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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manufacturers of contact lenses and lens care products,¹ we are submitting these comments in reference to the draft guidance document entitled "Consumer Directed Broadcast Advertising of Restricted Devices" (Guidance), the availability of which was published in the February 10, 2004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

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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 risks³ 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

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 Lenses⁶

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.

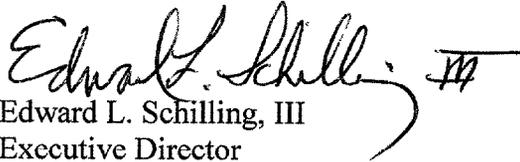
potential for harmful effects and the need for collateral measures simply do not rise to the magnitude where special restrictions on marketing, distribution, or use are justified. While it is true that in the absence of “restricted device” status, advertisements for all contact lenses would be subject 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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Executive Director
The Contact Lens Institute

cc: James Saviola, O.D.
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