



# Optical Laboratories Association

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Contact: Robert Dziuban,  
Executive Director  
Phone: 1-800-477-5652  
+1-703-359-2830  
Fax: +1-703-359-2834  
Email: [ola@ola-labs.org](mailto:ola@ola-labs.org)

## **OLA Submits Comments to FDA**

### **Lab Association Comments on FDA Draft Guidance on Impact Testing**

**Fairfax, VA, January 30, 2008**— Optical Laboratories Association (OLA) has submitted comments to the Food and Drug Administration (FDA) on the Draft Q&A Guidance on Impact Testing, release by FDA in October 2007.

“OLA Members have a major portion of the responsibility for compliance with impact testing requirements, and are very heavily invested in impact testing of spectacle lenses. We are very glad to have the opportunity to participate in the dialogue with FDA about changes in the implementation of the impact testing regulations,” stated Bob Dziuban, OLA executive director. “Our comments focused on two specific areas where we believe FDA should review and change the guidance published in the Draft Q&A document. OLA joins with all the organizations in the optical industry in requesting that FDA give careful consideration to the need for the changes in the Draft Q&A Guidance, and the economic impact those changes will have on consumers.”

The Executive Summary of the OLA Comment is as follows:

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.

The complete text of the OLA Comment is available on request to 800-477-5652 or [ola-labs.org](http://ola-labs.org).

The Optical Laboratories Association (OLA) is an international business association founded in 1894 to serve the needs of the optical laboratory industry. OLA’s current members include 335 companies, representing 515 wholesale and retail laboratories, and industry suppliers, in the U.S., Canada, and 12 other countries. OLA produces a variety of education and training materials for optical laboratories including technical, legal, and regulatory bulletins and manuals; and for eye care professionals, including the *Lens Menu*, the *Progressive Identifier*, the *Lens Center*, and the *Indispensable Dispensing GUIDE*. OLA sponsors an international conference and exposition - “*THE OLA*” - the world’s largest equipment and materials show exclusively for optical laboratories. For more information contact OLA at 1-800-477-5652 or +1-703-359-2830, fax +1-703-359-2834, email: [ola@ola-labs.org](mailto:ola@ola-labs.org), or visit the OLA website: [www.ola-labs.org](http://www.ola-labs.org).

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**For more information, press only:**

Carmen Sevilla, 703-359-2830, [Carmen@ola-labs.org](mailto:Carmen@ola-labs.org)