

September 9, 2002

Honorable Tommy G. Thompson  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Thompson:

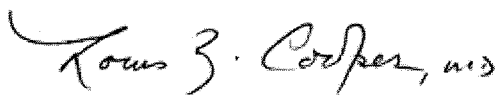
On behalf of the 57,000 pediatricians represented by the American Academy of Pediatrics, I write to express our opposition to efforts by the Food and Drug Administration to reclassify colored contact lenses that do not correct vision as cosmetics instead of medical devices.

In the image-conscious world of adolescence, non-corrective colored contact lenses are viewed as a harmless novelty. However, like prescription contact lenses, there are significant risks with improperly using lenses and use can result in medical complications such as severe infections, ulceration, lacerations or in extreme cases, scarring of the cornea. In addition, the shape and size of the eyeball differs from individual to individual, making a "one size fits all" over-the-counter approach to providing contact lenses risky.

It is essential that anyone wearing any kind of contact lenses be properly fitted for those lenses and receive guidance from medical professionals as to their appropriate use. If the wearer does not adhere to specific medical and safety precautions (i.e., proper sanitation of the lenses, limiting hours of daily use, etc.) their risk of complications is greatly increased and can result in short and long term health implications ranging from eye pain to serious cornea disease and even blindness.

To reclassify colored contact lenses that do not correct vision from a device to a cosmetic undermines the public health protections that the Food and Drug Administration has been charged with upholding. The American Academy of Pediatrics strongly urges you to withdraw any plans to reclassify this device.

Sincerely,

A handwritten signature in cursive script that reads "Louis Z. Cooper, MD".

Louis Z. Cooper, MD, FAAP  
President