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**VIA OVERNIGHT MAIL**

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments Regarding Draft Impact-Resistant Lenses Questions and Answers Guidance

To Whom it May Concern:

I am submitting these Comments regarding the Food and Drug Administration's ("FDA's") October 26, 2007 draft guidance document entitled "Impact Resistant Lenses: Questions and Answers" ("Draft Q&A") on behalf of my client, the Optical Laboratories Association ("OLA"). Specifically, our Comments will focus on the following: (1) Question 5 of the Draft Q&A, which addresses the issue of whether plastic-prescription lenses ("lenses") that are used in impact resistance testing should subsequently be sold; (2) the provisions regarding third-party testing and certification, discussed at Questions 25 and 26 of the Draft Q&A; and (3) certain terminology and definitions used in the document. OLA appreciates the opportunity to provide its input on the Draft Q&A.

## I. Executive Summary

OLA recommends that FDA remove Question 5 from the Draft Q&A, or revise the guidance to reflect data indicating that lenses that pass impact testing once remain safe for use. OLA has collected data on 2,550 lenses that passed impact testing in accordance with 21 CFR § 410. In all but 0.27% of instances, those lenses passed impact testing a second time. OLA believes that this data indicates that lenses that have passed impact testing remain safe under the standards of 21 CFR § 410. Because Question 5 of the Draft Q&A would have an adverse financial impact on consumers, with no additional safety benefit, OLA respectfully urges FDA to remove or revise this provision.

OLA further recommends that FDA revise its provisions regarding third-party testing and certification of impact resistance found at Questions 25 and 26 of the Draft Q&A. OLA believes that the current third-party certification process contemplated by Question 26 is inconsistent with the principle, reflected throughout the Draft Q&A, that lenses should be tested by the "manufacturer" in their finished form. Further, OLA believes where a third party conducts impact testing on a lens that it has rendered in finished form through edging, surfacing, etc., the results of that testing will not accurately reflect the impact resistance of the same lens when it is rendered in finished form by the "manufacturer." Finally, OLA believes that optical laboratories that participate in third-party testing and certification of impact resistance will be required to assume considerable increases in liability insurance premiums, resulting in higher prices to consumers. Therefore, OLA urges FDA to require that third-party testing be conducted on lenses that have been rendered in finished form by the "manufacturer."

Finally, OLA recommends that FDA revise certain terminology and definitions used in the Draft Q&A to more accurately reflect the language used in the optical industry.

## II. Introduction

Founded in 1894, OLA is the primary trade association dedicated to serving the optical laboratory community. OLA is organized under Section 501(c)(6) of the Internal Revenue Code and currently has 341 member companies, which represent 505 retail and wholesale optical laboratories in the U.S., Canada, and 14 other countries. In addition, OLA takes a leading role in producing and distributing educational and training materials for optical laboratories, both from a technical and business perspective. Finally, OLA sponsors its annual international exposition and conference – "The OLA" – which is the largest trade show dedicated exclusively to optical laboratories. As such, OLA provides its Comments to FDA as the leading voice representing the optical laboratory industry. Further, OLA is particularly qualified to provide input regarding the technical assumptions underlying the Draft Q&A and the potential effects of the guidance document on the eyewear lens industry and consumers.

## III. Comments to the Draft Q&A

### A. Question 5 Should be Removed or Revised

In its current form, the Draft Q&A provides the following for Question 5:

> **5. Q.** Should you sell plastic-prescription lenses that have been used as part of the sample that was impact tested?
>
> **A.** No. Drop ball testing and other similar tests weaken plastic lenses due to stress placed on the plastic. Impact testing causes microscopic cracks in the lenses which significantly reduces the lens strength. You should discard lenses that have been impact tested or you may use the lenses for demonstration purposes. See Question #20 for guidance on how to ensure demonstration lenses are not used by the public.

