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

Re: Draft Guidance entitled "Impact-Resistant Lenses: Questions and Answers"

Docket 2007D-0364

Request for extension of comment period

This letter is submitted by the Vision Council of America (VCA), a trade association whose members consist of over 264 companies who manufacture and distribute prescription lenses, spectacles, equipment and related optical products. VCA member companies manufacture and distribute over 90% of all prescription lenses sold in the U.S. and process over 50% of the lenses used to fill individual patient eyewear prescriptions.

As the US trade association representing the optical industry, we are requesting an extension on the comment period for the Draft Guidance for Industry and FDA Staff: Impact-Resistant Lenses: Questions and Answers issued on: October 26, 2007. Comments on the Q&A are currently due 90 days after their publication date, which is January 28, 2008.

The reason for our request is that VCA members believe that the Draft contains incorrect information concerning the impact resistance of edged lenses and contradictions in critical areas regarding who should test and how to test. The draft Q&A indicates that the edging of prescription lenses is a significant factor in reducing the impact resistance ability of the product. VCA member lens manufacturers conduct a battery of tests on lenses each day to insure the safety of their products. Data collected and compiled by lens manufacturers for decades indicates that the edging process does not significantly reduce the impact resistance ability of a spectacle lens. This data also indicates that testing does not substantially affect the impact resistance of the tested lens.

Lens manufacturing and distribution has changed dramatically since the original FDA regulation was implemented in 1972 and an extension of the comment period will enable VCA to provide the FDA with current data concerning lens impact resistance, the economic impact of the proposed guidelines, and information concerning the frequency and extent of eye injuries caused by lens breakage.

VCA shares the FDA's interest in developing guidelines which will assist the industry in providing safe lens products to the American consumer. We believe that we can help the FDA to achieve this goal by providing you with information that will assist in the development of meaningful and accurate guidelines.

We appreciate the agency's consideration of this request and look forward to working with the FDA on this important issue.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'E. Greene', is written over a white background.

Edward Greene, CEO
Vision Council of America

cc: John Stigi, Director, Division of Small Manufacturers, International Relations and External Affairs Staff.
William Suttan, Deputy Director, Division Small Manufacturer, Intern Relation and Extern Affairs Staff
Daniel Shultz, MD, Director Center of Devices and Radiological Health