

HF-35



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

m360m

Refer to: FEI 3002682243

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

April 12, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bruce H. DeWoolfson, Ph.D.
President & CEO
Euclid Systems Corporation
2810 Towerview Road
Herndon, Virginia 20171

Dear Dr. DeWoolfson:

During an inspection of your facility located in Herndon, Virginia, during the period of January 18 through February 16, 2000, Food & Drug Administration (FDA) investigators determined that you manufacture and distribute for export, Orthokeratology (itaflurofocon B) Contact Lenses. These lenses are devices within the meaning of Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

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 in the manufacture, processing, packaging, storage, or distribution of Orthokeratology (itaflurofocon B), toric, and aspheric contact lenses, are not in conformance with the Quality System Regulation for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to maintain adequate process validation documentation, in that there was no validation protocol or complete documentation for the software used to produce contact lenses, including the reverse geometry design algorithms, email/text to programmable lathe controller data input, and lathe operation and calibration software.
- Failure to document that lens manufacturing equipment is appropriately constructed, placed, and installed (e.g., failure to document Installation, Operational, or Performance Qualifications for the [redacted] lathes used to manufacture contact lenses).

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We acknowledge receipt of your FDA-483 response letter dated March 1, 2000. This letter will be made part of the official file. With the exception of the aforementioned items, your response appears to be adequate, provided that the corrections promised are thorough and properly implemented. Your implementation of these corrections will be reviewed during our next inspection.

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 on the Inspectional Observations (FDA 483), issued to you during 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 and promptly initiating permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning devices so they may take this information into account when considering the award of contracts or issuing certificates of export.

Additionally, no pending applications for pre-market approval (PMAs) will be approved, and no premarket notifications [510(k)s] will be found 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 do so may result in regulatory action being initiated by the FDA 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 any additional steps you have taken to correct the noted violations and the timeframe within which the corrections will be completed. Corrective actions performed should indicate the name of the person responsible for effecting correction. Please include any supporting documentation indicating that correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the timeframe within which corrections will be completed. Please include in the response your intentions regarding the continued illegal exportation of these kits.

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Your reply should be addressed to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Bowers', written in a cursive style.

Lee Bowers
Director, Baltimore District