DEPARTMENT OF REAL PRINCIPLE VICES				
POOD AND DRUG ADMINISTRATION				
60 Eighth Street NE	•		03/22/2006 - 05/15/2006	
Atlanta, GA 30309 (404) 253-1161 Fax: (	404) 253-1202		032500	
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TO: Mr. Thomas H. Ec	glaton, VP of Open	ations statement		
Bausch & Lomb Inc		8507 Pelham R		
Greenville, SC 29615	-9598		e/Pharmaceutical	
This document lists observations as observations, and do not supresent observation, or have implemented, action with the FDA representative questions, please contact FDA at the	<ul> <li>final Agency determination:</li> <li>or plan to implement, correct</li> <li>during the inspection or su</li> </ul>	regarding your compliance, we action in response to an basit this information to FI	If you have an objection reg observation, you may discus	arding an
The observations noted in this i firm is responsible for conducti regularments.	Form FDA-483 are not an e ing internal self-audits to la	exhaustive listing of objections of and correct any a	ctionable conditions. Und nd all violations of the qua	er the law, your slity system
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OBSERVATION 1		٠.		
The design plan does not descri and development scrivities, and				
MEDICAL DEVICE REGUL	ATIONS			
Specifically, a complete design incomplete and does not provid				lan provided is
a) The initial design plan shows Project (1996) began in 2001 and resulted in product (1996). The formulation contains a different preservative (1996) and was cleared by the Agency in 2003. The product was not commercialized by the firm. Project (1996) is an alternate product project (1996), 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 essessment allow the two products with two perservative agents.  Alexidine) under one design project.				
b) Raw material specifications were not determined and firmly established prior to process validation. For example,  The Discourse of the product formulation was changed to a second to be a second to b				
c) Tasks for determining analytical in-process and finished product specifications were not easigned in the design plan and they were not firmly established prior to the product launch of ReNu w/MoistureLoc Multipurpose Solution. For example, 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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TO: Mr. Thomas H. Eggleton, VP of Op	erations	
Bausch & Lomb Inc	8507 Pelham Rd	
	THE STARTE AND PARTIE	
Greenville, SC 29615-9598	Medical Device/Pharmaceutical Manufacturer	
401, Product Development Management Process.		
Design input requirements that are incomplete were not addressed.  Specifically, several design inputs for ReNu w/ MoistureLoc Multi-Purpose Solution and several 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; and the complete of cycles with Group 1-4 lenses (no rub, no rinse); ISO/FDA Regimen Test using the product to demonstrate lipid removel with after a glocur and to day sock in glass visits; leboratory cleaning study to demonstrate lipid removel with lenses; and, a biocidal efficiely study that demonstrates efficacy against "clinically significant microorganisms" (non-ISO organisms).		
OBSERVATION 3  Design reviews were not performed at appropriate times	•	
required in the formally established procedures, BL-PRO	Nu w/ MoistureLoc Multi-Purpose Solution has not been performed as O-408, Project Post Launch Review. The review should occur during bistureLoc Multi-Purpose Solution was initially distributed from the	

# **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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Bausch 6 Lomb Inc  ###################################	(404) 253-1161 Fax: (404) 253-1202	- · · · ·		
Bauech 6 Lomb Inc  On Water Description  Greenville, SC 29615-9598  Hedical Device/Pharmaceutical  Manufacturer  c) Complaint # \$105000012 was initially reported as a chemical burn, but was letter updated as Keratitis. The complaint has not been reported as an MDR.  OBSERVATION 8  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 RaNiu MoistureLoo 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 ReNiu w/ MoistureLoc Multi-Purpose Solution  A. The firm does not have complete validation deta for RaNiu w/ MoistureLoc Multi-Purpose Solution  (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 competibility study. The product was formulated with the surface of the studies of the surface of th	TO: Mr. Thomas H. Eggleton, VP of Opera	tions		
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RaNu w/MoistureLoc Multi-Purpose Solution.  Well and American validation data was accepted in lieu of performing a complete revalidation of the manufacturing processes.  B) The following deviations are noted in the initial validation study and the state of the European Pharmacopeis (EP) clarity test was not performed on Lot # 234068  The European Pharmacopeis (EP) clarity test was not performed on Lot # 234068  Constitution of 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	European Pharmacopeia clarity test. The validation data ava	use the comments of the bulk mix tanks and filling lines,		
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I. The European Pharmacopeis (EP) clarity test was not performed on Lot # 234068  Continued 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.	European Pharmacopeia clarity test. The validation data ava the filling process, the hold time study, and purging processe compounding batches and no USP sterility testing was perfe RaNu w/MoistureLoc Multi-Purpose Solution.	use the control of the bulk mix tanks and filling lines, is were not re-validated. Chemistry testing was limited to the sensed for the scaled-up batches of		
clarity test in 2003.  2. Becteriostasis/Fungistasis (B/F) testing was not performed for all validation suns as specified in the established protocol	European Pharmacopeia clarity test. The validation data ava the filling process, the hold time study, and purging processe compounding batches and no USP sterility testing was perfe RaNu w/MoistureLoc Multi-Purpose Solution.	use the control of the bulk mix tanks and filling lines, is were not re-validated. Chemistry testing was limited to the sensed for the scaled-up batches of		
	European Pharmacopeia clarity test. The validation data ava the filling process, the hold time study, and purging processe compounding batches and no USP sterility testing was perfet RaNu w/MoistureLoc Multi-Purpose Solution. and validation of the manufacturing processes.	use the control of the bulk mix tanks and filling lines, is were not re-validated. Chemistry testing was limited to the semed for the scaled-up batches of validation data was accepted in lieu of performing a complete re-		
	European Pharmacopeia clarity test. The validation data ava the filling process, the hold time study, and purging processe compounding batches and no USP sterility testing was perfe RaNu w/MoistureLoc Multi-Purpose Solution. validation of the manufacturing processes.  B) The following deviations are noted in the initial validation.  I. The European Pharmacopeis (EP) clarity test was not part and the study. It was used in the 2003 validation study.	use the country that cleaning of the bulk mix tanks and filling lines, is were not re-validated. Chemistry testing was limited to the semed for the scaled-up batches of validation data was scoopted in lieu of performing a complete remaind and the scaled-up batches of validation data was scoopted in lieu of performing a complete remaind on Lot # 234068		