As a preliminary matter OLA notes that FDA's previous iteration of the Impact Resistance Questions and Answers guidance document did not address the question of whether a lens that has undergone impact testing should subsequently be sold. Further, the impact-resistance regulations at 21 CFR § 410 do not consider the sale of impact-tested lenses. Therefore, FDA's addressing of this issue in connection with the current Draft Q&A is a matter of first impression under the regulations that OLA respectfully submits should be closely examined.

#### 1. Rationale Regarding Subsequent Sale of Impact-Tested Lenses

In answering Question 5, FDA states that impact testing "significantly reduces the lens strength" as an explanation for its guidance that lenses that have been impact tested should not be sold. As stated in the Overview portion of the Draft Q&A, the ultimate goal of the guidance document is to promote the safe use of eyewear products. The impact resistance test is designed to ensure that those lenses ultimately provided to consumers meet certain minimum impact resistance standards shown to provide an acceptable level of protection.

Taken as a whole, the regulations, as reflected by the Draft Q&A, stand for the general proposition that lenses will be considered safe for use where they pass impact resistance testing in accordance with 21 CFR § 410. As such, if lenses that have passed impact testing in fact pass a subsequent impact test, such lenses should likewise be considered safe for use under the regulations. As discussed in detail below, OLA's research has determined that only a statistically insignificant

percentage of lenses that have passed impact testing fail a second impact test. Therefore, contrary to FDA's rationale in response to Question 5, OLA believes that considerations of safety should not preclude the subsequent sale of lenses that have been impact tested.

2. OLA Data Regarding Impact Resistance of Previously Tested Lenses

In order to determine whether lenses that have passed impact testing are weakened so as to no longer be safe for use, OLA collected data on 2,550 lenses that passed initial impact testing. The testing, which occurred at 34 different laboratory locations, was performed on a wide variety of materials, lens styles, and thicknesses. Lenses were tested in the uncut, cut, and edged form. In addition, some lenses featured scratch-resistant and/or anti-reflective coating, while some lenses were left uncoated.

Of the 2,550 lenses tested, 2,543 lenses passed a second impact test and 7 lenses failed a second impact test. These results indicate that lenses that have previously passed impact testing failed a second test only 0.27% of the time. The detailed data reflecting OLA's testing is included as an attachment to these Comments. OLA believes that this data strongly indicates that lenses that have passed impact testing are no less able to pass the impact resistance test standard required by 21 CFR § 410 than lenses that have not undergone the testing.[1] Therefore, this data demonstrates that FDA's conclusion that that impact testing "significantly reduces the lens strength" is unwarranted.

3. Economic Effect of Question 5 on Consumers

Because OLA believes that the subsequent sale of lenses that have passed impact testing does not raise appreciable safety concerns, it is important to also consider the potential financial effects of Question 5 on consumers. An inability to sell lenses that have passed impact testing will have an adverse impact on optical laboratories and other parties acting as "manufacturers" under the regulations. These higher costs will result in increased prices to consumers, without any demonstrated corresponding increase in the safety of the lenses.

4. Recommendation

OLA is unaware of any data demonstrating that lenses that have passed impact testing are less safe in any statistically significant way than those that have not undergone the testing, and in fact has collected data that demonstrates that the level of safety is approximately equal. Therefore, it is OLA's recommendation that Question 5 be removed from the Draft Q&A in its entirety. Because neither 21 CFR § 410 nor the previous Impact Resistance Questions and Answers guidance document address the question of sale of impact-tested lenses, OLA urges that the status quo should be maintained without further guidance from FDA.

In the alternative, if FDA feels it is necessary to address the sale of impact-tested lenses in the finalized guidance document, OLA recommends that FDA revise the current draft of the answer portion of Question 5. OLA urges that any such revision should reflect the data, discussed herein, indicating that lenses that have passed impact testing once are safe for use, and therefore may be dispensed.

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[1] In addition, Empire Optical, an OLA member optical laboratory that has submitted separate comments to the Draft Q&A, collected data on 1,450 lenses that passed initial impact testing. It is OLA's understanding that each and every lens passed impact testing a second time. When considered in conjunction with OLA's data, 3,993 of 4,000 lenses that passed initial impact testing passed the test a second time. Therefore, in only 0.18% of cases did the lenses fail the second impact test.

