Class I Medical Device Recall: CooperVision AVAIRA AQUAFORM Sphere Soft Contact Lenses

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: November 15, 2011

Product(s): AVAIRA AQUAFORM Comfort Science enfilcon A Daily Wear SPHERE Soft Contact Lenses (disposable)

Go to the CooperVision recall web page at www.coopervision.com/international-recall [1], and enter the package lot number to determine whether the lenses have been recalled or contact the toll-free consumer hotline at 1-855-526-6737.

These lenses were manufactured from February 1, 2011 through August 24, 2011 and distributed from March 2, 2011 through November 15, 2011.

Use: For the correction of myopia or hyperopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Recalling Firm:

CooperVision Inc.
6150 Stoneridge Mall Road, Suite 370
Pleasanton, California 94588

Reason for Recall: The unintended presence of a silicone oil residue on AVAIRA Sphere soft contact lenses. Symptoms may range from hazy, blurry vision, discomfort to eye injuries requiring medical treatment.

Public Contact:

Consumers may contact CooperVision on their toll-free hotline at 1-855-526-6737.

FDA District: New York

FDA Comments:

On November 19, 2011, the firm sent a recall notification letter to the US distributors and health care practitioners. Other foreign distributors were sent the recall letter later.

Affected contact lens wearers should stop wearing their lenses immediately and

contact their eye care practitioner for advice. Avaira Sphere contact lens wearers should check CooperVision's recall web site www.coopervision.com/international-recall [1] to enter the package lot number found on the contact lens carton or blister label to determine if their lenses have been recalled. Alternatively, consumers can contact CooperVision's toll-free consumer hotline at 1-855-526-6737 (M-F, 9:00 am – 5:00 pm EST). If you discover your lenses are among the recalled lots, return them to the point of purchase or to your eye care practitioner.

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [2] either online, by regular mail or by FAX.

Additional Links:

- Firm Press Release: CooperVision Announces Expanded Recall of Avaira Line of Contact Lenses [3]
- Related Class I Recall Notice: Avaira Toric Soft Contact Lenses [4]

SOURCE [5]

Source URL (retrieved on *07/22/2014 - 1:02pm*):
http://www.mdtmag.com/news/2011/12/class-i-medical-device-recall-coopervision-avaira-aquaform-sphere-soft-contact-lenses?qt-recent_content=0

Links:
[1] http://www.coopervision.com/international-recall
[2] http://www.fda.gov/Safety/MedWatch/default.htm
[3] http://www.coopervision.com/about-us/pressrelease/coopervision-announces-expanded-recall-avaira-line-contact-lenses
[4] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm275835.htm
[5] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm282733.htm