



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2004 11 3 04 JUL - 11 3:29

Timothy Milburn, O.D.
735 Court Street
Medina, OH 44256

Re: Docket No. 03P-0291

Dear Dr. Milburn:

This letter responds to your citizen's petition dated June 18, 2003, which was filed by the U.S. Food and Drug Administration (FDA or the agency) on June 24, 2003. Your petition expresses concern about mail order and internet companies that sell contact lenses to consumers without verification of a valid, current prescription. Your petition also refers to the National Contact Lens Enforcement Petition (NCLEP), which requests that FDA enforce current laws against such sales. The relief requested falls within authority granted to the Federal Trade Commission (FTC) by The Fairness to Contact Lens Consumers Act (FCLCA), 15 U.S.C. §§ 7601 - 7610 (Pub. L. 108-164), which was signed into law on December 6, 2003. Because Congress has considered the precise issue raised by your petition, and has carefully delineated FTC's authority to address this issue, we have determined that your concerns are most appropriately addressed to FTC, rather than FDA. Accordingly, we are denying your petition.

Background

The petitions correctly note that FDA has jurisdiction over contact lenses. This authority derives from the agency's authority under the Federal Food, Drug, and Cosmetic Act (FDCA). Under this authority, the agency has issued regulations classifying rigid gas permeable and soft contact lenses and defining the level of regulation needed to control the risks presented by these devices, *see* 21 CFR §§ 886.5916, 886.5925. FDA also regulates contact lenses intended for vision correction as prescription devices, which means they must be labeled with the prescription legend, 21 C.F.R. § 801.109. FDA has also communicated with the public about the risks of obtaining decorative contact lenses without appropriate professional involvement. The FCLCA does not affect FDA's authority to regulate contact lenses under the FDCA.

The FCLCA, which became effective on February 4, 2004, authorizes the FTC to regulate retail sales of prescription contact lenses directly to consumers. The FCLCA directs the FTC to issue rules regarding, among other things, the use and verification of contact lens prescriptions by retail sources. The FTC published a notice of proposed rulemaking on February 4, 2004 (69 *Federal Register* 5440), which proposes a system of regulation governing the prescription and sale of contact lenses. Central to the proposed regulatory framework is the requirement that all contact lens sellers obtain a copy of or verify the prescription of any person seeking to purchase

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contact lenses. The proposal also discusses FTC's authority to take enforcement action against violations of the FCLCA, noting "the Commission will enforce this part in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*" 69 *Federal Register* 5450. The relief requested in the petitions, then, falls squarely within the authorities Congress has conferred on FTC, which FTC is implementing in its rulemaking.¹

FDA will continue to use its authorities to ensure contact lens consumers have adequate information and manufacturers of contact lenses comply with FDA's requirements for their products. The document "Buying Contact Lenses on the Internet, by phone, or by Mail: Questions and Answers" currently appears on FDA's web site. This document contains advice on several issues related to the purchase of contact lenses, including:

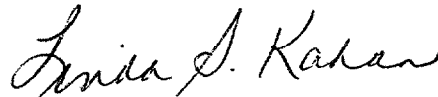
- valid contact lens prescriptions
- regular check-ups for ocular health;
- reporting problems to FDA.

We are enclosing a copy of the document with this response. The document may also be accessed on FDA's Internet site at <http://www.fda.gov/cdrh/consumer/buycontactqa.html>.

Conclusion

The FCLCA empowers the FTC to take action against retailers who sell contact lenses without receiving a copy of or verifying a valid prescription. Although the FCLCA does not restrict FDA's ability to regulate contact lenses, we nonetheless believe the FCLCA provides the most direct avenue of relief for the violations described in your citizen's petition. For this reason, we are denying your petition.

Sincerely yours,



Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health

¹ We note further that the decision of an agency to take enforcement action lies within its discretion. Thus, while FDA welcomes information from the public about possible violations of its laws, the agency is not obligated to pursue each allegation that a violation has occurred. The principle of enforcement discretion recognizes that an agency may decline to bring an enforcement action the agency is legally authorized to bring for such reasons as limited resources, competing priorities, and other reasons that the agency is in the best position to assess. See *Heckler v. Chaney*, 470 U.S. 821 (1985).