DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417	05/29/2007 - 06/25/2007* FEI NUMBER 3003843509

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Richard A. Meier, COO/CFO/President of Eye Care

FIRM NAME	STREET ADDRESS
Advanced Medical Optics, Inc.	1700 E Saint Andrew Pl
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Ana, CA 92705-4933	Initial Distributor, Manufacturer, Specification Developer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, the following complaints were not reported to FDA according to the time line established by the firm and FDA (Reports for events of serious injury to be submitted within 30 days following the end of the calendar quarter):

a) Complaints referencing a diagnosis of Acanthamoeba keratitis:

Complaints # 61130/31131; date aware 2/28/06
Complaint # 68786; date aware 5/29/06
Complaint # 65138; date aware 4/18/06
Complaint # 76379; date aware 8/31/06
Complaint # 82755; date aware 11/14/06
Complaint # 83286; date aware 11/20/06
Complaint # 83458; date aware 11/17/06
Complaint # 83616; date aware 11/22/06

b) Complaints referencing "eye infections" and medical intervention associated with Serratia marcescens:

Complaint # 66614, date aware 5/5/06
Complaint # 83854, date aware 11/27/06
Complaint # 69062, date aware 6/2/06

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EXEMPTION (b)(4) ENTIRE

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OBSERVATION 2

Not all data from quality data sources are analyzed to identify existing and potential causes of nonconforming product and other quality problems.

Specifically, records for the following complaint investigations were incomplete in that:

a) The investigations for complaint numbers 61130 and 61131 reference patients diagnosed with Acanthamoeba keratitis infections. Microbial evaluations of the returned complaint units were found to indicate the presence of protozoans; however the type of protozoans were not identified. Additionally, retained samples were not tested using the same method as the complaint units.

b) Investigations for complaint numbers 66614, 83854, 69062 and 90216 reference returned complaint units the firm determined to be positive for Serratia marcescens. The amount of bacteria in each complaint unit was not quantified. The firm did not isolate the bacterium and test it against retained units to support whether each lot was effective against Serratia marcescens.

c) Investigations for complaint numbers 69062, 90216 and 83286 did not determine the type or material composition of contact lenses worn by the complainant.

OBSERVATION 3

Corrective and preventive action procedures addressing implementation and recording of changes in methods and procedures to correct and prevent identified quality problems were not implemented.

Specifically, the firm did not follow its CAPA procedures, QSOP002, Rev. 09 in that an Action Request was not created for:

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a) The voluntary recall of Complete® MoisturePlus™ contact lens solutions products.

b) The decision to readdress MDR reportability for corneal ulcers, eye infections, and keratitis.

OBSERVATION 4

Design verification did not confirm that the design output meets the design input requirements.

Specifically, the Antimicrobial Efficacy-Regimen Test (4 Hour Soak) dated 10/30/02, performed to verify a No-Rub 4 Hour Regimen, was performed under best case conditions. Three lots of Complete Upgrade C 9451X, (Lot #s E19670, E19671 and E19686) whose preservative, Polyhexamethylene Biguanide, were found to be at the upper end of the preservative specification a[redacted]and[redacted]ppm, respectively were used in the study and present a best case approach to determining the antimicrobial efficacy of the contact lens solution.

(b)(4) EXEMPT

OBSERVATION 5

Procedures for verifying that design output meets design input were not implemented.

Specifically, Protocol # 195A, "Protocol for 90 Day Discard Date Procedure for AMO, Complete C, Formulation 9451X, 355ml Container" was not followed in that:

a) The firm did not use the three lots of product specified in the protocol and did not provide an explanation in the report of why the change was made.

b) The firm did not meet the initial inoculum of[redacted]for four of the five organisms used in the study and did not provide an explanation in the report of why the inoculum levels were not met.

(b)(4) EXEMPT

OBSERVATION 6

Procedures for planning and conducting reviews of the design results at appropriate stages of the device's design development were not implemented.

Specifically, the firm did not follow its design control procedures, Eye Care Product Development Process Manual, Version 2, in that a design review was not conducted to evaluate design inputs prior to the Research Release for Complete® MoisturePlus™.

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OBSERVATION 7

Appropriate procedures have not been defined and documented for controlling environmental conditions.

Specifically, labeling for Complete® MoisturePlus™ indicates "Store away from heat. Protect from freezing" and "Store at room temperature". There are no procedures to ensure this temperature range is maintained during shipment of finished devices.

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FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

William S Vitale, Investigator

Jennifer M. Gogley, Microbiologist

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