DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787)-474-9500 Fax:(787) 729-6809	04/21/2008 - 04/25/2008 FEI NUMBER 3002911336

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Rolando Torres Colon, General Manager

FIRM NAME	STREET ADDRESS
Cooper Vision Caribbean	#500 Carr 584 Lot 7 Amuelas Industrial Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Juana Diaz, PR 00795	Medical Device Manufacturer

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 I OBSERVED:

OBSERVATION 1

Process validation activities and results have not been fully documented.

Specifically,

Your firm failed to fully review and document deviations to pre-established acceptance criteria during the execution of the performance qualification protocol for the sterilization process of contact lenses in single blisters, conducted as part of product transfer activities. According to the information included in the final report for the Performance Qualification Protocol for Single Blister Sterilization o (b) (4) Autoclave, no deviations and no exceptions were obtained during the execution of the exercise in 07/2002 and the sterilization process was considered validated in the (b) (4) Autoclave (b) (4) My review of the raw data included with the protocol disclosed the following discrepancies that are not included or evaluated in the final report:

1. Identification of temperature indicators revealed the replacement of units during the exercise.
2. Identification of cycles and available raw data show that one additional cycle was executed (from the established criteria).
3. Identification of reported test results of Biological Indicators show that one additional cycle was executed.
4. Raw data for cycle "Run 1 Max" executed during the exercise show a temperature failure (120 Deg) in one of the chamber's temperature indicators; temperature readings and alarms are clearly reported on the printed data. Information on the test results for the Biological Indicators for this particular cycle is not included in the package nor is referenced in the final report.

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OBSERVATION 2

Complete complaint files are not maintained.

Specifically,

Your firm failed to fully document the evaluation of the manufacturing process of product lots manufactured locally during the investigation of consumer complaints reporting patient reactions. The evaluation of complaints associated to such defects during the period of 2005 to 07/2007 do not include a comprehensive evaluation of manufacturing records in order to asses the impact-if any- of reported inspection results or other conditions, on the reported defect.

OBSERVATION 3

The procedures for implementing corrective and preventive actions were not complete.

Specifically,

The approved procedure for the evaluation of data established at the site to assist in the need for an investigation or CAPA during the evaluation of negative trends, Trend Procedure # 0412, does not include specific provisions on how to document the evaluation of quality data sources that are evaluated periodically without the need of a CAPA file -such as NCR's, defect rates- and could be consequently re-classified as a result of the evaluation. The procedure does not provide minimum requirements for the documentation of evaluations completed or method to ensure completion of investigations as required.

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Observation Annotations

Observation 1: Promised to correct.

Observation 2: Reported corrected, not verified.

Observation 3: Reported corrected, not verified.

SEE REVERSE OF THIS PAGE		DATE ISSUED
	4/25/08	04/25/2008

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FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Noreen Muñiz, Investigator

SEE REVERSE OF THIS PAGE	4/25/08	DATE ISSUED 04/25/2008