

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

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FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade 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 Federal Trade Commission ("FTC" or "Commission") is seeking public comments on its proposal to extend through April 30, 2010 the current OMB clearance for information collection requirements contained in its Contact Lens Rule ("Rule"). That clearance expires on April 30, 2007.

DATES: Comments must be filed by February 16, 2007.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to "Contact Lens Rule: FTC File No. [R411002]," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope and should be mailed or delivered, with two complete copies, to the following address: Federal Trade Commission, Room H-135 (Annex J), 600 Pennsylvania Ave., NW., Washington, DC 20580. Because paper mail in the Washington area and at the Commission is subject to delay, please consider submitting your comments in electronic form, as prescribed below. However, if the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled "Confidential."¹

Comments filed in electronic form should be submitted by following the instructions on the web-based form at <https://secure.commentworks.com/>

¹ Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

ContactLensRule. To ensure that the Commission considers an electronic comment, you must file it on the Web-based form at the <https://secure.commentworks.com/ContactLensRule> Weblink. If this notice appears at <http://www.regulations.gov>, you may also file an electronic comment through that Web site. The Commission will consider all comments that [regulations.gov](http://www.regulations.gov) forwards to it.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission and will be available to the public on the FTC Web site, to the extent practicable, at <http://www.ftc.gov>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy at <http://www.ftc.gov/ftc/privacy.htm>.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be addressed to Keith Fentonmiller, Attorney, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-2775.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act ("PRA"), 44 U.S.C. 3501-3520, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 C.F.R. 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 paperwork clearance for the regulations noted herein.

The FTC invites comments on: (1) Whether the required collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (2) the accuracy of the agency's estimate of the burden of the required 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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before February 16, 2007.

The Contact Lens Rule ("Rule"), 16 CFR Part 315, was promulgated by the FTC pursuant to the Fairness to Contact Lens Consumers Act ("FCLCA"), Pub. L. No. 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 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 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.

Commission staff estimates the paperwork burden of the FCLCA and Rule based on its knowledge of the eye care industry. Staff believes there will

be some burden on individual prescribers to provide contact lens prescriptions, although it involves merely writing a few items of information onto a slip of paper and handing it to the patient, or perhaps mailing or faxing it to a third party. In addition, there will be some recordkeeping burden on contact lens sellers—including retaining prescriptions or records of “direct communications”—pertaining to each sale of contact lenses to consumers who received their original prescription from a third party prescriber.

Burden statement:

Estimated total annual hours burden: 950,000 hours (rounded to the nearest thousand).

In its 2003 PRA-related **Federal Register** Notice and corresponding submission to OMB, FTC staff estimated that the annual paperwork burden for the various disclosure and recordkeeping requirements under the FCLCA and then-proposed Rule would be approximately 600,000 disclosure hours for contact lens prescribers and approximately 300,000 recordkeeping hours for contact lens sellers, a combined industry total of 900,000 hours.

No provisions in the Rule have been amended since staff’s prior submission to OMB. Thus, the Rule’s disclosure and recordkeeping requirements remain the same. However, the number of contact lens wearers in the United States has increased to approximately 38 million.² Thus, assuming an annual contact lens exam for each contact lens wearer, 38 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 633,333 hours. [(38 million × 1 minute)/60 minutes = 633,333 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 CFR 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. Essentially, 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 approximately 10% of sales in the contact lens market³ and, by extension, that approximately 3.8 million consumers—10% of the 38 million contact lens wearers in the United States—purchase their lenses from them.

At an estimated five minutes per sale to each of 3.8 million consumers, contact lens sellers will spend a total of 316,667 burden hours complying with the recordkeeping requirement. [(3.8 million × 5 minutes)/60 minutes = 316,667 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 labor costs: \$32,819,000 (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. Thus, for simplicity, staff will focus on their average hourly wage in estimating prescribers’ labor cost burden.

According to Bureau of Labor Statistics from May 2005, salaried optometrists earn an average wage of \$45.91 per hour and clerical personnel earn an average of \$11.82 per hour.⁴ With these categories of personnel, respectively, likely to perform the brunt of the disclosure and recordkeeping aspects of the Rule, estimated total labor cost attributable to the Rule would be approximately \$32.8 million. [(\$45.91 × 633,333 hours) + (\$11.82 × 316,667 hours) = \$32,819,322].

The contact lens market is a multi-billion dollar market; one recent survey estimates that contact lens sales totaled \$2.35 billion from June 2005 to June 2006.⁵ Thus, the total labor cost burden estimate of \$32.8 million represents approximately 1% of the overall market.

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).

William Blumenthal,

General Counsel.

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² See Statistics on Eyeglasses and Contact Lenses,” All About Vision, August, 2006, available at <http://www.allaboutvision.com/resources/statistics-eyewear.htm>. See also Barr, J. “2004 Annual Report,” Contact Lens Spectrum, Jan. 2005, available at <http://www.clspectrum.com/article.aspx?article=12733>.

³ 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>.

⁴ The Bureau of Labor Statistics are available online at http://www.bls.gov/oes/current/oes_nat.htm#b43-0000.

⁵ The Vision Council of America and Jobson Optical Research have conducted large scale continuous consumer research under the name VisionWatch, which reports on vision care industry and is available at http://visionsite.org/s_vision/doc.asp?CID=791&DID=2524.