in the estimated number of contact lens wearers (from 38 million in 2013 to 41 million in 2016) and staff's belief that the percentage of sales in the industry that requires an original prescriber to correct a prescription from a third-party seller is currently higher than what was previously estimated (from 5.1% in 2013 to 15% in 2016) along with the instances where an original prescriber voluntarily confirms a request to a third-party seller that is already correct (from 5.1% in 2013 to 15% in 2016). Additionally, there is an increase in the estimated amount of time that prescribers spend responding to verification requests from third-party sellers (from 3 minutes per request in 2013 to 5 minutes per request in 2016). Finally, there is an upward adjustment in our annual labor costs stemming from updated labor categories that now include ophthalmologists as a portion of prescribers' costs. Previously, such costs were covered exclusively by optometrists which have a lower mean hourly rate.

(16) Statistical Use of Information/Publication of Results

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

(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.