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.

(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 July 5, 2019, the FTC sought public comment on the Rule's information collection requirements and on the associated estimates of PRA burden. 84 Fed. Reg. 32,170. The FTC received no comments that were germane to the issues that the agency sought comment on pursuant to the PRA renewal request. Pursuant to OMB regulations, 5 CFR Part 1320, that implement the PRA, 44 U.S.C. 3501 et seq., the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule.

(9) Payments and Gifts to Respondents

Not applicable.

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[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).

(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.

(12) Estimated Annual Hours and Labor Cost Burden

Estimated annual hours burden: 2,104,050 hours.

This figure is derived by adding 1,045,650 disclosure hours for contact lens prescribers to 1,058,400 recordkeeping hours for contact lens sellers, for a combined industry total of 2,104,050 hours. This estimate is an increase from the 1,903,315 annual burden hours submitted to OMB in 2016. The higher estimate is due to an increase in the estimated number of contact lens wearers in the United States from 41 million to 45 million.[7]

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

[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] Centers for Disease Control, Healthy Contact Lens Wear and Care, Fast Facts, *https://www.cdc.gov/contactlenses/fast-facts.html*.

the prescription submitted for verification is expired or otherwise invalid. Staff believes that the burden of complying with these requirements is relatively low.

The number of contact lens wearers in the United States is now estimated by the Centers for Disease Control to be approximately 45 million.[8] Therefore, assuming an annual contact lens exam for each contact lens wearer, approximately 45 million people would receive a copy of their prescription each year under the Rule.[9]

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 750,000 hours. [(45 million × 1 minute)/60 minutes = 750,000 hours]. In all likelihood, this estimate overstates the actual burden because it includes the time spent by prescribers who already release prescriptions to patients in the ordinary course of business.

As stated above, prescribers may also be required to provide or verify contact lens prescriptions to sellers. According to recent survey data, approximately 36% of contact lens purchases are from a source other than the prescriber.[10] Assuming that each of the 45 million contact lens wearers in the U.S. makes one purchase per year, this means that approximately 16,200,000 contact lens purchases (45 million x 36%) are made from sellers other than the prescriber.

Based on prior 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 1,773,900 verification requests annually [(16,200,000 x 73%) x 15% = 1,773,900 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 at most an additional 15% of prescriptions (and, in all likelihood, significantly less). Using a combined response rate of 30%, the FTC estimates that prescribers' offices respond to approximately 3,547,800 requests annually.

According to the industry comments to the 2016 PRA submission, responding to verification requests requires approximately five minutes per request. Using that data, we estimate that these responses require an additional 295,650 hours annually. [(3,547,800 × 5

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[8] *Id.*

[9] In the past, some commentators have suggested that typical contact lens wearers obtain annual exams every 18 months or so, not every year. However, because prescriptions under the Rule are valid for a minimum of one year, we continue to estimate that patients seek exams every 12 months. Staff believes a calculation that assumes compliance with the Rule will provide the best estimate of the Rule's contemplated burden.

[10] Jason J. Nichols & Deborah Fisher, "2018 Annual Report," Contact Lens Spectrum, Jan. 1, 2019, *https://www.clspectrum.com/issues/2019/january-2019*.

minutes)/60 minutes = 295,650 hours]. Combining these hours with the hours spent disclosing prescriptions to consumers, we estimate a total of 1,045,650 hours for all contact lens prescribers to comply with the Rule. [750,000 hours + 295,650 hours = 1,045,650 hours].

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 has (a) received from the patient or prescriber, or (b) 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 16,200,000 sales by non-prescriber sellers annually and approximately 73% of those sales require verification. Therefore, sellers verify approximately 11,826,000 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 11,826,000 orders, contact lens sellers will spend a total of 985,500 burden hours complying with this portion of the requirement. [(11,826,000 × 5 minutes)/60 minutes = 985,500 hours].

Approximately 27% of sales to non-prescriber sellers do not require verification and thus require only that the seller retain the prescription provided. Staff estimates that this recordkeeping burden requires at most one minute per order (in many cases, this retention is electronic and automatic and will not require any time) for 4,374,000 orders [16,200,000 sales × 27%], resulting in 72,900 burden hours. [(4,374,000 orders × 1 minute)/60 minutes = 72,900 hours].

Combining burden hours for all orders [985,500 hours + 72,900 hours], staff estimates a total of 1,058,400 hours for contact lens sellers. It is likely that this estimate 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, and those whose records are generated and preserved automatically when a customer orders online, which staff believes is the case for many online sellers.

Estimated total labor cost burden: Approximately $84,548,448.

This figure is derived from applying hourly wage figures for optometrists, ophthalmologists, and office clerical staff to the burden hours described above. This estimate is higher than the $73,082,912 labor cost estimate submitted to OMB in 2016 due to an increase in the estimated number of contact lens wearers in the United States and wage increases for optometrists, ophthalmologists, and office staff.

According to Bureau of Labor Statistics, salaried optometrists earn an average wage of $57.68 per hour, other physicians and surgeons—such as ophthalmologists—earn an average wage of $98.02 per hour, and general office clerks earn an average wage of $16.92 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 total approximately $84,548,448. [$66,640,319 prescriber hours (($57.68 × 888,802.5 optometrist hours = $51,266,128) + ($98.02 × 156,847.5 ophthalmologist hours = $15,374,192)) + $14,618,765 for seller hours ($16.92 × 1,058,400 office clerk hours = $17,908,128) = $84,548,448.]

A recent survey estimated that the U.S. contact lens market revenue is approximately $5,012,800,000 (not counting examination revenue) in 2017.[12] Therefore, the total labor cost burden estimate of $84,548,448 imposed by the Rule represents a cost of approximately 1.69% of the overall retail revenue generated.

(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

[11] Press Release, Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics – May 2018, *https://www.bls.gov/news.release/ocwage.t01.htm.* Median salaries for prescribers and clerks ($53.75 for optometrists, $96.58 for other physicians and surgeons, and $15.74 for general office clerks) are lower than average salaries and, consequently, would result in a lower overall burden imposed by the Rule. It is possible that medians are more representative since they do not include outliers that can distort the mean. Salaries can also vary by region. The average hourly wage for optometrists in New Mexico, for instance, is $41.76 per hour, whereas optometrists in North Dakota earn an average of $84.18 per hour. *Id*. *https://www.bls.gov/oes/current/oes291041.htm*. However, since Contact Lens Rule PRA submissions have historically used national mean salaries to estimate the burden, the FTC will continue to do so for this submission.

[12] "Vision Markets See Continued Growth in 2017, VisionWatch Says," Vision Monday, March 20, 2018, *http://www.visionmonday.com/business/research-and-stats/article/vision-markets-see-continued-growth-in-2017-visionwatch-says/*. *See also*, Steve Kodey, US Optical Market Eyewear Overview, 4, *https://www.ftc.gov/sites/default/files/filefield_paths/steve_kodey_ppt_presentation.pdf*. The FTC does not possess market data for 2018.

machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

(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 2016. The increased estimates for burden hours are largely due to an upward adjustment in the estimated number of contact lens wearers (from 41 million in 2016 to 45 million in 2019). Additionally, there is an upward adjustment in our annual labor costs stemming from slightly higher estimated hourly rates.

(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.