



Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS MAIL

AUG 15 2001

Mr. Jean M. Blanchard
President
Les Laboratories Blanchard
1552 Que King Quest
Sherbrooke, Quebec CANADA J1J 2C3

Dear Mr. Blanchard:

We are writing to you because on March 19-22, 2001, an investigator from the Food and Drug Administration (FDA) inspected your facility and determined that your firm manufactures contact lenses that are exported to the United States.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System (QS) regulation found in Title 21, Part 820 of the U.S. Code of Federal Regulations (CFR). The following deviations were identified:

1. 21 CFR 820.30

21 CFR 820.30 requires manufacturers to establish and maintain procedures to control the design of devices in order to ensure that specified design requirements are met. Observation 1 on the FD 483 indicates that there was no documentation of design control reviews, design validation or verification for the ESStech Multi Aspheric or the ESStech Multi Toric contact lenses. Observation 2 of the FD 483 indicated that your firm did not have any design control standard operating procedures. At the close of the inspection you indicated that design validation and verification had been completed but had not been documented. The design control notebook maintained by your firm had no verification or validation data.

Your written response to the FD 483 provided SOTP P-24, a procedure for Design Control. No comments were made as to how this procedure would be implemented or how employees would be trained to use it. You still did not provide any retrospective validation or verification data. Your response is considered inadequate.

2. 21 CFR 820.20 (a)

21 CFR 820.20 (a) requires that management with executive responsibility shall establish a policy and objectives for, and a commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented and maintained at all levels of the organization. Observation 3 on the FD 483 indicates that your firm did not have a written quality policy or a quality plan. At the close of the inspection, you indicated that your firm had a quality manual but the actual quality policy was not incorporated into the manual. Your written response supplied a written quality policy but did not indicate how this policy would be implemented or maintained so that all levels of your organization understood it.

3. 21 CFR 820.20 (b)(1)

820.20 (b)(1) requires a manufacturer to establish the appropriate responsibility, authority and interrelation of all personnel who manage, perform and assess work affecting quality and to provide the independence and authority necessary to perform these tasks. Observation 4 of the FD 483 indicates that there is no written documentation of the appointment of management representatives. At the close of the inspection you indicated that you would supply written documentation that would be included in your quality manual. Your written response provided a list of Management Responsibilities and Control System Authority. The list says that it is a January 2001 update. This list was not provided to our investigator during the March 2001 inspection. Please clarify when this list was made.

4. 21 CFR 820.198 (a)(3)

820.198 (a)(3) requires that a manufacturer shall establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit. Such procedures shall ensure that complaints are evaluated to determine whether the complaint represents an event that is required to be reported to FDA under part 803 or 804 under Medical Device Reporting. Observation 5 of the FD 483 indicates that the firm's written complaint handling procedures SOPT P1(3) are incomplete in that the procedures do not define a complaint nor do the procedures designate the person to review, evaluate, investigate and document possible failure of the contact lens.

Your written response provided a revised SOTP P-16(4) that provides definitions for "Complaint/Defective", "Comfort", and "Cosmetic". It also names individuals responsible for evaluating, documenting and investigating complaints. It indicates reports are to be reviewed, but does not designate who will review these reports. The procedure does not indicate how your firm determines whether a complaint needs to be reported under parts 803 or 804. Your response did not indicate how employees were to be trained to use this procedure. Your response is inadequate.

5. 21 CFR 820.198(e)

820.198 (e) requires that when an investigation of a complaint is made, the formally designated unit shall maintain a record of the investigation. The record shall include; the name of the device, the date the complaint was received, any device identification(s) and control number(s) used, the name, address, and phone number of the complainant, the nature and details of the complaint, the dates and results of the investigation, any corrective action taken and any reply to the complainant. Observation 6 on the FD 483 indicates that written records of complaint analysis investigations are not kept. Your firm was putting an analysis description on a separate paper that was discarded after completing an investigation. You promised that you would begin keeping records of investigations and analyses of complaints at the close of the inspection. Your written response provided a revised SOTP P-19(5) that added corrective action to your Audit Inspection CheckList. Your revised checklist lists "Complaints investigated, filed and Maintained" as a check-off item. This response is not adequate. We will need to re-inspect your facility to determine whether you are adequately documenting investigations and analyses of complaints.

