



JUL 19 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sharon Briggs  
Manager, Regulatory Submission  
Vistakon, Division of Johnson and Johnson Vision Care, Inc.  
P.O. Box 10157  
Jacksonville, FL 32247-0157

Re: N18-033/S035  
ACUVUE® 2 COLOURS Brand (etafilcon A) Soft (hydrophilic)  
Contact Lens with UV Blocker  
Filed: January 29, 2001  
Amended: April 3 and 23, 2001

Dear Ms. Briggs:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA) supplement and issued an approval order on April 12, 2001. We received your letter which noted the indications statement included in the FDA approval letter dated April 12, 2001, was not consistent with the indications statement in the approved package insert text. The April 12, 2001, approval order incorrectly stated:

The ACUVUE® 2 COLOURS Contact Lenses are indicated for daily wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The ACUVUE® 2 COLOURS (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.

The ACUVUE® 2 COLOURS (etafilcon A) Soft (hydrophilic) TORIC Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism or less.

The ACUVUE® 2 COLOURS (etafilcon A) Soft (hydrophilic) TORIC-BIFOCAL Contact Lens is indicated for daily wear for the correction of distance and near vision in presbyopic aphakic or non-aphakic persons with non-diseased who may have 10.00D of astigmatism or less.

ACUVUE® 2 COLOURS UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The ACUVUE® 2 COLOURS Contact Lenses may be prescribed for daily wear. Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "Wearing Schedule.") When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

The indications statement in the FDA April 12, 2001, approval order should have stated:

The ACUVUE® 2 COLOURS Contact Lenses are indicated for extended wear to enhance or alter the apparent color of the eye and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The ACUVUE® 2 COLOURS (etafilcon A) Soft (hydrophilic) BIFOCAL Contact Lens is indicated for extended wear for the correction of distance and near vision in presbyopic, aphakic or non-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less.

The ACUVUE® 2 COLOURS (etafilcon A) Soft (hydrophilic) TORIC Contact Lens is indicated for extended wear for the correction of visual acuity in aphakic or non-aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D of astigmatism or less.

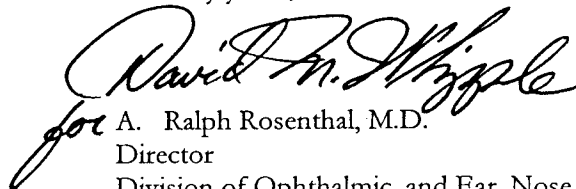
The ACUVUE® 2 COLOURS (etafilcon A) Soft (hydrophilic) TORIC-BIFOCAL Contact Lens is indicated for extended wear for the correction of distance and near vision in presbyopic aphakic or non-aphakic persons with non-diseased who may have 10.00D of astigmatism or less.

ACUVUE® 2 COLOURS UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The ACUVUE® 2 COLOURS Contact Lenses may be prescribed for extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal as recommended by the Eye Care Practitioner. Eye Care Practitioners may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement (see "Wearing Schedule.") When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only.

We hope that this omission has not inconvenienced you. If you have any questions about this corrective action, please contact Ms. Eleanor McGhee at (301) 594-1744.

Sincerely yours,



for A. Ralph Rosenthal, M.D.

Director  
Division of Ophthalmic, and Ear, Nose and  
Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health