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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
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July 7, 2008

**WARNING LETTER
CIN-08-10787-18**

VIA FEDERAL EXPRESS

Peter L Mastores
President
Volk Optical, Inc.
7893 Enterprise Drive
Mentor, OH 44060-5309

Dear Mr. Mastores:

During an inspection of your firm located in Mentor, Ohio on April 29 through May 20, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is the manufacturer of diagnostic contact lenses, and the specification developer for sterile disposable Vitrectomy lenses. Under section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received your responses, dated June 10 and 30, 2008, concerning our investigator's Form FDA 483 Observations (Form 483) that was issued to you at the close of the inspection. However, at this time we cannot fully evaluate the adequacy of your response because you are still in the process of revising procedures for the numerous proposed corrective actions. We address your response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure of your corrective and preventive procedure to include requirements for analyzing and trending sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems; and failure to document these activities, as required by 21 CFR § 820.100(a) and (b).

Specifically, you are not analyzing or trending quality data sources, such as types of complaints, reason for returns, servicing data, scrap rate and non-conforming material information.

The revised Corrective and Preventive Action procedure, dated 6/4/08, included in your response, appears adequate. The Analysis of Data procedure, dated 6/30/08 also appears adequate. Please provide an example of the monthly trending of quality data and the process map for the analysis of data.

2. Failure to investigate complaints involving the possible failure of a device to meet any of its specifications, as required by 21 CFR § 820.198(c).

Specifically, 19 of the 19 complaints reviewed had incomplete failure investigations.

Your response states that the Complaint Handling procedure will be revised and implemented by July 18, 2008. Please provide copies of your revised procedure. You also state that you are re-evaluating and investigating the 3 complaints listed on the FDA-483 under observation #2. The investigator listed those complaints as examples, but stated that 19 of the 19 complaints sampled for review (Sampling pulled from 1070 complaints received within the past year) had incomplete failure investigations. Your response is inadequate, because it does not address trending the complaints received in the past year to determine if other failure investigations need to be performed and if corrective actions need to be taken.

3. Failure to adequately control products that do not conform to specifications, as required by 21 CFR § 820.90(a).

Specifically, the FDA investigator found numerous instances of non-conforming product during the inspection where the product was not identified and the disposition of the product was not recorded, as required by your "Nonconforming Product Control" procedure.

Your response states that the Nonconforming Product procedure will be revised and implemented by August 22, 2008. Please provide a copy of this procedure.

4. Failure to validate a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR § 820.75(a) and (b).

Specifically, you have not validated the ultrasonic cleaning, polishing, sealing, gluing/curing and bonding processes used in the production of your Class II lenses. Additionally you have not validated the CNC mills used to manufacture the components of these lenses.

Your revised Validation of Process/Equipment procedure, dated 6/6/08, included in your response, appears adequate. Your response also states that you have initiated a comprehensive process validation remediation program to assure all applicable processes are validated. The target completion date for this program is December 5, 2008. Please provide a summary of the processes that will be validated and the timeline for completion of each of these validations.

5. Failure to develop process controls procedures; and failure to monitor and control production processes to ensure that a device conforms to its specifications, as required by 21 CFR § 820.70(a).

Specifically, parameters, which could adversely affect the product, for ultrasonic cleaning (concentration and time), polishing (process time, type of pad, and speed), sealing (temperature time and pH), gluing/curing (time and light intensity), and bonding (temperature and time) are not being monitored and recorded.

Your response states that the Production Control procedures and related forms will be revised and implemented by August 29, 2008; and the required process controls will be implemented by October 3, 2008. Please provide a copy of these documents when completed.

6. Failure to document the evaluation of potential suppliers, as required by 21 CFR § 820.50(a)(1).

Specifically, you had no qualification records for 1 of the 4 main suppliers reviewed by the FDA investigator.

Your response states that the Supplier Selection and Evaluation procedure and related forms will be revised and implemented by September 12, 2008. Please provide a copy of these documents when completed. Your response does not address your projected date for assuring all suppliers are evaluated and qualified. Please provide a timeframe for the completion of your supplier evaluations.

7. Failure to demonstrate that the design was developed in accordance with the design control requirements of the QS regulation [21 CFR § 820.30(a) through (j)]: Specifically, the following design controls were inadequate during the development of the design of the Wide Field Contact Lens:

- Failure to perform design reviews at appropriate stages of the development of the device's design development, as required by 21 CFR § 820.30(e). Your only documented review for the wide field lens project was conducted prior to the approval of the design inputs.
- Failure to confirm during design verification that the design output meets the design input requirements, as required by 21 CFR § 820.30(f). Specifically, the design verification tests for Outside Diameter of Glass, Field of View, and Spatial Resolution were out of specification and performed prior to the design inputs being approved; and the Weight of Glass test was not performed.
- Failure to establish acceptance criteria prior to the performance of design validation activities, as required by 21 CFR § 820.30(g). Specifically, no acceptance criteria was established; and only one site was used for validation testing. There is no statistical rationale for the use of one site; and there is no documented review of the feedback from the validation testing performed by this site.
- Failure to establish procedures to assure that the device design was correctly transferred into production, as required by 21 CFR § 820.30(h). You did not develop design transfer procedures, and there is no documented review and approval of the release of this design to production. Additionally, the device master record for this lens is incomplete and has not been approved.

Your response states that the Design and Development procedure and related forms will be revised and implemented by July 18, 2008. Additionally, you are developing a new Risk Management procedure which will be completed and implemented by August 15, 2008. Please provide a copy of these documents when completed. Your response also states you are re-evaluating and re-mediating the Wide Field Lens design history file, as well as re-evaluating all current Volk design and development programs to ensure full compliance with the design control requirements. You state this action will be completed by December 5, 2008. Please provide a list of the design history files that are being re-evaluated and a timeline for the projected completion of each review.

8. Failure to include the primary identification label and labeling in the device history record for each device, as required by 21 CFR § 820.184(e).

Your response to this observation appears to be adequate.

Our inspection revealed that the slit lamps lens devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 806 – Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to the following:

Failure to document the justification for not reporting the correction and removal action for the slit lamp lens to FDA, which shall contain conclusions and follow-ups, and be reviewed and evaluated by a designated person, as required by 21 CFR § 806.20(b)(4).

The Correction and Removals procedure, dated 6/30/08, provided in your response appears adequate.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, 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 submission to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter as to the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your written response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio, 45237. If you have any questions concerning the contents of this letter you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may forward a facsimile to her at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of violations at your firm. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483, issued at the closeout of the inspection, may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations to bring your products into compliance.

Sincerely,



Virginia R. Connelly
Acting District Director
Cincinnati District