DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202	03/22/2006 - 05/15/2006 1032500

TO: Mr. Thomas H. Eggleton, VP of Operations

Bausch & Lomb Inc	8507 Pelham Rd
Greenville, SC 29615-9598	Medical Device/Pharmaceutical 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 WE OBSERVED:

OBSERVATION 1

The design plan does not describe the design and development activities, define responsibility for implementation of design and development activities, and identify and describe the interfaces with other groups or activities as appropriate.

MEDICAL DEVICE REGULATIONS

Specifically, a complete design plan was not done for ReNu w/ MoistureLoc Multi-Purpose Solution. The plan provided is incomplete and does not provide clear traceability through the design project. For example:

a) The initial design plan shows Project [redacted] began in 2001 and resulted in product [redacted] The formulation contains a different preservative ([redacted]) and was cleared by the Agency in 2003. The product was not commercialized by the firm. Project [redacted] is an alternate product project [redacted]), ReNu w/ MoistureLoc Multi-Purpose Solution containing Alexidine, which was added to the same original design and development plan in 2004. Initial feasibility and risk assessment show the two products with two perservative agents [redacted] Alexidine) under one design project.

b) Raw material specifications were not determined and firmly established prior to process validation. For example, [redacted] was used for pre-clinical and clininical studies however, the product formulation was changed to [redacted] at initial validation then back to [redacted]

c) Tasks for determining analytical in-process and finished product specifications were not assigned in the design plan and they were not firmly established prior to the product launch of ReNu w/MoistureLoc Multipurpose Solution. For example, [redacted] release specification was lowered after beginning process validation.

d) The firm does not have a test method to evaluate the degradation of Alexidine in the ReNu w/MoistureLoc Multipurpose Solution.

e) The design history file does not contain a statement of readiness from R&D as required in established procedure BL POL-

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401, Product Development Management Process.

OBSERVATION 2

Design input requirements that are incomplete were not addressed.

Specifically, several design inputs for ReNu w/ MoistureLoc Multi-Purpose Solution[redacted] are outstanding and were not addressed by the project team before bringing the product to the market. For example, the following value added design inputs remain open: qualification of a no rub, no rinse regimen for the CE Mark; [redacted] of cycled lenses [redacted] cycles) with Group 1-4 lenses (no rub, no rinse); ISO/FDA Regimen Test using [redacted] and [redacted] after a [redacted] hour and [redacted] day soak in glass vials; laboratory cleaning study to demonstrate lipid removal with [redacted] lenses; and, a biocidal efficacy study that demonstrates efficacy against "clinically significant microorganisms" (non-ISO organisms).

OBSERVATION 3

Design reviews were not performed at appropriate times, following the review schedule.

Specifically, the post-launch product review for the ReNu w/ MoistureLoc Multi-Purpose Solution has not been performed as required in the formally established procedures, BL-PRO-408, Project Post Launch Review. The review should occur during the first year after the product is launched. ReNu w/MoistureLoc Multi-Purpose Solution was initially distributed from the Greenville site in August 2004. [redacted]

OBSERVATION 4

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,

a) The firm failed to notify the Agency of 35 serious injury reports of Fusarium Keratitis from Singapore's Minister of Health in February 2006 relating to ReNu MoistureLoc Multi-Purpose Solution. None of the complaints were reported to the Agency as of April 7, 2006.

b) Complaint #S105000240 - #S105000245 were initially reported to the firm as Keratitis complaints in July 2005. These complaints have not been reported to the Agency as of May 9, 2006.

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c) Complaint # S105000012 was initially reported as a chemical burn, but was later updated as Keratitis. The complaint has not been reported as an MDR.

OBSERVATION 5

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, the firm failed to report the removal of ReNu MoistureLoc Multi-Purpose Solution from the market in Singapore and Hong Kong in February 2006.

OBSERVATION 6

A validated process was not revalidated when changes or process deviations occurred.

Regarding the validation of ReNu w/ MoistureLoc Multi-Purpose Solution:

A. The firm does not have complete validation data for ReNu w/ MoistureLoc Multi-Purpose Solution [redacted]). Initial scale-up activities at the Greenville plant were performed in 2003 on an unnamed similar product [redacted] utilizing [redacted] in the product formulation [redacted] replaced [redacted] (which was used in the original product formulation for pre-clinical and clinical studies) after white particles were noted on soft contact lens while performing a lens compatibility study. The [redacted] product was formulated with [redacted] and used in the validation study; however, the formulation was not commercialized. In 2004 the firm performed a limited validation study on the currently marketed Renu w/ MoistureLoc Multi-Purpose Solution utilizing [redacted] in the product formulation. The corrective action to avoid the appearance of white particles on the lenses was to use the [redacted], USP with a European Pharmacopeia clarity test. The validation data available shows that cleaning of the bulk mix tanks and filling lines, the filling process, the hold time study, and purging processes were not re-validated. Chemistry testing was limited to the compounding batches and no USP sterility testing was performed for the scaled-up batches of ReNu w/MoistureLoc Multi-Purpose Solution. [redacted] validation data was accepted in lieu of performing a complete re-validation of the manufacturing processes.

