

**SUBJECT: ALFOODACT 022-2006: Advanced Medical Optics Announces Voluntary Recall of 18 Lots of Complete(R) MoisturePLUS(TM) Contact Lens Care Products Distributed and Sold in the U.S.**

**Date Issued: November 27, 2006**

**1. REFERENCE:**

a. DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.

b. Allied Communications Publication 121, US SUPP-1 (f).

c. [http://www.fda.gov/oc/po/firmrecalls/advmedical11\\_06.html](http://www.fda.gov/oc/po/firmrecalls/advmedical11_06.html)

**2. BACKGROUND:**

Advanced Medical Optics, Inc., a global ophthalmic surgical and eye care products company, today announced a nationwide, voluntary recall of certain lots of its 12-ounce COMPLETE® MoisturePLUS(TM) multipurpose contact lens care solution and Active Packs. Three lots sold in Japan were found to have bacterial contamination, which compromised sterility. Because of this production-line issue at its manufacturing plant in China, AMO is recalling 18 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.

**3. PRODUCTION DATES/IDENTIFYING CODES:**

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

<b>Package Lot No.</b>	<b>Product Description</b>	<b>Bottled Lot Number(s) in Kit</b>
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	COMPLTE 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

**4. Manufacturer/Establishment Number:**

Advanced Medical Optics  
China

**5. DISTRIBUTION:** Worldwide

**6. REASON FOR RECALL:** bacterial contamination

**7. INSTRUCTIONS AND ADDITIONAL INFORMATION FOR MESSAGE RECIPIENTS:**

(1) Immediately inventory stocks to identify the above items and secure in a "Medical Hold" status to provide assurance of no further issue/sale/use of the item.

(2) Ships at sea are authorized to destroy or dispose of recalled products at their discretion. Documentation for the number of pounds and cases, and any additional pertinent information must be signed by the Accountable Officer and is required for the purpose of recouping to the government the cost of the product involved. Information shall be forwarded by priority message to this center.

(3) Accountable Activities should return recalled product to the manufacturer through the appropriate distribution channels for replacement and/or credit.

7. The Point of Contact for this ALFOODACT message is [CW4 Ramona Martin](#), Consumer Safety Officer, at DSCP-FTW. VOICE, DSN: 444-2905, Commercial (215) 737-2905, or by FAX, DSN: 444-7526, or Commercial, (215) 737-7526

Any individual or office that would like to receive recall messages electronically can forward their email address to [Ramona.Martin@dla.mil](mailto:Ramona.Martin@dla.mil).

Previous recalls and frequently asked questions are available at the following web site:  
<http://www.dscp.dla.mil/subs/proserv/alfood/afamess.htm>.

The navigation tool to the left allows you to view DSCP Alerts and Archived Vendor Recalls also.

Very Respectfully,

*Ms. Ramona Martin*

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