Contact Lens Institute

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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).

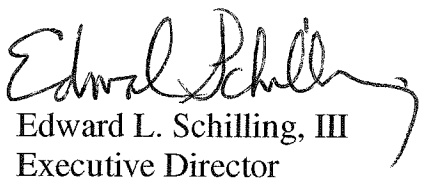
Whether Regulations Governing Restricted Device Advertising are Necessary

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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April 28, 2004

VIA OVERNIGHT EXPRESS DELIVERY

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

Re: Docket No. 2004D-0042
Consumer Directed Broadcast Advertising of Restricted Devices

To Whom It May Concern:

On behalf of the Contact Lens Institute (CLI), an association of research-oriented manufacturers of contact lenses and lens care products,[1] we are submitting these comments in reference to the draft guidance document entitled "Consumer Directed Broadcast Advertising of Restricted Devices" (Guidance), the availability of which was published in the February 10, 2004 Federal Register.

I. Introduction

We hereby request that the Guidance be revised to: (a) recognize that reminder advertisements which merely identify the trade name and established name of the device and do not contain any representation concerning the safety or effectiveness of the device, including indications or directions of use, are exempt from a "brief statement" requirement and thus not subject to the Guidance, and (b) clarify that compliance with the "brief statement" requirement (see §502(r) of the Federal Food, Drug, and Cosmetic Act (Act)) for broadcast media advertisements can be ordinarily satisfied by conspicuously identifying: (i) one or more approved/cleared indications, (ii) the most serious and common warnings, precautions, side effects, and contraindications (collectively referred to as "risks") which are relevant to both the indication(s) being advertised and to the risks justifying "restricted device" status for the advertised indication(s), and (iii) adequate provision for the dissemination of full prescribing information.

Additionally, we request that the Agency rescind the restricted device status for 7-day extended wear lenses and UV lenses.[2] The basis for this request is our opinion that restricted device status for these lenses is not necessary and is inconsistent with the statutory standard. The Act limits "restricted device" status to those devices for which, because "of their potentiality for harmful effects or collateral measures necessary for their use," there cannot be reasonable assurance of their safe and effective use without special restrictions upon their sale, distribution, or use (see §§520(e) and 515(d)(1)(B)(ii) of the Act). In this regard, we note that print and

[1] CLI consists of the following members: Alcon, Advanced Medical Optics, Bausch & Lomb, CIBAVision, CooperVision, Vistakon.

[2] It is also our opinion that, under the statutory standard (Section 520(e) of the Act), 30-day extended wear lenses should not be subject to restricted device status. However, in view of the relatively short marketing history in the US of these lenses, we are not, at this time, requesting that their restricted device status be rescinded.

broadcast media advertisements for 7-day extended wear lenses and UV lenses have not historically been required to contain a brief statement of the relevant risks[3] and there simply does not exist any new data or information which would justify imposing a brief statement requirement for such advertisements. Indeed, both UV lenses and 7-day extended wear lenses have for years been regulated as prescription devices without any independent requirement for a brief statement. The available information, and clinical and regulatory experience, establish that restricted device status is not necessary to provide reasonable assurance of the safety and effectiveness of 7-day extended wear and UV lenses.

II. Reminder Advertisements

It is respectfully submitted that advertisements for prescription devices which merely identify the trade name and established name of the device and do not contain any representations concerning the safety and effectiveness of the device, including indications and directions of use, should be exempt from any "brief statement" requirement. The exempt status of reminder advertisements for prescription drugs (see 21 C.F.R. § 202.1(e)(2)(ii))[4] would seem to be equally applicable to reminder advertisements for restricted devices. Under such circumstances, a requirement for a brief statement would appear to be unnecessary and, as is the case with prescription drugs, so-called reminder advertisements for prescription devices should be specifically exempted from the brief statement requirement.

III. Brief Statement

It is respectfully submitted that broadcast media advertisements for restricted devices should be considered to be in compliance with §§502(q) and (r) of the Act if: (a) the advertisements are neither false nor misleading within the meaning of §§201(n) and 502(q) of the Act; (b) the advertisement identifies one or more of the approved/cleared indications; (c) the advertisement contains a "brief statement" of the risk information that is relevant to the advertised indication(s) and the risks justifying restricted device status for the advertised indication(s); and (d) there is adequate provision for the dissemination of full prescribing information.

Accordingly, insofar as the recently published draft guidance on "Consumer-Directed Broadcast Advertising of Restricted Devices" is interpreted as requiring that a broadcast advertisement identify all of the devices' intended uses and all of the most important precautionary information, it should be clarified or modified. Specifically, the Guidance should be clarified or modified to allow the sponsor of the advertisement to select one or more uses upon which to base the advertisement, and, concomitantly, to limit the content of the risk statement to that relevant to the uses being advertised. In this respect, the above-referenced

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[3] With the exception of 30-night lenses, prior to 2003 the conditions of approval for contact lenses subject to PMAs did not seek to impose a "brief statement" requirement. The approval letters for 7-day extended wear lenses did not purport to impose prescription limitations in accordance with Section 502(e) of the Act. Similarly, while approval letters for UV lenses required that all advertising and promotional materials for such lenses contain the prescribed UV Warning and Note, the letters did not impose a "brief statement" requirement. It was not until early 2003 that FDA changed the conditions of approval for 7-day extended wear lenses and UV lenses subject to PMA and PMA Supplement approval orders so as to impose a "brief statement" requirement. Significantly, this change was adopted without any prior notice, discussion, or factual or legal justification being provided.

