**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Ave.<br>Jamaica, NY 11433<br>(718) 340-7000 Fax:(718) 662-5661<br>Industry Information: www.fda.gov/oc/industry | 10/14/2011 - 10/24/2011*<br>FEI NUMBER<br>3005724763 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** James Della Valle, Vice President Distribution

| FIRM NAME | STREET ADDRESS |
|---|---|
| CooperVision Inc. | 180 Thruway Park Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| W Henrietta, NY 14586-9798 | Packager/Labeler |

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

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the (b) (4) packaging lines that are operated by the (b) (4) and (b) (4) machines are not adequately validated according to established procedures.

Performance Qualification:

1) The firm relies on the machines to perform quality checks to determine if the label information was printed correctly on the blisters. During the PQ testing the firm did not open up the cartons to see if the blisters inside had the correct label information or if the label information printed on the blisters matched the label information printed on the cartons.

2) The procedure did not define the number of runs or the number of units per run. In addition, the procedure did not define the statistical analysis methods that would be used or the number of data points that would be needed for the statistical analysis. In practice, these machines on average label and pack (b) (4) cartons per month and each run (lot) is typically (b) (4) units. During PQ, the firm tested (b) (4) runs with (b) (4) units per run.

3) The firm did not document the type of errors they obtained (i.e. incorrect labeling information on carton, damaged package, etc.) even though these errors are defined in the procedure.

Installation Qualification and Operational Qualification:

1) The results for the testing performed during IQ were not adequately documented. For some sections the firm just stated pass or fail for the overall section and not for the individual tests that were performed within that section.

2) The firm stated they use the preventative maintenance schedule that is outlined in the owner's manual for these (b) (4)

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Ave.<br>Jamaica, NY 11433<br>(718) 340-7000 Fax:(718) 662-5661<br>Industry Information: www.fda.gov/oc/industry | 10/14/2011 - 10/24/2011*<br>FEI NUMBER<br>3005724763 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: James Della Valle, Vice President Distribution

| FIRM NAME | STREET ADDRESS |
|---|---|
| CooperVision Inc. | 180 Thruway Park Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| W Henrietta, NY 14586-9798 | Packager/Labeler |

machines. The manual calls for (b) (4) cleaning of the sensors that are used to read the bar code off the silver stock (unlabeled blisters), the label information that is printed on the blisters and the information that is printed on the cartons. In practice, the firm cleans these sensors once every (b) (4) weeks. The firm did not perform any testing during OQ to determine the ability of the sensors to perform their function if they are not maintained according to the preventive maintenance requirements outlined in the manual.

## OBSERVATION 2

Procedures for finished device acceptance have not been established.

Specifically, the firm has not established procedures for finished device acceptance for labeling operations for any of its products.

## OBSERVATION 3

Procedures for device history records have not been established.

Specifically, the firm has not established a procedure for device history records.

## OBSERVATION 4

Procedures for corrective and preventive action have not been adequately established.

Specifically, the firm did not implement its procedure, Corrective and Preventive Action, SOP Number QAP082, Revision Number 11, for initiating a CAPA when required by its Risk Assessment Matrix. If the Risk Assessment number falls into the Red categories on the Risk Assessment Matrix, a CAPA must be raised. For its labeling operations if a complaint or non conforming report is categorized as a P5-mislabeled for the following reasons then it falls into the Red category and a CAPA must be opened: incorrect human readable information on the primary packaging label, incomplete/illegible information on secondary packaging or no insert included in the secondary packaging. The following complaints and non conforming reports should have had a CAPA initiated.

1) Complaint CC136149 - Category: P5-Mislabeled, Product: Proclear Toric, Description: box does not match blisters

2) Complaint CC144253 - Category: P5-Mislabled, Product: MINI, Description: lens label states tinted and this product is not actually tinted.

3) Complaint CC161176 - Category: P5-Mislabled, Product: Hydrasoft Toric, Description: last vial in box was incorrect. Outside of package marked 8.3/14.2 10-25-1.75x50. Last vial in box is 8.9/15.0 500-2.50x170.

4) Complaint CC161446 - Category: P5-Mislabeled, Product: Biomedics Toric, Description: carton is labeled -4.00-1.75x120 and blisters are labeled -2.50-1.75X50.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Marc S Neubauer, Investigator<br>MSN | 10/24/2011 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Ave.<br>Jamaica, NY 11433<br>(718) 340-7000 Fax:(718) 662-5661<br>Industry Information: www.fda.gov/oc/industry | 10/14/2011 - 10/24/2011*<br>FEI NUMBER<br>3005724763 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** James Della Valle, Vice President Distribution

| FIRM NAME | STREET ADDRESS |
|---|---|
| CooperVision Inc. | 180 Thruway Park Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| W Henrietta, NY 14586-9798 | Packager/Labeler |

5) Non Conforming Report NCR83768 - Category: Secondary packaging process, Description: QA - 3 cartons that were opened by Auditor did not have inserts in them.

## OBSERVATION 5

Complaints involving the possible failure of labeling to meet any of its specifications were not investigated where necessary.

Specifically, the firm did not do a root cause investigation for the following complaints that dealt with mislabeling:

1) Complaint CC136149 - Category: P5-Mislabeled, Product: Proclear Toric, Description: box does not match blisters

2) Complaint CC144253 - Category: P5-Mislabled, Product: MINI, Description: lens label states tinted and this product is not actually tinted.

3) Complaint CC161176 - Category: P5-Mislabled, Product: Hydrasoft Toric, Description: last vial in box was incorrect. Outside of package marked 8.3/14.2 10-25-1.75x50. Last vial in box is 8.9/15.0 500-2.50x170.

4) Complaint CC161446 - Category: P5-Mislabeled, Product: Biomedics Toric, Description: carton is labeled -4.00-1.75x120 and blisters are labeled -2.50-1.75X50.

Specifically, the firm did not perform a root cause investigation nor did they determine whether the issues extended to other lots for the following unconfirmed complaints.

1) Complaint CC143835 - Product: Biomedics 55 UV, Description: Box is labeled -3.75 and two lenses inside the box are +3.25.

2) Complaint CC146840 - Product: Proclear Toric, Description: Patient claims that 2 +475 - 1.75 10 lenses were in a box that was labeled +5.75 - 1.75 60.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Ave.<br>Jamaica, NY 11433<br>(718) 340-7000 Fax:(718) 662-5661<br>Industry Information: www.fda.gov/oc/industry | 10/14/2011 - 10/24/2011*<br>FEI NUMBER<br>3005724763 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** James Della Valle, Vice President Distribution

| FIRM NAME | STREET ADDRESS |
|---|---|
| CooperVision Inc. | 180 Thruway Park Dr |
| **CITY, STATE, ZIP CODE, COUNTRY** | **TYPE ESTABLISHMENT INSPECTED** |
| W Henrietta, NY 14586-9798 | Packager/Labeler |

## Observation Annotations

| | | | |
|---|---|---|---|
| Observation 1: | Promised to correct within 24 weeks. | Observation 2: | Promised to correct within 24 weeks. |
| Observation 3: | Promised to correct within 24 weeks. | Observation 4: | Promised to correct within 24 weeks. |
| Observation 5: | Promised to correct within 24 weeks. | | |

*** DATES OF INSPECTION:**
10/14/2011(Fri), 10/17/2011(Mon), 10/18/2011(Tue), 10/20/2011(Thu), 10/24/2011(Mon)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Marc S Neubauer, Investigator<br>Marc S Neubauer | 10/24/2011 |