CooperVision Announces Expanded Recall of Avaira Line of Contact Lenses

Date:

Wednesday, November 16, 2011

PLEASANTON, CA USA – CooperVision announced today that it is expanding its worldwide recall of the Avaira brand product line of contact lenses to include a limited number of lots of Avaira Sphere contact lenses. In continued collaboration with the United States Food and Drug Administration, CooperVision is expanding the recall because it identified certain lots of Avaira Sphere lenses that did not meet its updated quality requirements due to the level of a silicone oil residue.

The presence of the residue (silicone oil) on Avaira Sphere contact lenses may cause hazy vision or discomfort, severe eye pain or eye injuries requiring medical treatment. Not everyone experiences the same symptoms.

“The company is confident we found the problem and have taken corrective action to fix the problem,” said Christine Moench, Vice President, Global Regulatory Affairs and Quality Assurance. “The health and safety of our customers is our top priority.”

If you wear Avaira Sphere contact lenses and experience any symptoms, CooperVision recommends that you stop wearing the lenses immediately. Contact your eye care practitioner for advice.

Avaira Sphere contact lens wearers should:

- CooperVision will launch a recall site www.coopervision.com/international-recall [1] on Wednesday November 16th for wearers to enter the package lot number found on the contact lens carton or blister label to determine if their lenses have been recalled.
- Alternatively, contact CooperVision on a toll-free consumer hotline at 1-855-526-6737(hours of operation 9:00am - 5:00pm EST Monday-Friday)
- If you discover your lenses are among the recalled lots, return them to the point of purchase or to your eye care practitioner.
- Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online at www.fda.gov/MedWatch/report.htm [2]

- Regular Mail; use postage-paid, pre-addressed Form FDA 3500 available atwww.fda.gov/MedWatch/getforms.htm [3]

[3]- Fax 1-800-FDA-0178.

In August 2011, CooperVision announced a recall of limited lots of Avaira Toric contact lenses. CooperVision has identified the issue and has corrected it through its quality system process.

CooperVision will continue to supply Avaira Sphere lenses that are not affected by this recall.

As part of the expanded recall, CooperVision is notifying its customers and requests that eye care practitioners contact their patients regarding this recall. Communication efforts are focused at eye

care professional and distributors to effectively reach lens wearers. CooperVision recall efforts include:

- Sending worldwide recall notifications to Avaira Sphere CooperVision customers.
- Issuing a press release via PR Newswire and Globe Newswire regarding the recall of limited lots of CooperVision Avaira Sphere lenses.
- Providing information on the CooperVision website for lens wearers to check if their lenses are impacted (www.coopervision.com/international-recall [1]).
- An information notice has been posted on www.coopervision.com.
- Offering a toll-free consumer hotline (1-855-526-6737 hours of operation 9:00am - 5:00pm EST Monday-Friday).
- Providing retailers and distributors access to patient communications materials.
- Providing support and detailed information to eye care practitioners to remove recalled lots of Avaira Sphere lenses from the market place.
- Offering customer care resources to answer questions from patients.

The total number of Avaira Sphere lenses manufactured that are affected by the recall is 6.6M, of which 4.9M were shipped to customers globally. CooperVision intends to replace the recalled product with available Avaira Sphere inventory from lots that are not impacted by this recall action.

About CooperVision

CooperVision, a unit of The Cooper Companies, Inc. (NYSE: COO), is one of the world's leading manufacturers of soft contact lenses. The Company produces a full array of monthly, two-week and daily disposable contact lenses, all featuring advanced materials and optics. CooperVision has a strong heritage of solving the toughest vision challenges; such as astigmatism, presbyopia and ocular dryness; and offers the most complete collection of spherical, toric and multifocal products available. Through a combination of innovative products and focused practitioner support, the company brings a refreshing perspective to the marketplace, thereby creating real advantages for customers and wearers.

Category Tags:

- Monthly Contacts [4], Multifocal Contacts [5], Nearsighted/Farsightedness [6]

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