

GEMINI EYE CARE CENTERS

AFFILIATED WITH CLEAR CHOICE LASER EYE CENTERS

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September 8, 2003

Dockets Management Branch
Food & Drug Administration
5630 Fishers Lane, Rm. 1061
HFA - 305
Rockville, MD 20852

Re: Docket Number 2003P-0291

FDA:

For the record, I would like to state our dissatisfaction and dismay with the lack of enforcement of existing laws governing the rule of soft contact lenses.

Disregard of common sense expiration dates, and the substitution by mail-order companies to totally different soft lenses than prescribed is common place.

Some of our patients have told us that they don't even need an exam for contact lenses because the mail-order company that they deal with will sell them contacts based solely on an eyeglass exam, with no knowledge of their corneal curvature, etc.

A recent example of soft lens substitution happened to one of my patients a few months ago. This patient requested a copy of his contact lens prescription, after going thru our normal trial fitting procedure. We complied with his wishes. About 30 days later he was back in the office with very red eyes. I asked him if he had gotten his contact lens Rx filled and he replied that he had been wearing "mail-order" contacts based on my prescription. I asked him to bring in the boxes that they sent him.

Upon examining the boxes, it was evident that they had not sent him the lenses I prescribed. Upon further questioning he told me that the mail-order company said they "were out of the lenses I prescribed" but could send him some "just as good" from another manufacturer. The only thing that fit the prescription was the power. The material, the base curve and the diameter were all different.

2003P-0291

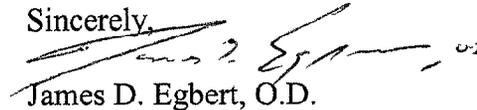
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BOTTOM LINE - they had sent him contacts that he could see with ($\pm .25$ diopter), but which were much too tight on his eyes.

This sort of thing and the selling of non-prescription cosmetic soft lenses - just five minutes from our office, reinforces the view that anyone can wear any type of soft lenses and no professional care is required.

All we are asking is for mail-order companies to operate under the same laws as we do.

Sincerely,



James D. Egbert, O.D.

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