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Federal Trade Commission/Office of the Secretary
Room 159-H (Annex A)
600 Pennsylvania Avenue, N.W.
Washington DC 20580

By Email to: contactlensrule@ftc.gov

Re: Contact Lens Rule, Project No R411002

Arlington Contact Lens Service (AC Lens) is pleased to submit the following comments regarding the proposed regulations to implement the “Fairness To Contact Lens Consumers Act” (HR3140).

AC Lens Background

We are a privately held company engaged in Internet and Mail-Order Contact Lens Sales since December 1996. According to the definition VII C, we appear to be classified as a “small entity” as we do not fall under the definition of “larger businesses” (Mail Order Houses or Electronic Shopping entities greater than \$21 million in size).

Our company welcomes the passage of this law as representing a significant step forward for contact lens consumer’s rights and as a boost to interstate commerce. As requested, we have referenced our comments to the specific question and subsection listed in the “Notice of Proposed Rulemaking: Request for Public Comment”

Question 3 (Definition of “Business Hour”)

The requirement for 8 business hours prior to passive approval is fair and reasonable and the exclusion of some Federal Holidays is also reasonable. However, we think the definitions would benefit from the following modifications:

1. The definition of Federal Holidays should be restricted to include only major holidays to comprise *those holidays where the majority of retail businesses nationally* are closed. This list might include July 4 and Thanksgiving, for example, but should not include Columbus Day and other Federal holidays that are *typically busy retail days* in most parts of the country.
2. The definition of business hours should be extended to include Saturday as most optical stores and optometrist’s offices are open for business for at least a portion of that day, and the exclusion of Saturday causes an unreasonable delay for the consumer. In the worst case, a consumer placing an order on Friday after 5:00pm,



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may not have their prescription released until Tuesday morning – a significant, and we think unreasonable, delay.

In response to question 3. (c):

1. The exclusion of state or local holidays would put an unreasonable burden on smaller entities located in other states that have no practical way to track state and local holidays in all 50 states.
2. The exclusion of prescriber vacation days or weekdays where a doctor may take a part or whole day off would place an unreasonable burden on the seller who would have to track such closures, and would unreasonably delay the delivery of the contact lenses to the consumer.

Question 7 (c) (Use of telephone messages in communication with prescribers):

We do believe it is appropriate to include telephone messages in the definition of “direct communication” provided the message includes the full patient information as required by the act. To do otherwise would place a significant burden on smaller entities like our company in that our ability from our offices in the Eastern time zone to communicate with offices on the west coast and Hawaii/Alaska would be severely compromised if we were required to verify prescriptions only during normal business hours in other time zones. This would lead to increased labor costs for our company in having to staff our offices outside of our normal working hours, and would lead to increased delays for the consumer.

Question 7 (d) (Confirmation of receipt of faxes and emails):

We believe it is reasonable to require an electronic confirmation that a fax was transmitted successfully and that an email was not returned as undeliverable, but any requirement for an active acknowledgement from the recipient would be directly contrary to the acts provisions of allowing “passive verification” of the order in the absence of communication from the prescriber.

Question 12 (Private Label Lenses):

We welcome the provisions of the act that allow the substitution of the (generic) “national brand” for specific private label lenses. However, we recognize that in some cases, the manufacturer of such products produces literally dozens of such private label lenses. It is difficult for a smaller entity like ourselves to track the proliferation of such lenses in relation to the equivalent “national brand”. We would welcome a rule that required manufacturers to periodically publish a current list of all such private label lenses together with the generic equivalent.

