CooperVision EMEA Marketing

Delta Park, Concorde Way, Segensworth North

Fareham PO15 5RL, United Kingdom

www.coopervision.com

November 14, 2011

URGENT: FIELD SAFETY NOTICE

COMPANY INITIATED LIMITED LOT MEDICAL DEVICE RECALL – AVAIRA SPHERE CONTACT LENSES

Dear Eye Care Practitioner,

CooperVision is expanding the current Avaira™ Toric recall to include specific lots of **Avaira™ Sphere** contact lenses. ['This recall originally did not apply to product sold by CooperVision in **COUNTRY**, but as a result of this expansion, the recall is now active in **COUNTRY**' – INSERT OR DELETE AS APPROPRIATE]. We regret the inconvenience and disruption this may cause you and your patients.

After a comprehensive investigation of all Avaira manufacturing lines, CooperVision is expanding the recall to certain lots of Avaira Sphere lenses. We identified certain lots of Avaira Sphere lenses that did not meet our updated quality requirements due to the level of a residue (silicone oil). The presence of the residue (silicone oil) on Avaira Sphere lenses may cause hazy vision or discomfort, severe eye pain or eye injuries requiring medical treatment. Not everyone experiences the same symptoms.

Our records indicate you received some of the affected **Avaira Sphere** product. Enclosed you will find a list of affected lens lots shipped to your account.

- Please immediately examine your inventory;
- Stop any further distribution of lenses subject to the recall;
- Quarantine affected lenses;
- Contact your patients that received the affected **Avaira Sphere** product and have them return the recalled lenses to you;
- Ask all of your **Avaira Sphere** patients to check the www.coopervision.com/international-recall website to confirm if they have affected or unaffected lenses.

[THE FOLLOWING IN YELLOW NEEDS TO REFLECT THE LOCAL MARKET RETURNS POLICY – BELOW AN EXAMPLE]

As soon as possible, please complete the attached response form and fax it to [FAX NUMBER]. Please return the response form and affected **Avaira Sphere** contact lenses to the following address:

[ADDRESS – LOCAL DISTRIBUTION CENTRE / ATTENTION: QUALITY ASSURANCE]

[Included is a prepaid return label. Your account will be credited once the product is returned and processed.]

If you have a trial lens fitting set of **Avaira Sphere** that may include impacted lenses, we will send you a separate communication. If you receive this communication**,** please discontinue use of this fitting set. A CooperVision sales representative will be visiting your practice to remove and replace the impacted trial lenses. [LOCAL MARKET TO CHECK THEIR PROCESS FOR RECALL OF FITTING SET]

This action is being taken in full co-operation with the Food and Drug Administration in the United States and other appropriate health authorities. No other **Avaira Sphere** lot numbers are affected.

We at CooperVision appreciate your assistance and sincerely regret any inconvenience this situation may cause you or your patients. If you have any further questions, please feel free to contact us at [LOCAL MARKET TEL].

Sincerely,

URGENT: COMPANY INITIATED LIMITED LOT MEDICAL DEVICE RECALL - AVAIRA™ SPHERE CONTACT LENSES

RECALL RESPONSE FORM

PLEASE COMPLETE AND FAX THIS FORM TO [LOCAL RECALL FAX NUMBER]

RETURN ORIGINAL COMPLETED FORM WITH PRODUCT.
IF YOU DO NOT HAVE ANY PRODUCT FOR RETURN, PLEASE CHECK APPROPRIATE BOX BELOW AND FAX THIS FORM TO [LOCAL RECALL FAX NUMBER]

Avaira Sphere Soft Contact Lenses

[ ] We do not have any stock of **Avaira Sphere** [MARKET TO INSERT 3 OR 6 PACK] OR single unit trial lenses

[ ] We are returning _____ of **Avaira Sphere**
Quantity of cartons

[ ] We are returning _____ of **Avaira Sphere**
Quantity of single unit trials

[ ] We have notified our patients to return their lenses to this office and will return product once we have received it.

[ ] We have not received any complaints of adverse effects associated with the use of this product.

Account Number: _____

Account Name: _____

Phone Number: _____

Date: _____

Signature: _____

CooperVision™