

John Stigi
Director, Division of Small Manufacturers
International Relations and External Affairs Staff

William Suttan
Deputy Director, Division of Small Manufacturers
Internal Relations and External Affairs Staff

Daniel Shultz, MD
Director, Center of Devices and Radiological Health

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



211 West Wacker Drive
Suite 1700
Chicago, Illinois 60606

toll free 800.331.2020
phone 312.363.6001
fax 312.363.6052

www.preventblindness.org

RE: Docket 2007D-0364 (Draft Guidance entitled "Impact-Resistant Lenses: Questions and Answers")

Dear Sirs,

This year, Prevent Blindness America celebrates its 100th year of saving sight. Over the course of our first century, we have become the nation's leading volunteer eye health organization dedicated to fighting blindness and saving sight. With our mission in mind, we write you to express our interest in the draft guidance entitled "Impact-Resistant Lenses: Questions and Answers."

We commend the FDA for its interest in developing guidelines which will assist the optical community in providing safe lens products to the American consumer. However, we question whether this update provides added safety in light of modern lens technology and the current experience of the industry. We further understand that the draft guidelines could add extra costs to the consumer and potentially increase the time to complete prescriptions.

While cost is certainly a factor in our ongoing efforts to ensure quality eye care is available for all Americans, our mission dictates that should safety and cost be at odds, we err on the side of safety over cost. Having an opportunity to review both the draft guidance as well as recent testing conducted by the Vision Council, we see no science-based indication that safety would be increased by the proposed updated guidance.

Thus, on behalf of the Board of Directors of Prevent Blindness America, we state our opposition to any new guidelines that would increase cost without an increase in safety.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. O'Neill, Jr.", written in a cursive style.

John D. O'Neill, Jr.
Chairperson

A handwritten signature in black ink, appearing to read "Hugh R. Parry", written in a cursive style.

Hugh R. Parry
President and CEO