B) The following deviations are noted in the initial validation study [redacted].

1. The European Pharmacopeia (EP) clarity test was not performed on Lot # 234068 [redacted]) that was used in the 2003 validation study. Raw material specifications included a requirement for the EP clarity test in 2003.

2. Bacteriostasis/Fungistasis (B/F) testing was not performed for all validation runs as specified in the established protocol (0308-ME-0154). [redacted] runs were performed; however B/F testing was performed on only one run.

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60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202	03/22/2006 - 05/15/2006
	FEI NUMBER 1032500
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Mr. Thomas H. Eggleton, VP of Operations	
FIRM NAME	STREET ADDRESS
Bausch & Lomb Inc	8507 Pelham Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Greenville, SC 29615-9598	Medical Device/Pharmaceutical Manufacturer

3. The first bottle out of filling on the [redacted] batch [redacted] was out of specification on the lower end for [redacted] At the time of fill the release specifications were [redacted]. The release specifications were subsequently lowered to [redacted] and this run was accepted.

OBSERVATION 7

Procedures have not been followed to prevent contamination of equipment or product by certain substances.

Specifically,

a) On 4/19/06 in the upper mix room, peeling paint and paint chips were observed on agitators located on the tops of tank [redacted] and the solenoid above tank [redacted] These tanks are currently used for the production of contact lens solutions.

b) The cleaning, inspection, and sanitization of fill lines [redacted] used in the production of [redacted] Sensitive Eyes, Boston Cleaner, ReNu w/Moisture Loc Multi-Purpose Solution were not documented as per SOP #40-102-19, "Weekly and Monthly Cleaning and Inspection of APA", for the monthly cleaning conducted for the month of February 2006.

OBSERVATION 8

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

Specifically,

Temperature conditions within the aseptic processing area are not being documented to ensure such conditions are consistently within established specifications of [redacted] degrees Celsius.

OBSERVATION 9

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

Specifically as of 3/23/06

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TO: Mr. Thomas H. Eggleton, VP of Operations

FIRM NAME Bausch & Lomb Inc	STREET ADDRESS 8507 Pelham Rd
CITY, STATE, ZIP CODE, COUNTRY Greenville, SC 29615-9598	TYPE ESTABLISHMENT INSPECTED Medical Device/Pharmaceutical Manufacturer

a) The Fusarium Keratitis investigation did not include sterility or biocidal testing for ReNu w/ MoistureLoc Multi-Purpose Solution product lots implicated in complaints received from Hong Kong.

b) The firm had not performed sterility testing on the return/retain samples in conjunction with the Fusarium investigation for complaints received from Malaysia and Singapore.

OBSERVATION 10

Procedures for controlling the storage of product in storage areas and stock rooms were not implemented to prevent mix-ups, damage, other adverse effects.

Specifically,

a) On 4/4/06 the firm failed to locate a product lot implicated in a customer complaint, ReNu w/ MoistureLoc Multi-Purpose Solution, Lot# GG5055, which was identified as being part of the current inventory in the firm's validated inventory control systems [redacted]

b) On 4/24/06 the firm was unable to locate [redacted] cases of ReNu MoistureLoc Multipurpose Solution, Lot #AJ5065.

c) On 5/9/06 the firm was unable to locate [redacted] units of ReNu MultiPlus Multipurpose Solution, Lot #GC6061.

OBSERVATION 11

Quality audits were not conducted to verify that the quality system is effective in fulfilling your quality system objectives.

Specifically,

a) Review of the Internal Audit schedule indicated that the firm has not conducted or established a routine auditing of their complaint handling system.

b) The firm does not have procedures defining the frequency by which supplier audits will be conducted.

c) The firm has never audited the supplier of [redacted], a component used to manufacture ReNu w/ MoistureLoc Multi-Purpose Solution.

d) Contract laboratories/suppliers used in raw material and finished product testing have not been audited at a

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CITY, STATE AND ZIP CODE/COUNTRY Greenville, SC 29615-9598	TYPE ESTABLISHMENT INSPECTED Medical Device/Pharmaceutical Manufacturer

defined frequency. For example:
-Lab A was last audited on 12/11/98
-Supplier A was last audited on 9/11/01
In addition, the last biennial audit of Lab B was conducted on 12/3/2003.

