Vision Council of America

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Re: Draft Guidance entitled "Impact-Resistant Lenses: Questions and Answers"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

These initial comments are submitted by the Vision Council of America (VCA), a trade association whose members consist of over 300 companies who manufacturer 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. VCA shares FDA's interest in ensuring safe lenses are provided to the American consumer.

VCA is submitting these initial comments for consideration by the Food and Drug Administration (FDA) and will be supplementing this submission with additional information, including supporting data for test results described herein. The Vision Council of America understands that the record in this guidance will be reopened for an additional ninety (90) days.

VCA members represent the majority of companies who design and produce lens materials, lens blanks, coating materials, lens processing equipment. Members also engage in lens processing and Rx production. As a result, VCA members have unique knowledge regarding the control of impact resistance through extensive lens processing and design studies.

The VCA would like to work with FDA in developing a guidance document that is consistent with the FDA regulations as well as consumers. It is with these goals in mind that VCA submits these initial comments.

- The VCA urges FDA to not adopt the Draft Q&A for the several reasons summarized below and because the guidance is inconsistent with 21 CFR 801.410,

- The draft Q&A indicates that the edging of prescription lenses is a significant factor in reducing the impact resistance ability of the product. While edging may reduce impact resistance at impact levels higher than the referee test, at the referee test impact level there is no reduction of impact resistance.

- Testing the impact behavior of lenses using higher levels of energy is neither relevant nor predictive of conformance to the CFR. The VCA, using the test in the

CFR tested 540 lenses, 270 edged and 270 not edged, and concluded that edged lenses, regardless of the edging methods used did not fail at rates different from non edged product. Edging does not cause lenses to be non compliant

- In contrast to edging, VCA testing using the referee test has shown that other processing variables have significant effect on impact resistance. These variables include; lens thickness or mass, backside surface quality, and the combinations of coatings or treatments applied. VCA's recent test data will be made available for FDA review at the agency's request

- The guidance inappropriately specifies that dispensers or retail stores who receive lenses are responsible for testing. This is a significant departure from the CFR, the previous guidance, and current industry practice. The 1987 Q&A defined the manufacturer as the party who performs those significant processes and treatments, as listed above, and, is the party who is required to test. It is important that testing continue to be conducted by the manufacturer whose work on the lens has the greatest influence on impact resistance. This is the only practical procedure as this manufacturer is the only party that can take corrective action, and is in the best position to investigate per the CFR.

- The guidance states that lenses that have been tested cannot be sold. Plastic lenses have been shown not to suffer a loss of impact resistance as a result of being tested utilizing the Referee test. The VCA has test results to confirm this refutation. Some lenses may be cosmetically damaged by the test, and typically be rejected as cosmetically defective. The CFR does not include any restrictive comments with regards to the sale-ability of lens after testing with the 50 inch drop-ball test.

- The guidance suggests that eye injuries from broken lenses are common. CPSC data collected over a recent five year period indicate that eye injuries resulting from broken lenses occur at low levels VCA members have reviewed this data and will provide the FDA with an analysis of injury data from the CPSC National Electronic Injury Surveillance System.

VCA appreciates the opportunity to submit these comments as well as its supplemental information. As stated at the outset VCA will expand on this letter and provide testing and other research information to the FDA in the next 90 days. We thank you for your consideration.

Respectfully submitted,

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