This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 30, 1989

Dear Eyecare Practitioner:

This is to inform you that the Food and Drug Administration is requesting manufacturers of cosmetic extended wear soft contact lenses to indicate a recommended wearing time of 1 to 7 days in the product labeling, and to strengthen warnings about the risk of ulcerative keratitis and the importance of proper lens care in reducing this risk.

Our concern about the safety of wearing these lenses beyond seven days is based partly on a multi-center study on ulcerative keratitis and contact lenses sponsored by the Contact Lens Institute (CLI) and conducted by Abt Associates, Inc. of Cambridge, Massachusetts and the Massachusetts Eye and Ear Infirmary of Harvard Medical School. We commend the CLI for sponsoring this study and for making the results available.

The principal findings of the CLI sponsored study are as follows:

- The annual incidence of ulcerative keratitis is estimated to be 20.9 per 10,000 persons wearing cosmetic extended wear soft contact lenses and 4.1 per 10,000 persons wearing cosmetic daily wear soft contact lenses.
- The risk of ulcerative keratitis is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily wear basis are excluded from the comparison, the risk among extended wear users is 10 to 15 times greater than among daily wear users.
- The risk of ulcerative keratitis among daily wear users who wear their lenses overnight is 9 times greater than among those who do not wear them overnight.
- The risk of ulcerative keratitis increases with increasing time intervals between removals for routine lens care, beginning with the first overnight use. The longer the lenses are worn before removal for cleaning and disinfecting, the greater the risk of ulcerative keratitis.
- The risk of ulcerative keratitis may be reduced if patients follow a recommended regimen of cleaning, rinsing, disinfecting, enzymatic cleaning and lens case cleaning. This is particularly important for users of extended wear lenses. For either type lens, there is some evidence suggesting that lens case cleaning may be especially important.
- For either type of lens, the risk of ulcerative keratitis among smokers is estimated to be 3 to 8 times greater than among nonsmokers.

It is clear from this data that both wearing time and lens care affect the risk, and that this relationship is complex. Because the data show that good lens care practices can have a large effect in reducing the risk, we do not believe that extended wear lenses should be removed from the market. Although we cannot identify from the data a wearing interval that will eliminate the risk of ulcerative keratitis, it is clear that a 30-day wearing cycle is no longer acceptable and that wearing times should be reduced. We believe at this point that seven days represents an easily-remembered interval which promotes compliance and which, in conjunction with adequate lens care, would substantially reduce the risk of ulcerative keratitis. In cooperation with eyecare professionals, we will continue to monitor the risk among wearers of various types of contact lenses and will take further action if indicated.

We intend to work with eyecare professional associations in developing new educational materials to help instruct patients on the importance of proper contact lens care in preventing infections. These materials will include the seven day wearing time for extended wear lenses, warnings about wearing daily wear lenses overnight and about the importance of proper lens care in reducing the risk of ulcerative keratitis, and a reminder that patients who smoke may be at increased risk for eye infections.

If you have questions regarding this matter, please contact Richard E. Lippman, O.D., F.A.A.O., Director, Division of Ophthalmic Devices, 8757 Georgia Avenue, Room 440, HFZ-460, Silver Spring, MD 20910.

Sincerely yours,

John C. Villforth
Director
Center for Devices and
Radiological Health

HFZ-250
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New FDA Recommendations & Results of Contact Lens Study