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PAGE 4 OF 3 PAGES

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DISTRIBUT AND SHARE STANDING	Printed on American				
60 Eighth Street NE	03/22/2006 - 05/15/	2006			
Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202	1032500				
NAME AND THE OF BRANCE AT TOWNSON ASSOCIATIONS					
TO: Mr. Thomas H. Eggleton, VP of Operation	tions				
Bausch & Lomb Inc	8507 Pelham Rd				
City, State, 12 Cook, County	TYPE STABLEHART HAPESTED				
Greenville, SC 29615-9598	Medical Device/Pharmaceutical   Manufacturer				
3. The first bottle out of filling on the seaso specifications were subsequently lowered to the seaso specifications were subsequently lowered to the season	The release specifications	were			
OBSERVATION 7  Procedures have not been followed to prevent contamination	of agriculture or arealyst by sectols substances				
Specifically,	or equipment or product by certain substances.				
Specifically,					
On 4/19/06 in the upper mix room, peeling paint and nain     and the solenoid above tank a     solutions.	nt chips were observed on agitators located on the These tanks are currently used for the production				
b) The cleaning, inspection, and sanitization of fill lines the production of the production of the Sensitive Eyes, Boston Cleaner, RaNu 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.					
Appropriate procedures have not seen defined and documented for composing environmental conditions.  Specifically,					
Tamparanus canditions within the security accessing and a					
Temperature conditions within the aseptic processing area are not being documented to ensure such conditions are consistently within established specifications of the degrees Ceisius.					
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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INSPECTIONAL OBSERVATIONS

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DETRICT ALLES	FOCO AN	DURING ADMINISTRATION   BRIDGE OF REPORTS
60 Eighth Street NE		03/22/2006 - 05/15/2006
Atlanta	, GA 30309 153-1161 Fax: (404) 253-1202	1032500
LINE THE MILE	CONTRACTOR TO WASHINGTON THE CONTRACTOR	
TO: Mx	. Thomas H. Eggleton, VP of Ope	rations
Bausch	4 Lomb Inc	8507 Pelham Rd
	lle, SC 29615-9598	Medical Device/Pharmaceutical Manufacturer
Solution p	reduct lots implicated in complaints received t	terility or blocidal testing for ReNu w/ MoistureLoc Multi-Purpose from Hong Kong.  um/retain samples in conjunction with the Pusarium investigation
Procedure	ATION 10 s for controlling the storage of product in stora ther adverse effects.	go areas and stock rooms were not implemented to prevent mix-ups,
Specifical	y,	
		ated in a customer complaint, RaNu w/ MoistureLoc Multi-Purpose art of the current inventory in the firm's validated inventory control
b) On 4/24	/06 the firm was unable to locate	cases of ReNu MoistureLoc Multipurpose Solution, Lot #AJ5065.
c) On 5/9/	06 the firm was unable to locate units of	RaNu MultiPlus Multipurpose Solution, Lot #GC6061.
OBSERV	ATION 11	
Quality au	dits were not conducted to verify that the quali	ty system is effective in fulfilling your quality system objectives.
Specificall	y,	
■)	Review of the Internal Audit schedule indicate of their complaint handling system.	ted that the firm has not conducted or established a routine auditing
b)	The firm does not have procedures defining the	ne frequency by which supplier audits will be conducted.
c)	The firm has never sudited the supplier of manufacture ReNu w/ MoistureLoc Multi-Pur	
d)	Contract laboratories/suppliers used in raw m	sterial and finished product testing have not been audited at a

