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February 27, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2005N-0354, Consumer-Directed Promotion of Regulated Medical Products

Dear Madam/Sir:

On behalf of the Contact lens Institute (CLI)[1], these comments concerning Direct-to-Consumer (DTC) promotion are being submitted in response to the Agency September 13, 2005 Federal Register Notice (70 F.R. 54054) and as a supplement to CLI's comments on DTC submitted to Docket 2004D-0042 on April 28, 2004. CLI's April 28, 2004 comments are attached hereto and should be considered an integral part of these comments.

The September 13, 2005 Federal Register Notice (Notice) identifies several issues concerning DTC promotion and requests comments relating to these issues. CLI's position with respect to many of the issues identified in the Notice is set forth in its April 28, 2004 comments. There are, however, issues identified in the Notice which CLI has not previously addressed and for which it believes comments are justified.\

Use of Certain Standard Advertising Strategies

It is CLI's position that the appropriateness of a particular advertising strategy should be assessed in the context of the promotional messages conveyed and whether the use of the strategy adheres to established legal and regulatory policies. In regard to the particular strategies identified in the Notice, CLI has the following comments:

[1] The Contact Lens Institute (CLI) is a trade association of the major research-based manufacturers of contact lenses and lens care products in the United States. The members of CLI include: Advanced Medical Optics, Inc., Alcon, Inc., Bausch & Lomb, CIBA Vision, CooperVision, Inc., and Johnson & Johnson Vision Care, Inc.

- **Coupons, Free Samples, Free Trials, and Guarantees**

The Agency specifically invited comments on the use of coupons, free samples, free trials, and money back guarantees. CLI believes that these tools can be a part of responsible DTC promotion, provided that they are offered in a manner that complies with the dictates of the Federal Food, Drug, and Cosmetic Act (Act), and do not trivialize the nature of the product involved (e.g., contact lenses are medical devices that are available only by prescription, require regular professional supervision and are not risk free). Indeed, these tools have been used for years by the contact lens and lens care industry in a manner that is consistent with the Act and provides direct benefits to the consumer. Therefore, rather than imposing special restrictions or requirements on use of coupons, free samples, free trials, guarantees, and other similar tools, CLI believes that the agency should evaluate the use of such tools on a case-by-case basis and, where there are abuses, take appropriate and prompt action..

- **Testimonials/Endorsements**

The September 13, 2005 Federal Register notice also sought comment on the use of testimonials from consumers/patients or from healthcare providers. It is CLI's position that testimonials and endorsements are appropriate forms of promotion, provided that the advertisement complies with FDA's regulatory requirements and also with the Federal Trade Commission's ("FTC") Guide Concerning Use of Endorsements and Testimonials in Advertising. See 16 C.F.R. Part 255. The FTC Guide includes specific requirements designed to ensure that testimonial advertising is truthful and not misleading. The FTC Guide provides that: (a) testimonials may not contain any representations which would be deceptive, or could not be substantiated, if made directly by the advertiser; (b) persons providing testimonials must be bona fide users of the product; (c) testimonials from experts (e.g., healthcare practitioners) must be based on actual exercise of the person's expertise in evaluating product features or characteristics with respect to which the person is an expert and which are relevant to an ordinary consumer's use of the product; and (d) any connection between the person providing the testimonial and the advertiser which might materially affect the weight or credibility of the endorsement must be fully disclosed. Further, the FTC Guide specifically provides that: "[c]laims concerning the efficacy of any drug or device as defined in the Federal Trade Commission Act, 15 U.S.C. 55, shall not be made in lay endorsements unless (1) the advertiser has adequate scientific substantiation for such claims and (2) the claims are not inconsistent with any determination that has been made by the Food and Drug Administration with respect to the drug or device that is the subject of the claim." 16 C.F.R. § 255.2(c).

It is CLI's position that compliance with existing FDA requirements and the FTC Guide will ensure that any use of testimonials in pharmaceutical or device advertising will be truthful and not misleading. This position is consistent with the FTC's viewpoint, as expressed to the FDA in comments on DTC promotion submitted in 2003.[2]

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[2] Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission on Request for Comments on Consumer-Directed Promotion, Docket No. 2003N-0344 (Dec. 1, 2003).

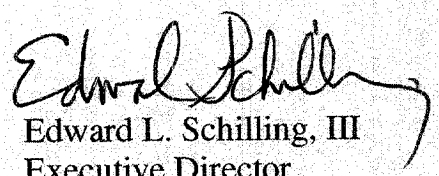
Whether Regulations Governing Restricted Device Advertising are Necessary

CLI believes that it is important that FDA's position relating to restricted device advertising be: (a) documented and transparent; (b) consistent with First Amendment restrictions on government regulation and the dictates of the Act; (c) adopted only after notice of any specific proposed restrictions and an opportunity for input on those proposed restrictions from the regulated industry and the public; and (d) enforced in an even-handed manner. However, it is also CLI's position that this can be accomplished through: (a) the issuance of a Level 1 Guidance document, (rather than the more cumbersome, less flexible and time-consuming formal rulemaking), and (b) the development of enforcement policies designed to assure that the published guidance is applied in a manner that results in similar situations being subject to similar agency responses, thereby helping to maintain a level playing field among competing firms.

What Action Should FDA Take When Companies Disseminate Violative Promotional Materials to Consumers?

FDA has a number of enforcement tools (e.g. untitled letters, warnings letters, publicity, injunction) which can and should, in appropriate circumstances, be used to prevent, halt and rectify the dissemination of promotional materials which violate the Act. Of course, the specific enforcement tool(s) to use should be decided on a case-by-case basis, taking into consideration such factors as the nature of the violation, any history of similar violations, and any resultant public harm. In this regard, CLI believes that FDA's current enforcement authority and policies are appropriate and there is no need for FDA to seek additional authority or to significantly alter its current policies.

Respectfully Submitted,



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