OLA further recommends that if FDA permits the sale of lenses that have passed impact testing, manufacturers that choose to test 100% of lenses be expressly permitted to encase those lenses in a plastic bag during testing. Plastic bags help to protect the lenses from cosmetic damage that may otherwise make sale inappropriate. This use of plastic bags in impact testing was expressly allowed by Appendix B to the 1987 version of this guidance document and OLA urges that FDA retain these provisions in the final version of the new Q&A.

**B. The Provisions Regarding Third-Party Testing and Certification Should be Revised**

At Questions 25 and 26, the Draft Q&A provides as follows:

**25. Q.** What is a "Certification Statement of Impact Resistance" and who issues it?

**A.** A "Certification Statement of Impact Resistance," is a written statement, guaranteeing that the lenses have been tested and are impact resistant. FDA may accept such a certification in lieu of test results, but a manufacturer must make the results available, upon request, to the FDA as soon as practicable. 21 CFR 801.410(g). The manufacturer issues the certification. We provide suggested wording in Appendix C.

**26. Q.** Can a third-party laboratory test the lenses?

**A.** Yes. A third-party laboratory can conduct the impact test and issue the certification. Although a third-party may conduct the testing, the name of the manufacturer should be recorded on the Certification Statement as the certifier.

1. Third-Party Testing and Certification are Inconsistent with the Requirement that Lenses Be Tested by the "Manufacturer" in Their Finished Form

OLA believes that the third-party certification provisions included at Question 26 are inconsistent with the principle, reflected throughout the Draft Q&A, that lenses should be tested in their finished form by the party acting as the "manufacturer" under the regulations. This guidance is expressed directly in the responses to Questions 21, 22, and 24. OLA believes that the reasoning behind this guidance – that lenses tested by the "manufacturer" in finished form will provide the most accurate impact resistance results – will be undermined where a third party tests lenses that it, rather than the "manufacturer," has rendered in finished form.

The response to Question 39 requires that testing be done at all locations of a "manufacturer" because: "There may be subtle differences at different locations that can affect the impact resistance of a lens (e.g., wear on a diamond wheel used in surfacing, age of polish, age of coatings, experience of operators)." This same principle should be applied with regard to third-party impact testing – subtle differences in equipment, maintenance, and experience, among other factors, have a considerable effect on the impact resistance of a finished lens. Therefore, where a third party conducts impact testing on a lens that it has rendered in finished form through edging, surfacing, etc., the results of that testing will not accurately reflect the impact resistance of the same lens when it is rendered in finished form by the "manufacturer."

2. Third-Party Testing and Certification Will Result in Higher Costs to Consumers

If the current Question 26 remains unchanged in the final Q&A, optical laboratories will often serve as the third-party laboratories that will contract to test and certify impact resistance of the unfinished lenses they provide to eye care professionals and other parties acting as "manufacturers." Because of the concerns expressed above regarding the accuracy of impact testing performed under

different conditions that those used by the "manufacturer" to render the lenses in finished form, OLA believes some optical laboratories will decline to provide the certification contemplated by Questions 25 and 26. However, some optical laboratories will provide the certification, leading to a market-driven scenario in which "manufacturers" will be more likely to purchase unfinished lenses from an optical laboratory that agrees to test and certify impact resistance.

OLA believes that those optical laboratories that elect to provide the certification of impact resistance will likely face significant increases in liability insurance premiums. A certification of impact resistance, even though provided in the name of the "manufacturer," will expose an optical laboratory to increased potential liability. Because an optical laboratory providing testing and certification will test lenses that it renders in finished form, the impact resistance reflected in that testing may not accurately reflect the impact resistance of the lenses the "manufacturer" renders in finished form. Third-party laboratories will be unable to recognize and account for the various differences in equipment, maintenance, and experience that could cause variations in impact resistance. Because of these concerns, OLA believes many optical laboratories that engage in testing and certification will face considerable increases in liability insurance premiums. These increase costs will ultimately result in higher costs to consumers.