[4] Significantly, reminder labeling for prescription devices are exempted from the requirement for "full prescribing" information (See, 21 C.F.R. § 801.109(d)).

Guidance should adopt a regulatory framework analogous to that provided by regulation of the advertisement of prescription drugs. Specifically, under 21 C.F.R. §§ 202.1(e)(3)(ii) and (a):

> "(ii) The information relating to effectiveness is not required to include information relating to all purposes for which the drug is intended but may optionally be limited to a true statement of the effectiveness of the drug for the selected purpose(s) for which the drug is recommended or suggested in the advertisement ...
>
> (a) The side effects and contraindications disclosed may be limited to those pertinent to the indications for which the drug is recommended or suggested in the advertisement..."

Medical devices subject to restricted device status should not ordinarily be required to provide information relating to risks not relevant to the uses being advertised or unrelated to the restricted device status of the advertised product. Thus, for example, advertisements for UV-absorbing contact lenses should not ordinarily be required to include a brief statement if the ad makes no claims pertaining to UV protection.[5] If the advertisement does claim UV protection, the brief statement should be required to extend only to those warnings, precautions, side effects, and contraindications directly relating to the UV attributes of the lens. Similarly, if advertisements for contact lenses approved for 30-day wear do not contain any representations for 30-day wear (e.g., the ad only indicates uses not subject to a brief statement requirement), the advertisement should not be required to include a brief statement, and if the ad makes claims concerning 30-day wear, then the brief statement should be required to extend only to those warnings, precautions, side effects, and contraindications directly relating to 30-day wear.

In other words, broadcast media advertisements for UV or 30-day wear contact lenses should not be required to include, as part of the "brief statement," warnings, precautions, side effects, and contraindications which are not relevant to the representations contained in the advertisements or to the risks justifying restricted device status. Of course, if, in light of the representations made in these advertisements, warnings, precautions, side effects, and contraindications not related to the lenses' restricted device status nevertheless become material, the body of the advertisement would, under the Act and the Federal Trade Commission Act, be required, as part of fair balance, to include a conspicuous reference to the relevant precautionary information.

IV. Restricted Device Status of 7-Day Extended Wear and UV Lenses[6]

It is respectfully submitted that "restricted device" status is inappropriate where the safety and effectiveness of a medical device, such as 7-day extended wear and UV contact lenses, can be reasonably assured without imposing special restrictions on its sale, distribution, or use. In the case of contact lenses, the applicable general Class II and Class III regulatory controls, including requirements for PMA or 510(k) clearance, adherence to QSR regulations, prescription limitations, and the prohibition against false or misleading promotional materials (including failure to reveal material facts in light of representations made (see §201(n) of the Act)) are adequate to provide reasonable assurance of safety and effectiveness and therefore "restricted device" status for such products is not necessary. In the case of marketed contact lenses, the

[5] As explained in Section IV of these comments, it is also our opinion that restricted device status for UV and 7-day extended wear lenses should be rescinded.

[6] See footnote 3.

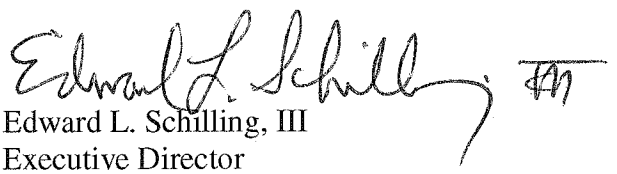
potential for harmful effects and the need for collateral measures simply do not rise to the magnitude where special restrictions on marketing, distribution, or use are justified. While it is true that in the absence of "restricted device" status, advertisements for all contact lenses would be subject to FTC, rather than FDA, jurisdiction, FTC's authority over such advertisements is adequate to assure that such advertisements are not false or misleading in any particular. Indeed, advertisements for daily wear and 7-day extended wear contact lenses have for years been adequately regulated by the FTC.

V. Summary

We respectfully request that the Guidance document be revised to: (a) exclude from its scope reminder advertisements; (b) clarify that information relating to "intended uses" do not have to identify all of the approved/cleared intended uses; and (c) clarify that information relating to "relevant warnings, precautions, side-effects, and contraindications" is ordinarily satisfied where the advertisement provides the most significant risk information relevant to the advertised intended uses and the product's restricted device status.

Additionally, we request that CDRH rescind the restricted device status for UV and 7-day extended wear lenses as being unnecessary and inconsistent with the statutory standards for restricted device status.

Respectfully Submitted,



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cc: James Saviola, O.D.
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Thomas O. Henteleff, Esq.