

**SUBJECT: ALFOODACT 014-2007 - Advanced Medical Optics Voluntarily Recalls Complete Moisture Plus Contact Lens Solutions.**

**Date Issued: May 29, 2007**

**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/amo05\\_07.html](http://www.fda.gov/oc/po/firmrecalls/amo05_07.html)

**2. BACKGROUND:** The U.S. Food and Drug Administration is alerting health care professionals and their patients who wear soft contact lenses about a voluntary recall of Complete® MoisturePlus™ contact lens solutions manufactured by Advanced Medical Optics of Santa Ana, Ca. The company is taking this action as a precaution because of reports of a rare, but serious, eye infection, *Acanthamoeba* keratitis, caused by a parasite. The link between the solution and the infection was identified as a result of an investigation by the Centers for Disease Control and Prevention (CDC). Consumers who wear soft contact lenses should stop using the solution, discard all partially-used or unopened bottles and replace their lenses and storage container. FDA and CDC want to gather information related to *Acanthamoeba* keratitis in contact lens users. Report adverse events related to these products to MedWatch, the FDA's voluntary reporting program: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm); Phone: (800) 332-1088; Fax: (800) 332-0178; Mail: MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20852-9787. Consumers who believe they are in possession of the recalled product may call the company at 1-888-899-9183. Additional information about *Acanthamoeba* infection is available from the CDC website at <http://www.cdc.gov/ncidod/dpd/parasites/acanthamoeba/index.htm>.

**3. PRODUCTION DATES/IDENTIFYING CODES:** All Dates/Codes/UPCs of Complete MoisturePlus Multi Purpose Solution manufactured by Advanced Medical Optics of Santa Ana, Ca.

**4. Manufacturer/Establishment Number:**  
Advanced Medical Optics  
Santa Ana, Ca.

**5. DISTRIBUTION:** Worldwide

**6. REASON FOR RECALL:** Increased risk of *Acanthamoeba* infection.

**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 LTC John C. Smith, Food Safety Officer, at DSCP-FTW. VOICE, DSN: 444-8461, Commercial (215) 737-8461, 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.

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