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May 21, 2002

The Honorable Henry Waxman
U.S. House of Representatives
2204 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Waxman:

I'm writing on behalf of the Contact Lens Institute (CLI), the association representing the major research-based manufacturers of contact lenses. The CLI strongly believes that public interest dictates that the historical regulation of both corrective and non-corrective (so-called plano or decorative) lenses as medical devices subject to pre-market approval, quality system regulations (GMPs), safety reporting, and prescription limitations should be preserved.

Both corrective and non-corrective lenses have the potential for significant public health consequences if they are not adequately tested, formulated, and manufactured or if they are dispensed without a prescription and supervision of qualified health care professionals. It is the CLI's position that FDA's recent interpretation of the Federal Food, Drug, and Cosmetic Act, which subjects non-corrective contact lenses to cosmetic status only, needs to be addressed. This new interpretation does not provide adequate regulatory safeguards, is not in the public interest, and justifies corrective legislation.

CLI is grateful to Congressman Waxman for his commitment to assuring that appropriate regulatory safeguards continue to be applied to all contact lenses marketed in the United States.

Sincerely,

Edward L. Schilling, III
Executive Director