September 11, 2002

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

Dear Mr. Secretary:

Prevent Blindness America is alarmed by the recent news that the Food and Drug Administration (FDA) is considering reclassifying tinted plano contact lenses as cosmetics instead of medical devices. This would be a very harmful policy decision for consumers.

Statistics show that in 2001, there were an estimated 1,500 injuries related to contact lenses treated in U.S. hospital emergency rooms. That figure is very low as many people are treated in doctor's offices, clinics, or not at all. It is hard to say how many of these injuries were caused by cosmetic lenses, but precautions must be taken with any kind of contact lenses.

Unauthorized plano contact lenses are already being sold on the beach, at flea markets and on the Internet illegally. Teens are the primary consumers of these colorful cosmetic lenses and there has been a rising incidence of serious eye injuries as a result. The array of colors and patterns is a tempting fashion statement for teens that are not aware of the dangers associated with ill-fitting or poorly manufactured contact lenses.

Problems associated with improperly fitted lenses include decreased flow of oxygen to the cornea, bacterial infections, swelling, eye pain, sensitivity to light, conjunctivitis (pink eye), corneal scratches, corneal ulceration, and loss of clarity. If left untreated, these conditions can result in permanent eye damage and loss of sight.

If consumers are able to purchase these contact lenses without a prescription legally, the number of eye injuries will skyrocket. Companies eager to make money will capitalize on this freedom at the expense of innocent consumers. Shouldn't the government do everything they can to protect our nation's youth from health dangers?

Prevent Blindness America ▪ 500 E. Remington Road ▪ Schaumburg, Illinois 60173
telephone **(800) 331-2020** fax **(847) 843-8458** www.preventblindness.org

As the nation's leading volunteer eye health organization, Prevent Blindness America is extremely concerned that many of the millions of people we serve every year will be hurt or perhaps even lose their sight if the FDA goes through with this policy change. Our nation's health would be best served if the FDA continues to regulate plano lenses as prescription medical devices. Thank you for your consideration of this crucial issue.

Sincerely,

Hugh R. Parry
President & CEO

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