

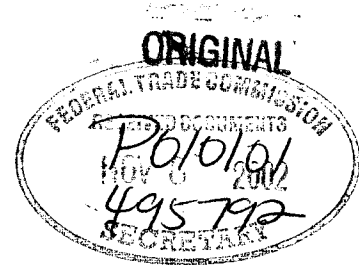


DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

November 7, 2002



Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, DC 20580

Re: Comments on ecommerce

Dear Mr. Clark,

I enjoyed very much the FTC sponsored workshop on Internet competition held October 8-10, 2002. During the contact lens discussion, there was some debate about vendors substituting lenses. Following the workshop, I felt it appropriate to provide comments on contact lens generic materials from the standpoint of material characteristics and lens design concerns.

Enclosed please find six hard copies of my comments as requested in the press release. I hope that the staff at FTC finds them to be helpful. I have also submitted these comments by email to the electronic mail stop ecompetition@ftc.gov. If you have any questions, I can be reached by phone at 301-594-1744, or by email at jzs@cdrh.fda.gov.

Sincerely yours,

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Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Comments regarding ecompetition – Contact Lenses Contact lens generic materials

Material Characteristics

Each contact lens cleared for marketing by the FDA has a “generic name” that identifies the specific plastic polymer used to make the lens. That name is established by the United States Adopted Names (USAN) Council of the American Medical Association based on the repeating monomer units that comprise the polymer. The generic name allows for identification of the contact lens material similar to generic drug compounds.

The generic materials have different physical and optical characteristics. Key differentiating characteristics include the water content and oxygen permeability (Dk). Two companies may offer the same generic material for sale, but utilized different lens designs.

Lens design elements are not considered in establishing a generic name. The thickness (t) of the lens design in combination with the oxygen permeability determines the oxygen transmissibility value (Dk/t). The Dk/t value quantifies the amount of oxygen provided to the cornea through the contact lens. The available has important implications on corneal metabolism. The fit of the lens to the cornea is determined by the base curve (shape) and diameter of the lens. Lens fit also affect corneal tolerance and patient acceptance.

The manufacturing method of molding lenses compared to lathe cutting lenses from blanks can result in different physical properties for the final lens. Manufacturers may use different polymerization and curing processes which may also result in different physical properties. In particular the tensile strength and elongation at break may differ for the different polymerization and curing processes. The result would be two lenses with the same water content and Dk, but they would have a different “feel” with one maintaining its inherent shape better than another.

Substitution of generic lens materials

This discussion assumes that the base curve and diameter of the lens is held constant when a generic substitution is considered. Some manufacturers market the same generic material under different brand names, but vary the lens curvature or diameter slightly. The implication of these variables on the lens fitting relationship to the cornea is best assessed by examination of the lens on the wearer’s eye by a licensed eye care provider.

When a licensed practitioner issues a contact lens prescription the brand name is used to indicate the lens of choice. If the practitioner recognizes that alternative brand names are available for lenses made of the same generic material, the option exists for denoting the acceptance of generic substitution. Whether or not the applicability of generic substitutions is a required element of a contact lens prescription would be determined by the laws and regulations of the State where the licensed eye care provided issues the prescription.

It would be an “off-label” use to prescribe a daily wear lens for extended wear. Many manufacturers only have FDA clearance to market a generic material for use only with daily wear contact lenses. Other manufacturers may have FDA approval to market a lens of the same generic material for both daily and extended wear. Differences in lens design, primarily lens thickness and

the resulting oxygen transmissibility (Dk/t) level can create unwanted physiological consequences for the wearer's cornea when the level of available oxygen is reduced. For this reason, blanket substitution of generic materials is not appropriate for all lens wearers from a corneal physiology standpoint. However, selected generic substitution may have little or no effect when the Dk/t differences are minimal or non-existent and the lens base curve and diameter is held constant.

The water content of a lens should not be the sole consideration when considering material substitutions. A 55% water content of 55% is shared for the two generic materials, etafilcon A marketed by Vistakon as the Acuvue lens, and methafilcon A marketed by Ocular Sciences under a variety of brand names. Despite the same water content, the chemical formulations of these two plastic polymers differ enough so that the oxygen permeability (Dk) values for methafilcon is approximately 19 units compared to 28 units for etafilcon. This would be a critical factor in a lens worn overnight on an extended wear schedule. The lens designs and thickness may attempt to compensate for the different oxygen transmissibility (Dk/t) values; however, this reduction in available oxygen may not result in acceptable corneal physiology.

Conclusion

- Switching generic materials to substitute of one generic material for another may present unwanted corneal health consequences for the wearer, particularly for extended wear, even when the base curve and diameter of the lens is held constant
- The physiological consequences of lens design differences for the same generic material are likely to be minimal for daily wear, but can more significant for extended wear when there is a difference in the oxygen transmissibility (Dk/t) value.
- Substituting one manufacturer's lens for another manufacturer's lens of the same generic material may result in the perception that "something is different" due to differences in physical characteristics, but the key variables of water content and oxygen permeability will be constant.
- The oxygen transmissibility (Dk/t) may vary on same generic material substitutions due to differences in lens design – primarily thickness.
- Water content alone should not be assumed to be the sole factor in determining similarities between generic materials.

Respectfully Submitted:

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