



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

339220

July 17, 2002

60 8th Street, N.E.
Atlanta, Georgia 30309

VIA FEDERAL EXPRESS

Ronald L. Zarrella
Chairman/Chief Executive Officer
Bausch & Lomb
Vision Care
1400 N. Goodman Street
Rochester, New York 14603-0450

WARNING LETTER
(02-ATL-32)

Dear Mr. Zarrella:

An inspection of your facility located in Greenville, South Carolina, was conducted between May 20 and June 10, 2002, by Investigators Claudette D. Brooks and Christie A. Beatty. Our investigators found that your facility continues to manufacture eye and lens care solutions and accessories. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigators documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the QSR as follows:

1. Inadequate Validation: Solution Flushes

Your facility has failed to appropriately validate the manufacturing processes currently utilized for all of your device products. Your facility could not provide adequate documentation to establish a high degree of assurance that all of your manufacturing processes were effective and could consistently produce a product meeting its predetermined specifications and quality attributes, in accordance with 21 CFR § 820.75. In particular, your facility has failed to determine the proper amount of solution that should be flushed through the filling lines prior to packaging. Your facility continues to have out-of-specification (OOS) results in finished product testing for appropriate amounts of [REDACTED] is the preservative/disinfectant used in the majority of your eye care products. Furthermore, your facility could not provide adequate documentation of the justification for, or efficacy of, the series of increases in the amounts of solution flushed through the system. These increases were

implemented in your firm's efforts to assure appropriate levels of [REDACTED] in the finished product. These changes were not appropriately reviewed and evaluated to determine their impact upon the product and process.

2. Inadequate Procedures for Finished Device Acceptance: Preservative Amounts

Your facility has failed to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, in accordance with 21 CFR § 820.80(d). Portions of lots have been released when testing revealed OOS levels of [REDACTED] in the finished product. This partial release is based on limited testing performed on product until acceptable levels are found in the packaged product.

3. Inadequate Production Processes: Flaking Paint Chips

Your facility has failed to develop, control, and monitor production processes to ensure that your devices conform to their specifications, in accordance with 21 CFR § 820.70. You have failed to establish and maintain procedures to adequately control environmental conditions, or other sources of contamination, which could reasonably be expected to have an adverse effect on product quality. Your firm produced approximately [REDACTED] lots of sterile eye care products during the period between March 18 and April 10, 2002. These products were aseptically filled in Class [REDACTED] rooms later found to have paint flaking from the ceiling grids. Available documentation was inadequate to explain and justify the decision to release [REDACTED] of these lots. Fill Room #1 was identified as being in an "out of control" situation on March 18 due to the presence of these paint chips. Paint chips were subsequently found in all [REDACTED] of your filling rooms during this period of time.

4. Inadequate Investigation: Flaking Paint Chips

Your facility failed to adequately investigate the cause of this nonconformity, which directly related to product quality, and identify appropriate actions needed to correct and prevent recurrence of these quality problems, in accordance with 21 CFR § 820.100. This problem was inadequately investigated by your Quality Assurance department prior to resumption of production. Your QA unit failed to respond appropriately to ongoing problems noted with paint chips in the production areas. Interim measures such as scraping of grids, additional cleaning, and covering grids with plastic strips were implemented with little or no documentation as to the evaluation of their effectiveness or impact on product quality. Your firm failed to follow its own procedure for the investigation of internal quality system failures which could impact on product quality. Additionally, there was no documentation regarding your firm's decision not to test additional samples which were initially pulled during this time and the reasoning behind the resumption of production. In fact, no documented investigation had been conducted and no corrective actions had been formally established by Quality Assurance at the time FDA initiated its most recent inspection.

Several other instances were noted where corrective and preventive actions were not appropriately documented. MER #FD2691 noted viscosity failures in finished lots of product.

Although an investigation was to be performed into mix time and temperature according to the MER, such an investigation had not been conducted. Other MER's which included reported problems with incoming goods were closed without any recorded corrective action.

5. Inadequate Procedures for Acceptance of Incoming Product

You have failed to establish and maintain appropriate procedures for the acceptance of incoming product to assure conformance to specified requirements, in accordance with 21 CFR § 820.80. [REDACTED] pallets of unlabeled cases of [REDACTED] were noted in the warehouse on 5/20. These products included at least three lots, all of which had expired. This product is used to adjust the pH of the bulk solution. The lots were described as being "In-Test."

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the FDA 483 (Inspectional Observations) was issued to, and discussed with, Thomas H. Eggleton, VP of Operations. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

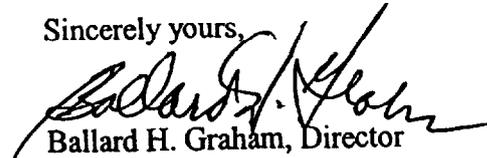
We are in receipt of a response to the FDA 483 dated June 28, 2002, from Mr. Eggleton. Although some corrective actions have been implemented, the response was inadequate in addressing the issue of process validation and the investigation into the particulate problem. A more detailed response to that letter will be forthcoming from the district.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QSR deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. You may contact Mr. Campbell at (404)253-1280 if you wish to set up a meeting at the district office to further discuss these issues.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Tom Eggleton, VP
Bausch & Lomb Inc.
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Greenville, SC 29615