OBSERVATION 12

Procedures have not been implemented to ensure that mix-ups, damage, or other adverse effects to product do not occur during handling.

Specifically,

a) No documentation, inspection, audit, or checklist were established or conducted to guarantee that the trucking company transporting finished product from the manufacturing plant to the distribution center is protecting materials and finished product from damage and contamination as specified in SOP #15-006-09. Additionally, the trucking company does not have a climate control system in the trailer to monitor temperature conditions.

b) There are no procedures indicating the amount of time finished products are allowed to remain stored in trailers before finding a location in the warehouse for storage.

OBSERVATION 13

Appropriate design, construction, placement, and installation of manufacturing equipment have not been ensured.

Specifically,

On 3/27/06 clean, uncapped product transfer hoses that are used in production were observed in direct contact with a shelving unit upon which a visible layer of a white powdery residue was observed. The shelving unit was installed to prevent hoses from coming in contact with the manufacturing room floor.

OBSERVATION 14

Maintenance activities, including the date and individuals performing those activities, have not been documented.

FINISHED PHARMACEUTICALS

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Specifically, integrity testing of the vent filters on the [redacted] Hot Purified Water (HPW) tanks was not conducted during the [redacted] month interval between June 2005 and March 2006 per SOP # 50-095-08.

OBSERVATION 15

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your established mix tank cleaning procedures, SOP# 40-017 entitled, "Clean In place System for Mix Tanks", require specific manual cleaning procedures for [redacted] that include a [redacted] minute manual rinse at [redacted] degrees Celsius, prior to the automated CIP cycle. Review of batch record documentation and cleaning cycle records found that this manual rinse is not being documented.

OBSERVATION 16

The written stability program for drug products does not include meaningful and specific test methods.

Specifically,

The current analytical test methods for OTC drug products are not stability-indicating to demonstrate levels of degradation or other impurities that may exist in such products.

OBSERVATION 17

Employees are not given training in the particular operations they perform as part of their function.

Specifically, [redacted] of the [redacted] operators within [redacted] operations have not participated in [redacted] media fills, as per SOP# 90-161-02, "Validation of Aseptic Fill Challenges", to ensure the operators remain current with relevant established procedures and cGMPs.

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OBSERVATION 18

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, there are no specific established procedures for the visual examinations of incubated vials conducted by microbiological technicians during media fill operations.

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Claudette D. Brooks, Investigator

Babatunde D. Babalola, Investigator

Bonita S. Chester, Investigator

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202	03/22/2006 - 05/15/2006
	FEI NUMBER 1051854

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Thomas H. Eggleton, VP of Operations

FIRM NAME	STREET ADDRESS
Bausch & Lomb Inc	130 Commerce Ctr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Greenville, SC 29615-5816	Repackager/Relabeler

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.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures for controlling the storage of product in storage areas and stock rooms were not established to prevent mix-ups, damage, other adverse effects.

Specifically, the firm does not monitor the temperature of the storage warehouse at the distribution center, although product labeling specifies that products should be stored at room temperature. For example, ReNu w/ MoistureLoc Multi-Purpose Solution and ReNu Multiplus Multi-Purpose Solution.

OBSERVATION 2

Procedures have not been documented to prevent contamination of equipment or product by certain substances.

Specifically, the firm does not have established procedures or practices for cleaning the packaging areas or packaging equipment in the distribution center. On 3/22/06 Boston Convenience Packs, Lot # AC6050 were being packaged on Line #[redacted] Twelve (12) oz ReNu w/ MoistureLoc Multi-Purpose Solution twin packs with 2 oz. ReNu w/ MoistureLoc, Lot #AC6035 was also being packaged on Line #[redacted] The packaging equipment including the equipment coverings, on both lines was dirty and dusty. Additionally, the entire packaging area was in need of cleaning.

Annotation: Reported corrected, not verified.

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TO: Mr. Thomas H. Eggleton, VP of Operations

FIRM NAME Bausch & Lomb Inc	STREET ADDRESS 130 Commerce Ctr
CITY, STATE ZIP CODE, COUNTRY Greenville, SC 29615-5816	TYPE ESTABLISHMENT INSPECTED Repackager/Relabeler

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Claudette D. Brooks

Claudette D. Brooks, Investigator

Babatunde D. Babalola, Investigator

Bonita S. Chester

Bonita S. Chester, Investigator

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