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Food and Drug Administration  
7200 Lake Ellenor Drive  
Orlando, FL 32809CERTIFIED MAIL  
RETURN RECEIPT REQUESTEDWARNING LETTER

FLA-97-24

February 13, 1997

Mr. Michael J. Pecora  
Chief Financial Officer  
Unilens Corporation  
10431 72nd Street, North  
Largo, Florida 33777

Dear Mr. Pecora:

During an inspection of your facility, in Largo, Florida on February 3-5, 1997, FDA Investigator Ronald T. Weber determined that you manufacture and distribute contact lenses which are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the 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 manufacture, processing, packing, storage or distribution are not in conformance with the Current Medical Device Good Manufacturing Practices as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to the following.

1. Failure to validate significant manufacturing processes and quality assurance tests, e.g., none of the processes used by Unilens have received complete process validation.
2. Failure to establish and implement an adequate failure investigation program, e.g., there were no records of investigation for the torn and cracked lenses manufactured with Hefilcon-A and the warped lenses manufactured with Fluoroperm 30.

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

Mr. Michael J. Pecora  
Page 2  
February 13, 1997

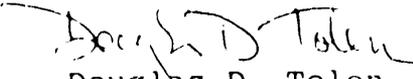
in the FDA 483, Inspectional Observations, issued to you, during the inspection may be symptomatic of serious underlying problems in your firm manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the 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 they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMAs) or export approval requests will be approved and no premarket notifications [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.

Please notify this office in writing within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including (1) each step that has or will be taken to correct the current violations, (2) the timeframe within which the corrections will be completed, (3) the person responsible for effecting correction, and (4) any documentation indicating correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Please direct your reply to Timothy J. Couzins, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, Ext. #264.

Sincerely,

  
Douglas D. Tolen  
Director  
Florida District