May 16, 2003

Honorable Henry A. Waxman
2204 Rayburn Office Building
US House of Representatives
Washington, DC 20515

Dear Congressman Waxman,

We are pleased to learn of your interest in clarifying the Food, Drug and Cosmetic Act to assure that decorative contact lenses are regulated as medical devices, not cosmetics.

Decorative contact lenses pose the same health risks as prescription contact lenses. Consumers who wear these lenses without an appropriate health evaluation and fit by an eye care professional can suffer serious complications, from eye infections to blindness. We recently raised concerns about the number of children who have purchased these products over the counter who have suffered injuries severe enough to require corneal transplants.

The FDA had, until recently, properly classified and regulated these lenses as medical devices. We applaud the FDA's aggressive use of its cosmetic authority to try to deal with this issue, and we believe the Agency's leadership is committed to solving this problem. Last month, however, the agency issued guidance to FDA staff in which it conceded that the regulatory control applicable to contact lenses prescribed for medical purposes "is not available for decorative contact lenses because those products are cosmetics under section 201(i) of the [Food, Drug, and Cosmetic] Act (21 U.S.C. 321(i))." As you know, this classification eliminates most of the safety requirements imposed on prescription lenses, including the requirement that they be sold pursuant to an evaluation and fitting by an eye care professional.

If allowed to stand, this interpretation could lead to an increase in the sale of these lenses without proper supervision by an eye care professional, and thus trigger additional unnecessary eye injuries similar to those widely reported in the press last summer. While creative, FDA's decision to use its cosmetics enforcement authority is at best only a stop-gap measure that cannot provide the kind of comprehensive protection from potential ocular injury that full device regulatory authority would provide.

The nation's optometrists and ophthalmologists are pleased to join together in urging immediate action to clarify the legal status of these lenses. The eye health of the public is clearly best served by maintaining the historic policy, based on sound clinical evidence, of regulating these lenses as prescription medical devices.

Thank you again for your interest in this important public health issue.

Sincerely,

Don Williamson, O.D.
Chair, Federal Relations Committee
American Optometric Association

William Rich, M.D.
Senior Secretariat of Federal Affairs
American Academy of Ophthalmology