



M248n

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

**PURGED** (with handwritten initials 'FA' in the 'G')

October 19, 1998

cc: HFI-35/FOI Staff  
DWA

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 01

Benson C. Brainerd  
President  
Lavoptik Co., Inc.  
661 Western Avenue North  
St. Paul, Minnesota 55103

Dear Mr. Brainerd:

During a recent inspection of your firm located in St Paul, MN, our Investigator determined that your firm manufactures sterile eye wash which includes sterile eye cups. The eye cups are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that this device is 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, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) and Good Manufacturing Practice (GMP) for Finished Pharmaceuticals, 21 CFR 211 as follows:

GMP for Medical Device Regulations

1. The complaint handling system is incomplete because returned goods are not categorized as complaints and therefore are not tracked, evaluated,

Benson C. Brainerd  
October 19, 1998

investigated, or documented, nor are oral complaints documented or tracked. Although complaint handling procedures call for complaints to be investigated, no investigations have been performed because returned goods from distributors are not viewed as complaints (21 CFR 820.198).

2. Procedures for implementing corrective and preventive actions have not been defined. Specifically, there are no requirements for identifying or investigating quality problems, nor is documentation of the problem required. For example, when outdated spore strips were used to sterilize one load of eye cups, the situation was handled without benefit of procedural guidance, resolution of the problem was not documented, and the corrective action needed to prevent recurrence of the problem was not defined (21 CFR 820.100).
3. Procedures for finished device inspection have not been defined. Finished sterile devices and device packaging are not subjected to procedures covering visual examination, mechanical testing, or any other systematic check to assure that devices meet acceptance criteria [21 CFR 820.80(d)].
4. Procedures for implementing changes to processes, procedures, and methods have not been defined. During April 1998 every procedure in the quality manual was updated, changed, or revised without benefit of a change control format [21 CFR 820.70(b)].

#### GMP for Drug Regulations

5. Complaint handling is incomplete in that product returned through the returned goods system is not evaluated as to whether or not it is a complaint, an investigation into the complaint is not being done, nor is there an explanation as to whether an investigation is required, and written records are not being kept on each complaint (21 CFR 211.198).
6. The equipment used to mix the sterile eye wash was last sterilized on February 2, 1998, per procedure "Sterilization of water storage tanks, mixing tanks, transfer lines, and filler." The procedure calls for the system to be sterilized every six months. As of September 9, 1998, this has not been done [21 CFR 211.67(a)].

Page Three

Benson C. Brainerd  
October 19, 1998

7. Procedure "Sterilization of water storage tanks, mixing tanks, transfer lines, and filler" calls for a sample of water to be tested for microbiological content after the sterile eye wash mixing system has been sterilized. This was due to be done by August 2, 1998, but as of September 9, 1998, the water had not been tested [21 CFR 211.67(b)].
8. The equipment used to mix the sterile eye wash had standing water in the plastic tubing and in the mixing tank. Approximately ~~two~~ batches of eye wash are mixed monthly. Procedures do not call for the system to be flushed prior to mixing the next batch, nor is it routine practice to flush or clean the system prior to mixing even though the system may have been sitting idle for several weeks [21 CFR 21.67(a)].

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. The specific violations noted in this letter and in the form FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

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 pending applications for Pre-Market Approval (PMA's) or export approval requests will be approved, and no pre-market notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Page Four

Benson C. Brainerd  
October 19, 1998

Please notify this office in writing within 15 working 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 ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which the corrections will be completed.

Your reply should be directed to Acting Compliance Officer Susan Warren at the address indicated on the letterhead.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

SMW/ccl