THE VISION COUNCIL

The Vision Council's Mass Lens Manufacturers

Comments on the 2010 FDA Q&A on Impact

November, 2012

INTRODUCTION

The "FDA Impact regulation" has been law since 1971. The specifics of what is required and how to test are found in FDA Title 21 CFR 801.410. The details contained in this law have not changed in ~30 years.

Periodically, the FDA determines it would be useful to provide guidance to the industry in the form of "Questions & Answers" which are non-binding comments on this law and reflect the thinking at the FDA at that time. The most recent Q&A was issued on September 2, 2010 and superseded the prior version issued in Sept 1987.

Technical members of The Vision Council's Mass Lens Manufacturers Committee (MLM) were asked to answer questions relating to the Q&A vs. the law. In this document, the MLM has provided their views on some of the questions contained in the 2010 FDA Q&A referencing FDA Title 21 CFR801.410. The MLM members are industry experts and their opinions do not represent legal counsel.

The MLM highly encourages not only the reading of the 2010 FDA Q&A, but the understanding of FDA Title 21 CFR801.410. The MLM also wishes to make clear the **FDA Title 21 CFR801.410 is the law that must be followed**.

Links to the FDA documents referenced:

FDA Title 21 CFR801.410:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.410

2010 FDA Q&A referencing FDA Title 21 CFR801.410:
http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070579.htm

225 Reinekers Lane
Suite 700
Alexandria, VA 22314

P: 703.548.4560
F: 703.548.4580
thevisioncouncil.org

One general comment from the MLM:

A question periodically asked in the optical industry is, "must one test a lens in the edged form"?

With the exception of glass lenses, the question is answered clearly in section c (3) of FDA Title 21 CFR801.410

"c(3) Each finished impact-resistant glass lens for prescription use shall be individually tested for impact resistance and shall be capable of withstanding the impact test described in paragraph (d)(2) of this section. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing. Prism segment multifocal, slab-off prism, lenticular cataract, iseikonic, depressed segment one-piece multifocal, bioconcave, myodisc and minus lenticular, custom laminate and cemented assembly lenses shall be impact resistant but need not be subjected to impact testing. To demonstrate that all other types of impact-resistant lenses, including impact-resistant laminated glass lenses (i.e., lenses other than those described in the three preceding sentences of this paragraph (c)(3)), are capable of withstanding the impact test described in this regulation, the manufacturer of these lenses shall subject to an impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form."

Comments from the MLM directed toward specific numbered Questions in the 2010 FDA Q&A:

Q4.

- Question 4 - Clearly explains that Plastic lenses can be tested EITHER in uncut form prior to edging, or in edged form.

Q5.

- Question 5 - lens is a finished device only after edging.

Q7.

- Question 7 - says manufacturers of SF lenses are not required to perform testing. HOWEVER Q34 - says they need to provide lab customers information on what thickness the SF blanks were tested. *Note: Some lens manufacturers report occasional issues with Customs personnel who request impact resistance certification for SF blanks, and it is recommended that SF blank manufacturers be prepared per question 34.*

Q9.

- Question 9 - Explains that a retailer must test if they perform processes on lenses that qualify as manufacture. See also Q20 for more information on manufacturers, and the clarification in Q51

Q10.

- Question 10 - Concurs with Q4 and explains that testing must occur, but EITHER as an uncut, or in edged form.

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Q11.

- Question 11 - The answer is not definitive; the prudent safe answer is, test. However, if you can answer yes to each of the factors identified in question 11, it appears that the FDA would not take enforcement action against you if you did not test. You would likely have border issues however, as the local personnel are trained to look for drop ball certificates.

Q18.

- Question 18 - note that the FDA includes all sports glasses, including goggles, in the impact resistant requirement regulatory category if the manufacturer makes any claim about protection from UV (Must meet sunglass regulations, including impact resistance) – if you make UV claims, Rx or plano, then the FDA regulates you.

Q20.

- Question 20 – provides some examples of actions that can identify a manufacturer for the FDA. It also notes that surfacing and coating are actions that definitely trigger the identification as a "manufacturer".

Note: to clarify, beveling typically refers to processing of glass lenses

Q21.

Question 21 - apparently mixes materials like glass and plastic. For glass, one must edge (bevel) before rendering impact resistant. Since it also states that plastic lenses can be tested in uncut form, it appears that when beveling is mentioned in the answer to 21, glass lenses are meant.

Q23.

- Question 23 - raises the possibility that drilling and coating are both special cases that shift responsibility to the driller/coater (as a manufacturer). Explains that drilling may weaken a lens and testing *"should"* then occur after drilling, but again, *not required*.

Q34.

- Question 34 - A manufacturer of semi-finished blanks can perform preliminary impact testing to confirm the strength of the semi-finished blank and provide that thickness information, but the Manufacturer that puts the lens in the final form as described in question 20 must test.

Q50.

- Q50 indicates requirements for registration, record keeping, Medical Device Reporting, and Quality Systems.

Q51.

- Question 51 - is a clarification to the statements in question 20. "Retail stores that only perform edging are not considered manufacturers"

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