

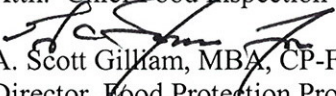


Mitchell E. Daniels, Jr.  
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.  
State Health Commissioner

**DATE:** October 17, 2011

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:**   
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program

**SUBJECT:** CooperVision, Inc. Recall

**SUGGESTED**

**ACTION:** **Unclassified Recall; Unintended presence of a residue on certain lots of Avaira Toric lenses, which may cause hazy vision, discomfort, or eye injuries requiring medical treatment; Information is provided in case of consumer inquiry.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The recall was initiated because of the unintended presence of a residue on certain lots of Avaira Toric lenses, which may cause hazy vision, discomfort, or eye injuries requiring medical treatment. Not everyone experiences the same symptoms. Since the initiation of the recall, the company has received some additional complaints of severe eye pain. Avaira Toric contact lens wearers that experience any symptoms should stop wearing the lenses immediately and speak with their eye care practitioner.

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

**CooperVision Continues the Voluntary Recall of Avaira™ Toric Contact Lenses**

**Contact:**  
Media:  
Erin Crew  
(646) 935-4263  
[Erin.crew@ketchum.com](mailto:Erin.crew@ketchum.com)

Consumer:  
855-526-6737

**FOR IMMEDIATE RELEASE** - October 13, 2011 - In full cooperation with the United States Food and Drug Administration, CooperVision, Inc. is continuing to work with the FDA, distributors, customers, eye care practitioners and lens wearers to complete the worldwide recall initiated on August 19, 2011 on certain lots of Avaira™ Toric contact lenses.

“Our first priority is always the health and safety of all CooperVision lens wearers and as such we responded quickly to complaints from our customers by initiating a voluntary recall” said Christine Moench, vice president, Global Regulatory Affairs and Quality Assurance. “We want to ensure that all consumers are aware of this action and know where to go for more information.”

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

If you wear Avaira Toric contact lenses and are not experiencing symptoms, CooperVision recommends that you:

- Go to the CooperVision recall web page at [www.coopervision.com/recall](http://www.coopervision.com/recall)<sup>1</sup>, and enter the lot number of your package to determine whether your lenses have been recalled.
- Alternatively, you may contact us on our toll-free consumer hotline (1-855-526-6737)
- If your lenses have been recalled, **immediately remove your existing lenses, discontinue lens wear; and return your lenses to your eye care practitioner or point of purchase.**

The recall was initiated because of the unintended presence of a residue on certain lots of Avaira Toric lenses, which may cause hazy vision, discomfort, or eye injuries requiring medical treatment. Not everyone experiences the same symptoms. Since the initiation of the recall, the company has received some additional complaints of severe eye pain. Avaira Toric contact lens wearers that experience any symptoms should stop wearing the lenses immediately and speak with their eye care practitioner.

We have ongoing relationships with practitioners to continue to identify all the affected lots in the market. To date, the recall has impacted approximately 600,000 Avaira Toric contact lenses in the U.S.

As part of the recall, CooperVision notified its customers and requested eye care practitioners contact their patients regarding this recall. Because CooperVision lenses are sold through distributors and eye care practitioners, communication efforts have been focused through these channels in order to most effectively reach lens wearers. Within the first two weeks of the initiation of the recall on August 19, 2011, CooperVision completed the following actions:

- Sent worldwide recall notifications to more than 9,000 Avaira Toric CooperVision customers.
- Contacted more than 7,000 U.S. eye care practitioners who have received or sampled Avaira Toric contact lenses.
- Issued a press release via GlobeNewswire from CooperVision’s parent, The Cooper Companies, regarding the voluntary recall of limited lots of CooperVision Avaira Toric lenses.
- Included information on the CooperVision website for lens wearers to easily and quickly check if their lenses are impacted ([www.coopervision.com/recall](http://www.coopervision.com/recall)<sup>2</sup>), established a toll-free consumer hotline (1-855-526-6737), and included an informational notice on [www.coopervision.com](http://www.coopervision.com)<sup>3</sup>.

- Instructed authorized distributors to send back all Avaira Toric products – not just specific lot numbers – so that CooperVision could ensure that affected lenses were removed.
- Provided retailers and distributors access to patient communications materials – including post cards and e-mail messages – to send to Avaira Toric lens wearers impacted by the recall.
- Worked with eye care practitioners to specifically remove affected lots of Avaira Toric products, by providing them with more than 3,500 customized reports detailing affected lots specific to their location.
- Deployed customer care resources to answer questions from patients, and a specialized team of customer care representatives were made available to contact patients on behalf of eye care practitioners.

The efficient and effective implementation of this recall remains a priority for CooperVision.

### **About CooperVision**

CooperVision, a unit of The Cooper Companies, Inc. (NYSE: [COO](#)<sup>4</sup>), 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. For more information, visit [www.coopervision.com](http://www.coopervision.com)<sup>5</sup>.

*Contact lenses are medical devices and can only be prescribed and dispensed by a licensed eye care professional.*

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[RSS Feed for FDA Recalls Information](#)<sup>6</sup> [what's this?<sup>7</sup>]

[Photo: Product Labels](#)<sup>8</sup>