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), assists 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 final 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 implements the Act's requirement that contact lens prescribers provide patients with a copy of their contact lens prescriptions upon completion of a contact lens fitting, and provide such prescriptions to third parties authorized to act on behalf of patients. *See* 15 U.S.C. § 7601. 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 enable 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 ocular 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 justifying the shorter date. *See* 15 U.S.C. § 7604(b). The Rule further requires that such records be kept for three (3) 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 through communication with the prescriber. For verification, the Act further requires contact lens sellers to maintain records of relevant communications with prescribers. Accordingly, the Rule requires that sellers maintain records of such

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[1] 15 U.S.C. § 7607.

communications, with the records maintained dependent on the mode of communication – telephone, facsimile, or email. The Rule also requires sellers to retain the prescriptions they may receive directly from the patient or prescriber. The Rule requires that sellers keep all these records for three years and make them available for inspection by the Commission, but does not otherwise require production of the records.

The information retained pursuant to the Rule's recordkeeping requirements will be used by the Commission to substantiate compliance with the Rule and may also provide a basis for the Commission to bring an enforcement action. Without the required records, it would be difficult either to ensure that entities are complying with the Rule's requirements or to bring enforcement actions based on violations of the Rule.

(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 verification of prescriptions via facsimile and/or email, may use information technologies 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 to reduce compliance burdens. Moreover, in its Notice of 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 filed or kept, or signatures 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.

[2] 69 FR 5440 (Feb. 4, 2004).

(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, the FTC staff believes that the burdens imposed by the Rule on small businesses will be relatively low. Based on the staff's knowledge of the eye wear industry, the small businesses affected by the Rule primarily will consist of contact lens prescribers in solo or small practices. Their burdens under the Rule primarily would 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.[3] The Rule permits some limitation on prescription release and verification. For example, the Commission has indicated that 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 either.

(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. *See* 15 U.S.C. §§ 7601, 7604. 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. *See* 15 U.S.C. § 7603(b).

The Commission's Rule requires that sellers retain the required records for a period of three (3) years. The FTC staff believes that a record retention period that is 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. *See* Section 19(d) of the FTC Act, 15 U.S.C. 57b(d).

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The collection of information in the Rule is consistent with all applicable guidelines

[3] The more significant recordkeeping burdens imposed by the Act are likely to fall primarily on nonprescriber contact lens sellers which the FTC staff believes are larger companies for the most part.

contained in 5 C.F.R. § 1320.5(d)(2).

(8) Public Comments/Consultation Outside the Agency

On December 24, 2009, the FTC sought public comments on its proposal to extend its current OMB clearance for the Rule's information collection requirements. 74 Fed. Reg. 68427. No comments were received.

(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 with 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. *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).

(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.

(12) Estimated Annual Hours and Labor Cost Burden

Estimated total annual hours burden: 850,000 hours (rounded to the nearest thousand).

Based upon staff knowledge of the industry, this figure is derived by adding approximately 567,000 disclosure hours for contact lens prescribers to approximately 283,000 recordkeeping hours for contact lens sellers, for a combined industry total of 850,000 hours. This is slightly lower than the estimates previously submitted to OMB (the similar figure was

950,000 hours in 2006); and is due to a drop in the estimated number of contact lens wearers from 36 million (2006) to 34 million (2008).

No provisions in the Rule have been amended since staff's prior submission to OMB. The Rule's disclosure and recordkeeping requirements, therefore, remain the same. As noted above, the number of contact lens wearers in the United States is estimated to be approximately 34 million.[4] Therefore, assuming an annual contact lens exam for each contact lens wearer, 34 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 disclosure requirement would be a maximum of 567,000 hours. [(34 million × 1 minute)/60 minutes = 566,667 hours].

As required by the FCLCA, the Rule also imposes two recordkeeping requirements. First, prescribers 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. The OMB regulation that implements the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement. 5 C.F.R. 1320.3(B)(3)(2).