6. 21 CFR 820.80 (e)

820.80 (e) requires manufacturers to document that the acceptance activities required by this part include the signature of the individual(s) conducting the acceptance activities. Observation 7 of the FD 483 indicates that the final device (lens testing) SOTP P10(3) Quality Control Test was not signed by the person who completed the test, but by another person. You admitted that you signed this form, although your brother actually completed the tests on twelve forms sampled by our investigator. Observation 8 on the FD 483 indicates that the final device lenses QA test is signed by the same person conducting the test and who signed as the QA representative.

Your written response provided a revised QA procedure for the finished lenses. The revised procedure indicates that the QA inspection can be performed by a person who knows how to inspect a lens but did not participate in the manufacturing (i.e.- the Vice President of Manufacturing or the Vice President of Audit ?) The President or the QA Responsible can sign the QA representative space. Your Control system authority listing indicates that Pierre Blanchard, Jean Blanchard and Gilles Castonquay are authorized to sign for lens release. Please clarify your response, we are not sure what your response means.

7. 21 CFR 820.120 (d)

820.198(d) requires manufacturers to establish and maintain procedures to control labeling and packaging operations to prevent labeling mix-ups. The label and labeling used for each production unit, lot or batch shall be documented in the Device History Record. Observation 9 of the FD 483 indicates that your firm's written procedure for labeling, SOTP No. P12 does not require the count for discarded labels to be documented and the DHR review of labeling is inconsistent. Your written response provided a revised Packaging and Labeling Procedure, SOTP P18(3). The revised procedure indicates that labeling will not take place until the area is cleared of all previous labels, records and lenses. The quantity of sample, rejected and accepted labels is to be recorded and initialed by the technician on the labeling sheet. The labeling is supposed to be performed by a technician and the work is to be controlled by the Vice President of Audit who is supposed to sign the Product Sterilization report. This information should be included as part of the Device History Record. We will need to verify your procedures during a re-inspection of your firm.

8. 21 CFR 820.184

820.184 requires manufacturers to maintain device history records (DHR). The DHR shall include, or refer to the location of, the following information: the dates of manufacture, the quantity manufactured, the quantity released for distribution, the acceptance records which demonstrate the device is manufactured in accordance with the Device Master Record, the primary identification label and labeling used for each production unit and any device identification(s) and control number(s) used. Observation 10 of the FD 483 indicates that there was no QC or QA review of device history files. You indicated that you reviewed the DHR but did not sign them to indicate that you reviewed them. Observation 11 indicates that the DHR are not complete in that all required information is not included in the files for Lost nos. KK10, KK13 and KK14. These records lacked a date or signature on them to indicate that labeling had actually been performed. The investigator also discussed the use of "whiteout", completely scratching out mistakes, and failing to initial or date errors with you at the close of the inspection. You agreed to revise your practices.

Your written response provided a revised SOTP P-27(4) for the Device History Record and Initiation of the Lot Number for ESSTECH PS, PSD, and SV (Polymacon) and QUATTRO (Hioxifilcon B) lenses and a revised SOTP P-38(3) Device History Record and Initiation of the Lot Number for Essential Soft Toric Multifocal (hioxifilcon B) lenses. We will need to verify that you are following these procedures during the next inspection of your firm.

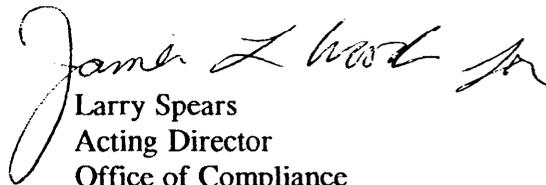
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and its implementing regulations. The specific violations noted in this letter and in the FD 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality systems. You are responsible for investigating and determining the causes of the violations identified by FDA. When violations involve systems problems, you must promptly initiate permanent corrective action.

We acknowledge that Les Laboratories Blanchard submitted to this office a response to our investigator's observations noted on the FD 483. We have reviewed your response and have concluded that it is inadequate because it has not completely addressed all of the concerns on the FD 483.

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. Given the serious nature of the violations that have been identified, all devices manufactured at Les Laboratories Blanchard may be detained without physical examination upon entry into the United States until these violations are corrected.

Your response should be sent to Ms. Mary-Lou Davis of the Dental, ENT and Ophthalmic Devices Branch at the above address. If you have any questions concerning this letter, you may call her at (301) 594-4613, extension 127 or FAX at (301) 594-4638.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Larry Spears".

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health