BILLING CODE: 6750-01-S

FEDERAL TRADE COMMISSION

Agency Information Collection Activities;

Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice.

SUMMARY: The information collection requirements described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (PRA). The FTC seeks public comments on its proposal to extend, for three years, the current PRA clearance for information collection requirements contained in the Contact Lens Rule. This clearance expires on September 30, 2016.

DATES: Comments must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comments part of the SUPPLEMENTARY INFORMATION section below. Write "Contact Lens Rule: FTC File No. P054510" on your comment, and file your comment online at https://ftcpublic.commentworks.com/ftc/contactlensrulepra by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the

Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the collection of information and supporting documentation should be addressed to Alysa S. Bernstein, Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Mail Drop CC-10528, Washington, DC 20580, at (202) 326-3289.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act ("PRA"), 44 U.S.C. 3501-3520, federal agencies must get OMB approval for each collection of information they conduct, sponsor, or require. "Collection of information" means agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing PRA clearance for the information collection requirements associated with the Commission's rules and regulations under the Contact Lens Rule, 16 CFR part 315 (OMB Control Number 3084-0127).

The FTC invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the

information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond. All comments must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

The Rule was promulgated by the FTC pursuant to the Fairness to Contact Lens Consumers Act (FCLCA), Pub. L. 108-164 (Dec. 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 the release and verification of contact lens prescriptions and contains recordkeeping requirements applying to both prescribers and sellers of contact lenses.

Specifically, the Rule requires that prescribers provide a copy of the prescription to the consumer upon the completion of a contact lens fitting, even if the patient does not request it, and verify or provide prescriptions to authorized third parties. The Rule also mandates 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 direct communication with the prescriber. In addition, the Rule imposes recordkeeping requirements on contact lens prescribers and sellers. For example, the Rule requires prescribers to document in their patients' records the medical reasons for setting a contact lens prescription expiration date of less than one

year. The Rule requires contact lens sellers to maintain records for three years of all direct communications involved in obtaining verification of a contact lens prescription, as well as prescriptions, or copies thereof, which they receive directly from customers or prescribers.

The information retained under the Rule's recordkeeping requirements is 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.

No substantive provisions in the Rule have been amended or changed since staff's prior submission to OMB.[1] Thus, the Rule's disclosure and recordkeeping requirements remain the same.

Estimated total annual hours burden: Approximately 1,796,764 hours.

This figure is derived by adding 843,159 disclosure hours for contact lens prescribers to 953,605 recordkeeping hours for contact lens sellers, for a combined industry total of 1,796,764 hours. This is higher than estimates submitted to OMB in 2013 (the respective 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), and an increase in the

[1] The FTC most recently submitted clearance three years ago. 78 FR 9391 (Feb. 8, 2013) and 78 FR 44122 (Jul. 23, 2013).

estimated percentage of verification requests that require the prescribers to make an affirmative response.

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.[2] 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.[3] Therefore, assuming an annual contact lens exam for each contact

[2] 16 CFR 315.5.

[3] Jason J. Nichols, 2015 Annual Report: Contact Lenses 2015, Contact Lens Spectrum, Vol. 31, Jan. 2016, pp. 18-23, 18.

lens wearer, approximately 41 million people would receive a copy of their prescription each year under the Rule.[4]

At an estimated one minute per prescription,[5] 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.

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.[6] Assuming that each of the 41 million contact lens wearers in the U.S. makes one purchase per year, this means that approximately

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[4] 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 most prescriptions are valid 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 exams and a reduced burden, we continue to estimate that patients seek exams every 12 months.

[5] In the past, some commenters have suggested that prescribers spend three to five minutes providing a prescription to each patient. However, the Paperwork Reduction Act defines "burden" in such a way that it excludes any effort that would be expended regardless of a regulatory requirement. 5 CFR 1320.3(b)(2). In most instances, an eye care professional would already spend time inputting the prescription into the patient's file regardless of the Rule, and the extra burden imposed by the Rule is merely copying that prescription for the patient, which we estimate at one minute.

[6] VisionWatch Eyewear U.S. Study, The Vision Council, Contact Lenses, December 2015, 11A.

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.

We estimate that responding to verification requests requires three minutes per request.[7] Using that data, we estimate that these responses require an additional 159,826 hours annually. [(3,196,524 × 3 minutes)/60 minutes = 159,826 hours].

[7] This estimate is based on the Comment of Roger Jordan of the American Optometric Association, April 9, 2013, at 2, available on the FTC's website at https://www.ftc.gov/policy/public-comments/initiative-479.

Combining these hours with the hours spent disclosing prescriptions to consumers, we estimate a total of 843,159 hours for contact lens prescribers. [683,333 + 159,826 hours = 843,159 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.[8]

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.

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[8] 5 CFR 1320.3(b)(2).

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].

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 $61,540,563.

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Based on information from the industry, staff estimates that optometrists account for approximately 85% 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, salaried optometrists earn an average wage of $55.65 per hour and general office clerks earn an average wage of $15.33 per hour.[9]

Assuming that optometrists are performing the brunt of the labor for prescribers and office clerks are performing the labor for non-prescriber sellers, estimated total labor cost attributable to the Rule would be approximately $61,254,481. [($55.65 x 843,159 prescriber hours = 46,921,798) + ($15.33 x 953,605 office clerk hours = 14,618,765) = $61,540,563].

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.[10] The total labor cost burden estimate of $61,540,563 represents approximately 1.3% of the overall retail market.

Request for Comments:

You can file a comment online or on paper. Write "Contact Lens Rule: FTC File No. P054510" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public

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[9] 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.

[10] The Vision Council, US Optical Industry Report Card, December 2015.

Commission website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential," as discussed in section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, the Commission encourages you to submit your

comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/contactlensrulepra by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov, you also may file a comment through that website.

If you file your comment on paper, write "Contact Lens Rule: FTC File No. P054510" on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610, (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610, (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at http://www.ftc.gov/ftc/privacy.htm.

David C. Shonka,
Acting General Counsel.
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