Second, the Rule requires contact lens sellers to maintain certain documents relating to contact lens sales. As noted above, a 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 through direct communication with the prescriber. The FCLCA 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 this requirement is low. Sellers who seek verification of contact lens prescriptions must retain one or two records for each contact lens sale: Either the relevant prescription itself, or the verification request and any response from the prescriber. Staff estimates that such recordkeeping will entail a maximum of five minutes per sale, including time spent preparing a file and actually filing the record(s).

Staff also believes that, based on its knowledge of the industry, this burden will fall primarily on mail order and Internet-based sellers of contact lenses, as they are the entities in the industry most reliant on obtaining or verifying contact lens prescriptions. Based on conversations with the industry, staff estimates that these entities currently account for

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[4] *See* Contact Lenses, Frequently Asked Questions, November, 2009, available at (http://www.allaboutvision.com/faq/contactlens.htm.). See also Nichols, J. "Annual Report: Contact Lenses 2008," Contact Lens Spectrum, Jan. 2009, available at (http://www.clspectrum.com/article.aspx?article=102473).

approximately 10 % of sales in the contact lens market[5] and, by extension, that approximately 3.4 million consumers—10 % of the 34 million contact lens wearers in the United States—purchase their lenses from them.

At an estimated five minutes per sale to each of 3.4 million consumers, contact lens sellers will spend a total of 283,300 burden hours complying with the recordkeeping requirement. [(3.4 million × 5 minutes)/60 minutes = 283,333.3 hours]. This estimate likely overstates the actual burden, however, 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 larger online sellers.

Estimated total labor cost burden: $32,317,000 (rounded to the nearest thousand).

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Staff estimates, based on its knowledge of the industry, that optometrists account for approximately 75 % of prescribers. Consequently, for simplicity, staff will focus on their average hourly wage in estimating prescribers' labor cost burden.

According to Bureau of Labor Statistics from May 2008, salaried optometrists earn an average wage of $50.58 per hour and general office clerical personnel earn an average of $12.90 per hour.[6] With these categories of personnel, respectively, likely to perform the brunt of the disclosure (for optometrists) and recordkeeping (for office clerks) aspects of the Rule, estimated total labor cost attributable to the Rule would be approximately $32.8 million. [($50.58 × 566,666.7 hours) + ($12.90 × 283,333.3 hours) = $32,317,001]

The contact lens market is a multibillion dollar market; one recent survey estimates that contact lens sales totaled $2.37 billion from Jan 1, 2006 to Dec 31, 2006.[7] Thus, the total labor cost burden estimate of $32.3 million represents approximately 1.5 % of the overall market.

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[5] The FTC's February 2005 study, "The Strength of Competition in the Rx Sale of Contact Lenses: An FTC Study," cites various data that, averaged together, suggests that approximately 10% of contact lens sales are by online and mail-order sellers. The report is available online at (http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf).

[6] Mean and median worker hourly wages for optometrists and general office clerks are drawn from the Bureau of Labor Statistics (BLS) Occupational Employment and Statistics Survey, May 2008, based on BLS-sampled data it collected over a 3-year period. *See* (http://www.bls.gov/news.release/pdf/ocwage.pdf) (Table 1).

[7] The Vision Council of America and Jobson Optical Research have conducted large scale continuous consumer research under the name VisionWatch, which reports on the vision care industry. The basis for this statistic is on file with the Federal Trade Commission.

(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.

(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 $35,000 per year. This estimate is based on the assumption that 10-15% of one full Attorney work year, 2.5% of one Economist work year, and 10% of one Investigator work year will be expended to enforce the Rule's requirements relating to disclosure and recordkeeping. Clerical and other support services are also included in this estimate.

(15) Program Changes or Adjustments

There are no program changes posed by the final Rule. The decreased estimates for burden hours and labor costs from the FTC's prior clearance request are due to a decreased number of contact lens wearers in the U.S. (previously estimated at 36 million, now 34 million).

(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.