UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

May 14, 1996

Marketing of Refractive Eye Care Surgery: Guidance for Eye Care Providers[1]

The Federal Trade Commission staff has received numerous inquiries concerning the promotion and advertising of radial keratotomy (RK) and photorefractive keratectomy (PRK) using the excimer laser systems recently approved by the U.S. Food and Drug Administration (FDA). The FDA and FTC staff issued a joint communique on PRK promotion and advertising on May 7, 1996. The FTC staff takes this opportunity to provide further guidance to eye care providers concerning the requirements of Section 5 of the Federal Trade Commission Act that may apply to the marketing of these, and other, refractive surgical procedures.

Requirements for Advertising Under the Federal Trade Commission Act

The FTC enforces the Federal Trade Commission Act (FTC Act), which among other things prohibits deceptive or unfair practices in or affecting commerce. 15 U.S.C. §§ 45, 52-57. An advertisement is deceptive under Section 5 of the FTC Act, and therefore unlawful, if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material, that is, likely to affect a consumer's choice or use of a product or service. It is important to note that advertisers are responsible for claims that are reasonably implied from their advertisements, as well as claims that are expressly stated.

In addition, under the FTC Act, advertisers must have substantiation for all objective claims about a product or service before the claims are disseminated. In the context of claims about the safety, efficacy, success or other benefits of RK or PRK, substantiation will usually require competent and reliable scientific evidence[2] sufficient to support the claim that is made.[3]

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[1] This guidance represents the views of the staffs of the Bureau of Consumer Protection and the Boston Regional Office, and not necessarily those of the Commission or of any individual Commissioner.

[2] "Competent and reliable scientific evidence" means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession to yield accurate and reliable results.

[3] The substantiation must also be examined in the context of the entire body of evidence, particularly if it produces results that are contrary to that body of evidence. Further guidance on the deception and substantiation standards are set forth in the Commission's Policy Statement on Deception (*Cliffdale Associates, Inc.*, 103 F.T.C. 100, 176 (1984), *reprinting* as Appendix letter dated Oct. 14, 1983, from the Commission to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives) and its Policy Statement on Advertising Substantiation (48 Fed. Reg. 10,471 (1984) *reprinted in Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir.1986), *cert. denied*, 479 U.S. 1086 (1987).