3. Recommendation

OLA recommends that the response to Question 25 be revised to explicitly provide that the "manufacturer" is the certifier and not merely the party issuing the certification. Therefore, the second-to-last sentence in the response to Question 25 should be revised to read: "The manufacturer is the certifier and issues the certification."

OLA further recommends that the response to Question 26 be revised to require that third-party testing be conducted on lenses that have been rendered in finished form by the "manufacturer." This change will alleviate concerns regarding the accuracy of impact testing conducted by third-party laboratories caused by differences in equipment, maintenance, and experience. It will also make Question 26 consistent with the rationale expressed in the response to Question 39.

**C. Terminology and Definitions Used in the Draft Q&A Should be Revised**

In order to more accurately reflect the language used in the optical industry, OLA recommends that the following terminology and definitions used in the Draft Q&A be revised:

**7. Q.** What is a "semi-finished" lens blank?

The answer given in the draft is incorrect. While for most glass lenses the front surface of the lens is shaped (not ground) during the manufacturing process, there are many glass lenses which have the front surface ground. Essentially all plastic lenses have the front surface of a semi-finished blank ground or molded to an optically finished curve.

OLA recommends that the answer to Question 7 use the definition given in ANSI Z80.1-2005:

A. FDA considers a "semi-finished" lens blank to be a lens blank having only one surface finished to a specific curve.

**9. Q.** What is a "plano" lens

The FDA answer defines a lens with no dioptic power. OLA recommends that the definition of a plano lens uses the definition given in ANSI Z80.1-2005: "A lens having essentially zero refractive power."

**24. Q.** Should retail laboratories perform impact-resistance testing?

The FDA recommendation uses the term "grinding Diopters." This phrase is not a commonly used term in the industry. Additionally, there are systems that mold or cast lenses to an individual prescriptions.

OLA recommends that the answer be revised to:

A. Yes. Because edging, drilling holes, surfacing, molding/casting and applying coatings may weaken the lens, the retail laboratory should make the lens impact resistant and test the lens before delivery to the user.

**35. Q.** Should manufacturers test plastic lenses in a variety of thicknesses?

The answer references manufacturers that sell partially ground lens blanks. Consistent with Question 7, "semi-finished lens blanks" should be used in place of "partially ground lens blanks."

**45. Q.** What should be submitted to the FDA at the U.S. Port of Entry?

The FDA response recommends labeling semi-finished non-prescription sunglass lenses as "[r]equires further processing, not a finished device." This is not necessary since, consistent with Question 7, semi-finished blanks have only one finished surface .

**51. Q.** Are there regulatory requirements for optical laboratories that set diopters and perform edge cutting?

The terms "set diopters" and "edge cutting" are not used in the industry. Additionally, there are systems that mold or cast lenses to an individual prescriptions. OLA recommends that the question be revised to:

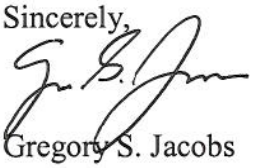
Q. Are there regulatory requirements for optical laboratories that perform surfacing and/or edging or cast/mold lenses to a specific individual prescription?

## IV. Conclusion

OLA recommends that Question 5 of the current Draft Q&A either be removed from the final version of the guidance document or revised to reflect data indicating that lenses remain safe for use

after passing one impact test. Further, OLA recommends that the third-party testing and certification provisions included at Questions 25 and 26 be revised to require that testing be performed on lenses rendered in finished form by the "manufacturer." Finally, OLA recommends that certain terminology and definitions used in the Draft Q&A be revised. OLA is willing to provide FDA with any further information regarding these Comments, and the data discussed herein, that will assist FDA in its consideration of these issues. Please contact Daniel Torgersen at (612) 520-6061 with any follow-up questions or discussion.

Sincerely,



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