INSPECTIONAL OBSERVATIONS

DEPARTMENT OF HEALTH AND BUILDN SERVICES POOD AND DRUG ADMINISTRATION SPRINT AND MAKE AND PARTIES ALABOR. 03/22/2006 - 05/15/2006 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 1032500 THE THE WILL OF REPORTED AS ARREST MANAGEMENT TO: Mr. Thomas H. Eggleton, VP of Operations Bausch & Lomb Inc 8507 Pelham Rd STY STATE 25 GOOD COUNTY Greenville, SC 29615-9598 Medical Device/Pharmaceutical Manufacturer

defined frequency. For example:

-Lab A was last sudited on 12/11/96

-Supplier A was last audited on 9/11/01

In addition, the last biennial sudit 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.

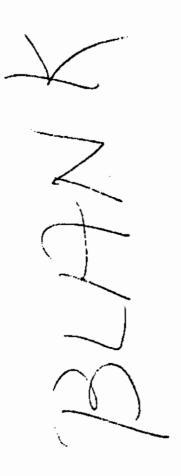
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60 Eighth Street NE	03/22/2006 - 05/15/	2006		
Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202	1032500			
MATERIAL SA HOWERS AND MARK MANUAL SECTION SEC	1032300			
TO: Mr. Thomas H. Eggleton, VP of Operat	ions			
Bausch & Lomb Inc	9507 Pelham Rd			
BAUSER & LOND THE	AND SATURATION OF THE PARTY OF			
Greenville, SC 29615-9598	Medical Device/Pharmaceutical Manufacturer			
Specifically, integrity testing of the vent filters on the the month interval between June 2005 and March 2006 pe		bucted during		
OBSERVATION 18				
Written procedures are not followed for the cleaning and mai manufacture, processing, packing or holding of a drug produ		in the		
Specifically,		•		
Your established mix tank cleaning procedures. SQP# 40-01' specific manual cleaning procedures for the other than that inclusive stromated CIP cycle. Review of batch record documentation being documented.	ide a <b>Com</b> inute manual rinso at <b>Co</b> degrees Celi	itus, prior to the		
OBSERVATION 16	,			
The written stability program for drug products does not inch	ude 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, "The of the properators within the state operations have not participated in the 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.				
		DATE MALLED		
OF THIS PAGE BOB, Colb., 850		05/15/2006		

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60 Eighth Stro Atlanta, GA			/2006 - 05/15/2006	
(404) 253-116	Fax: (404) 253-1202	10325	>0	
	as H. Eggleton, VP of		· · · · · · · · · · · · · · · · · · ·	
Bausch & Lomb	Inc	9507 Pelham Rd		
Greenville, S		Medical Device/Pho Manufacturer	ermaceutical	
		process controls designed to assure tire are represented to possess.	et the drug products have the	
	are no specific established proce hnicians during media fill opera	dures for the visual examinations of intions.	acubated vials conducted by	
FDA EMPLOYEE	s' names, titles, and s	IGNATURES:		
Claudette D. Brooks, Investigator  Banta S. Usatta  Boulta S. Chester, Investigator				
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DEPARTMENT OF HEALTH AND HUMAN REPVICES FOOD AND DRUG ADMINISTRATION			
Signal of Age and And Market Manager	CATEGO OF HISPERIEN		
60 Eighth Street NE	03/22/2006 - 05/15/2006		
Atlanta, GA 30309	PERMIT		
(404) 253-1161 Fax: (404) 253-1202	1051854		
WHE NO THE OF PENESUL TOWNSH REPORT MELLES			
10: Mr. Thomas H. Eggleton, VP of Operat	ions		
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Bausch & Lomb Inc	130 Commerce Ctr		
CHA' SIVIE SIN COOK CONNINA	TYPE BUT ALLE ALEKT ONE BUT ED		
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.

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**

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 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 # 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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FORM FDA. 45 (17.69) PLEVIOUS EDITION DESCRIPT INSPECTIONAL OBSERVATIONS PAGE 1 OF 1 PAGE

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
60 Eighth Str		03/22/2006 - 05/15/	2006
Atlanta, GA	30309	1051854	
	1 Fax: (404) 253-1202		
PRETALE	as H. Eggleton, VP of Opera	STREET AGENTIA	
Bausch & Lomb	Inc	130 Commerce Ctr	
Greenville, 50	C 29615-5816	Repackager/Relabeler	
PDA EMPLOYEE	S' NAMES, TITLES, AND SIGNATU	RES:	
Claudette de Claudette D. Brook		Babanende D. Babalola, Investigator	
Bonita S. Chester, 1	vister mestigator		
			BAYE HECOES
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