An even more insidious practice, which appears to be designed almost entirely to allow prescribers to avoid the increased competition likely to result from the passage of this act, is the development of “prescriber only” lenses. An instance of this practice was



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publicized in the industry newsletter “Contact Lenses Today” on March 28, 2004 in which it was stated that:

According to Florida-based contact lens retailer Visus LLC, by dispensing its proprietary VISUS 2 disposable contact lenses with online, fax and voice reorder capabilities for your patients, you can control the purchase price and keep 100% of the profits. The company recommends converting branded products to VISUS 2 to differentiate your practice from others. *In a recent promotional e-mail regarding compliance with the Fairness to Contact Lens Consumers Act, the company states that by dispensing its lenses, you can assume that you'll lose 0% of contact lens replacement orders to alternative sources.* (Emphasis added).

While the act does not appear to directly address such procedures, we believe that this growing practice should be a part of the FTC’s report to Congress on the use of private label lenses to limit competition in the industry.

Question 18 (e): “Does the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) limit or otherwise affect prescribers’ ability to respond to a verification request?”

No. In response to the question: “Does the HIPAA Privacy Rule permit an eye doctor to confirm a contact prescription received by a mail-order contact company?”, the US Department Of Health & Human Services replied “Yes. The disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is a treatment disclosure, and is permitted under the Privacy Rule at 45 CFR 164.506.”¹ This does not appear to be well understood by some prescribers although the effect of the rule has also been publicized in industry trade magazine articles.²

Question 21 (Record-keeping Requirements) We believe the requirement to maintain records of communication (including telephone and similar bills) is reasonable and indeed helpful in resolving complaints from prescribers as to when a specific request was initiated. We would add the proviso that the FTC should specify any restrictions on the form of such records, including acceptable electronic storage formats.

Question 19 (Definition of Inaccurate, Expired or Otherwise Invalid prescriptions)

¹ (www.hhs.gov Category: Privacy of Health Information/HIPAA /Smaller Providers/Small Businesses/Treatment/Payment/Health Care Operations, Answer #271 dated 7/18/2003).

² (see, for example, http://www.revoptom.com/index.asp?page=2_903.htm).



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1. There is no provision in the legislation for the prescriber to limit the number of boxes or units dispensed provided the prescription is current and we think that any attempt to introduce such a restriction would be unwarranted. Specifically, there is no medical reason to restrict an individual from replacing their lenses more frequently than the prescriber initially recommends. For example, many patients who wear conventional lenses designed to last a year or more find that they are more comfortable wearing and changing those lenses more frequently, in some cases as often as four times per year.

A rule that prevented a wearer from purchasing more than one pair of such lenses during a one-year prescription period would effectively prevent the patient from using a potentially healthier more frequent replacement schedule. While patients should not wear lenses beyond the expiration of their prescription, we think this is a matter of education between the prescriber and the patient, and not the responsibility of the seller.

2. We see no reasons to exclude Rigid Gas Permeable and other specialized made-to-order lenses from the provisions of the act. Many patients purchase additional lenses of this type after the initial fitting. We obtain these lenses from the same manufacturers and laboratories as the eye-doctor and are able to supply them to the consumer more conveniently and at a significant savings, without any loss in quality.

Question 26 (Enforcement Issues): Our company welcomes the enforcement provisions of the rule. However, we are concerned that the FTC may experience difficulties in enforcing those provisions with regard to companies operating outside the United States and shipping contact lenses into the country (including some Canadian companies). While we welcome the opportunity to compete fairly against such organizations, we hope the FTC will take steps to ensure that such companies are not able to operate unfairly by ignoring key provisions of the act.

State Licensing/Registration: We question the need for state registration in the light of the new federal legislation. However, we accept that states providing simple, relatively inexpensive registration procedures (such as Texas and California) do not represent a significant burden. In some cases, however, the state registration fees charged are unreasonable and burdensome to smaller businesses. For example, the State Of Illinois charges \$1,000 per year, a significant and we think unreasonable amount that if duplicated around the country would make state registration very difficult for smaller entities.



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Thank you for providing our company with the opportunity to comment on the proposed rule. Should you require any additional information, please do not hesitate to contact me.

Sincerely,

Peter M Clarkson, MD
President
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www.aclens.com