

FINAL

**To: United States – Eye Care Practitioners
(Use AMO letterhead)**

**URGENT MEDICAL DEVICE RECALL NOTICE
COMPLETE® MoisturePLUS™ CONTACT LENS CARE PRODUCTS
(12-Ounce Bottles and Active Packs)**

November 21, 2006

Dear eye care professional,

We want to inform you that we are initiating a voluntary recall of certain lots of COMPLETE® MoisturePLUS™ multipurpose contact lens care solution and Active Packs distributed and sold in the United States. Three lots sold in Japan were found to have bacterial contamination, which compromised sterility. Because of this production-line issue at our manufacturing plant in China, AMO is recalling lots distributed in the U.S. that were manufactured on the same production lines during the same production period. Non-sterility of a contact lens solution may have serious health consequences, including eye infection and microbial keratitis. AMO has not received any reports of adverse health events associated with the recalled product lots in the U.S.

Lot numbers are located on the top of the product box and on the side of the product bottle. **The recalled product lots include:**

Package Lot No.	Product Description	Bottled Lot Number(s) in Kit
ZB03087	COMPLETE MoisturePLUS Active Pack	ZB03085, ZB02845
ZB03724	COMPLETE MoisturePLUS Active Pack	ZB03713, ZB03506
ZB03734	COMPLETE MoisturePLUS Active Pack	ZB03713, ZB03506
ZB03735	COMPLETE MoisturePLUS Active Pack	ZB03713, ZB03510
ZB03736	COMPLETE MoisturePLUS Active Pack	ZB03713, ZB03510
ZB03739	COMPLETE MoisturePLUS Active Pack	ZB03737, ZB03510
ZB02710	COMPLETE MoisturePLUS 12oz (360 mL)	ZB02709
ZB02714	COMPLETE MoisturePLUS 12oz (360 mL)	ZB02713
ZB02718	COMPLETE MoisturePLUS 12oz (360 mL)	ZB02717
ZB02722	COMPLETE MoisturePLUS 12oz (360 mL)	ZB02721
ZB02746	COMPLETE MoisturePLUS 2 X 12 oz	ZB02745
ZB02750	COMPLETE MoisturePLUS 2 X 12 oz	ZB02749
ZB02771	COMPLETE MoisturePLUS 2 X 12 oz	ZB02770
ZB02792	COMPLETE MoisturePLUS 2 X 12 oz	ZB02791
ZB02796	COMPLETE MoisturePLUS 2 X 12 oz	ZB02795
ZB02800	COMPLETE MoisturePLUS 2 X 12 oz	ZB02799
ZB02804	COMPLETE MoisturePLUS 2 X 12 oz	ZB02803
ZB03535	COMPLETE MoisturePLUS 2 X 12 oz	ZB03534

Contact lens users who experience symptoms of an eye infection such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge or swelling, should remove their lenses and consult their eye care provider **immediately**.

Patients who believe they are in possession of the recalled product should discontinue use immediately and call 1-877-884-7779 Monday through Friday between 8 a.m. and 5 p.m. Eastern Time, or visit www.amo-inc.com for instructions. AMO is currently contacting retailers regarding return and replacement instructions.

Please report any adverse reactions experienced with the use of this product and/or quality problems to AMO by calling 1-800-347-5005 and to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by

fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch.

Product from the recalled lots was distributed nationwide to food, drug and mass merchandiser accounts. The recall does not include 4-ounce or 16-ounce bottles, or professional samples and packs provided to eye care practitioners. The U.S. recall includes approximately 183,000 units, representing less than one percent of COMPLETE® MoisturePLUS™ products in the U.S. on an annual basis.

While AMO believes the likelihood of users experiencing an adverse reaction is low based upon our investigation to date, we have taken a conservative approach and are conducting this recall in the best interests of our customers. This action is being conducted on a voluntary basis with the knowledge of the U.S. Food and Drug Administration (FDA).

The company commenced an investigation after testing of products sold in Japan determined that three distributed production lots were found to be non-sterile and contaminated with bacteria. As a result, AMO conducted a limited product withdrawal in Japan and notified appropriate global regulatory authorities, including the FDA. The subsequent investigation traced the manufacturing issue to two of the four production lines in its China facility that manufactured product during a specific period. This product was shipped to the U.S., Japan and Asia Pacific and is now the subject of this recall. AMO has temporarily ceased all manufacturing at the China facility and scheduled a special cleaning and sanitization of the manufacturing area and all applicable equipment.

Products manufactured in AMO's facility in Spain, which produces the vast majority of AMO's contact lens solution products distributed in the U.S. and Europe, are not affected by this recall.

We sincerely appreciate your business and continued trust in us, and we apologize for any inconvenience this may cause. AMO is committed to delivering high quality lens care products and will take all necessary measures to ensure that the COMPLETE® line of contact lens care products remain safe and effective for the daily disinfecting of all soft contact lenses.

Please do not hesitate to contact me if I can answer any questions or be of service.

Regards,

David W. Hansen, O.D., F.A.A.O.
Director, Professional Services
Advanced Medical Optics, Inc.
Dave.Hansen@amo-inc.com