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**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Our ref: 2950360

October 15, 1998

Brian R. Regan  
President  
Menicon USA, Inc.  
333 W. Pontiac Way  
Clovis, CA 93612

Dear Mr. Regan:

Your firm was inspected between September 21 and 23, 1998 by Investigator Barbara Moynier, California Department of Health Services, Food and Drug Branch, under contract with the U. S. Food and Drug Administration (FDA). Investigator Moynier, operating under the authority of the Federal Food, Drug, and Cosmetic Act, focused her inspection on the manufacture of hard contact lenses, bulk lenses, and extended wear gas permeable lenses. These products are medical devices as defined by Section 201(h) of the Act.

The 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 manufacturing, packaging, storage, or installation are not in conformance with either the Good Manufacturing Practice Regulation (GMPs) or the Quality Systems Requirements (QSRs) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820 as follows:

1. You have failed on a number of occasions to conduct investigations into complaints. During the inspection, at least eight such incidents were noted. It appears that your personnel often respond to customer complaints by refunding and replacing lenses rather than by investigating root causes of complaints such as warpage, unclear optics, scratches, and incorrect power. Failure to conduct and to properly document complaints was also noted during the previous inspection of your firm in February 1992. Investigator Moynier also noted numerous omissions of required information on your Customer Complaint Forms, and that your firm's complaint handling system does not ensure timely resolution of open complaints. [21 CFR 820.198]

- You have also failed to evaluate complaints in a timely manner to determine reportability under 21 CFR 803, the Medical Device Reporting (MDR) Regulations. During the inspection, undue delays in review and reporting were noted for eight complaints. The delay in reporting ranged from two months to eleven months after the date a complaint was received. The required time limit for reporting under the MDR regulations is 30 days after a firm becomes aware of an adverse event which reasonably suggests that a device may have caused, or would be likely to cause or contribute to a death or serious injury. [21 CFR 820.198]
2. The investigator observed that Menicon USA's quality system is undergoing review and revision. The inspection found that your quality system documents referred to documents which were not actually available or cleared for implementation. For example, the Device History Record Approval Procedure (QSP 00025-00) was presented to Investigator Moynier as Menicon USA's official SOP for performing QA releases in device history records. This procedure was in draft form and had not been approved for implementation. This observation demonstrates deficiencies in your document change control process. [21 CFR 820.40]
  3. Your equipment calibration program fails to identify remedial action which is required when accuracy and precision limits are not met. Several meters and gauges had not undergone routine calibration. [21 CFR 820.72]
  4. You have not established a design control procedure which defines development activities and which defines responsibility for implementation. [21 CFR 820.30(b)] This facet of the design control requirements is particularly important for a firm such as yours, which has made modifications to the original device's design specification and which must interface with the parent company in Japan regarding design issues.
  5. During the inspection, Investigator Moynier was advised that an audit conducted by your consultants had uncovered falsification of equipment calibration records by two employees of Menicon USA. This incident resulted in the termination of one of the employees, placement of the other on probationary status, and the engagement of an outside company to recalibrate the equipment. The situation apparently came to light only after an audit prompted by the pre-announcement of Ms. Moynier's inspection. We acknowledge the corrective measures which you have taken. However, we wish to emphasize that your quality system needs to incorporate management responsibility for proactively ensuring that Menicon's quality policy is understood at all levels, and that management with executive responsibility shall review the effectiveness of the system at designated intervals. [21 CFR 820.20]

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 FDA483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. We note with particular concern that previous inspectional observations have neither been addressed nor corrected. You are responsible for investigating and determining the causes of the violations.

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, requests for Certificates of Exportability and to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

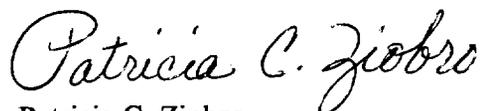
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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 as necessary to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to the following:

Andrea P. Scott  
Compliance Officer  
U. S. Food and Drug Administration  
96 North Third St.  
San Jose, CA 95112

Sincerely yours,



Patricia C. Ziobro  
Director  
San Francisco District