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September 11, 2002

The Honorable Tommy Thompson
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Room 615-F
Washington, DC 20201

Dear Secretary Thompson:

I am writing to convey the serious concern of the Contact Lens Institute ("CLI") with recently reported proposals to reclassify certain types of contact lenses and to treat them as "cosmetics" exempt from all medical device standards and from prescription-only status. CLI is an association of research-oriented manufacturers of contact lens and lens care products, whose members are Alcon, Advanced Medical Optics (formally Allergan), Bausch and Lomb, CIBA Vision, CooperVision and Vistakon (a division of Johnson and Johnson).

As manufacturers of virtually all of the currently marketed products that could be affected by such action, the members of CLI strongly believe that these proposals would significantly compromise the essential public health safeguards maintained by the FDA through its consistent and long-standing classification of all contact lens products as prescription-only medical devices. These proposals also would require the FDA to contradict its previously consistent and forceful public health warnings reinforcing the need for professional fitting of contact lenses and supervision of contact lens wear, including lenses intended to change or enhance the appearance of the eye. (See the attached "FDA Public Health Notification: Illegal Promotion of Contact Lenses," September 25, 1998)

CLI legal counsel have previously addressed these concerns to Mr. Troy and Dr. Feigal at the FDA. (See the attached Email message dated August 26, 2002.) In that communication, CLI also specifically requested that FDA provide public notice of the scope of and basis for any proposed change and an opportunity to comment prior to its implementation. We have, to date, received no response from the FDA.

We encourage you to assure that proper consideration is given to the risks that deregulation of these contact lens products would pose for the health of potential users. It is CLI's opinion that, from a public health and legal perspective, these lenses should continue to be regulated as prescription devices. In addition, a contrary interpretation could have a detrimental precedential effect on FDA's ability to maintain effective jurisdiction over other important products, the intended use of which can also negatively affect the structure and function of vital body organs and whose proper design, manufacture and safe use depend in significant part on their regulation by FDA as drugs and/or medical devices.

Sincerely,

Edward L. Schilling, III
Executive Director

cc: Eve Slater, Assistant Secretary, HHS (fax – 202/690-7203)
Lester Crawford, Deputy Commissioner, FDA (fax – 301/443-3100)
Daniel E. Troy, Esq., Chief Counsel, FDA (fax – 301/827-1137)
David W. Feigal, Jr. Director, CDRH (fax – 301/594-1320)
Thomas O. Henteleff, Esq.
Peter R. Mathers, Esq.

Peter R. Mathers

From: Peter R. Mathers
Sent: Monday, August 26, 2002 2:15 PM
To:
Subject: Tinted Contact Lenses

Dear Dr. Feigel and Mr. Troy:

We represent the Contact Lens Institute, a membership organization of research-based manufacturers of contact lenses and lens care products including Alcon, AMO (formerly Allergan), Bausch & Lomb, CIBA Vision, CooperVision, and Vistakon (division of Johnson and Johnson). We have been shocked by media reports published today (see the attached article from the LA Times) about internal consideration begin given at the FDA to deregulating certain types of contact lenses. As you know, FDA has consistently regulated all contact lenses for several decades as prescription medical devices.

As representative of the manufacturers of most if not all of the currently marketed products that could be affected by such action, th CLI is seriously concerned with the suggestion that the prescription medical device status of any contact lenses would be changed particularly in the absence of prior notice and an opportunity for knowledgable individuals and organizations to comment on the significant public health ramifications of such a change. Simply put, it is the position of the Contact Lens Institute that contact lense must undergo proper testing and FDA review to assure their safety in use on human eyes and that screening, fitting and oversight by qualified eye-care professionals (i.e., prescription status) is absolutely essential to protect the ocular health and vision of contact lens users. These concerns apply without regard to the "power" or design of particular lenses or category of lenses. Indeed, in our view, to single out a category of lenses and to eliminate these essential safeguards on the basis that they are "cosmetic" in nature would be irresponsible from a risk-benefit perspective and would set an extremely troubling precedent for the deregulation of other types of medical devices that represent far greater risks than contact lenses.

Tests of every contact lens product, submitted to FDA in the form of either PMAs or 510k notifications, document the effects of contact lenses on the structure or function of the body. Through design and testing, including clinical testing, these effects have been shown to be consistent with the safe use of contact lenses that have been approved for use in the United States and that are restricted to dispensing on the prescription of qualified medical professionals. Abrogating either the medical device clearance process or the prescription-only status of any contact lens product would, however, in our view be both legally and medically irresponsible.

Having only recently been apprised that individuals have been discussing these issues with the FDA, apparently in private, the CLI has not had time to prepare detailed comments, but fully intends to do so. We request prompt notification of the steps you are taking to assure that those comments, and those of other interested individuals and organizations, will be solicited and properly considered before the FDA commits to any course of action that changes the current legal and regulatory safeguards applicable to contact lenses and their safe use in the United States.

Thomas O. Henteleff
Peter R. Mathers
Kleinfeld, Kaplan and Becker