



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration  
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Denver, Colorado 80225-0087  
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February 21, 2003

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. James A. Brooks  
President/CEO  
Optech, Inc.  
6341 South Troy Circle, Unit E  
Englewood, CO 80111

Ref. #: DEN-03-11

Dear Mr. Brooks:

On January 6-13, 2003, Investigators Lori A. Medina and Elaine G. Stewart of our office conducted an inspection of Optech, Inc., Englewood, CO. Our investigators determined that your firm manufactures various products, including sterile, hydrophilic soft contact lenses. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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 manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Failure to establish and maintain written procedures for changes to a specification, method, process, or procedure and to verify or validate that change before implementation, as required by 21 CFR 820.70(b). For example, the expiration date for PolyVue contact lenses was changed from 24 months to 48 months, but stability data only supports a 24 month period.
2. Failure to establish and maintain adequate written procedures for rework, to include re-testing and re-evaluation of the nonconforming product after rework, to ensure that the

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product meets its current approved specifications, as required by 21 CFR 820.90(b). For example, validation has not been performed on contact lenses that are reprocessed and resterilized to verify resterilization does not affect the optical characteristics or shelf-life of the lenses.

3. Failure to control and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70(a). For example, time, temperature and minimum batch size specifications for steam sterilization of contact lenses are not always followed.
4. Failure to control product that does not conform to specified requirements as required by 21 CFR 820.90(a). For example, in-process lens button samples, found to be out of specification for dry diameter after power cut, were accepted for use.
5. Failure to validate computer software used as part of production as required by 21 CFR 820.70(i). For example, ~~X X X X X X X X X X X X X X~~ has not been validated.
6. Failure to establish sampling plans based on a valid statistical rationale and to ensure that sampling methods are adequate for their intended use, as required by 21 CFR 820.250(b). For example, there is not statistical rationale for the sample size of ~~X~~ lens button out of a batch of ~~X~~ lenses for the in-process Button Lot Acceptance Test.
7. Failure to establish and maintain procedures to adequately control environmental conditions as required by 21 CFR 820.70(c). For example, SOP 10-003-02, Monitoring of Bioburden on Lenses, dated September 10, 2001, does not identify action or alert limits for aerobic and anaerobic bioburden.
8. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. For example, vendor audits or verification of Certificate of Analysis information has not been performed for suppliers of raw material ~~X X X X~~.
9. Failure to document the review and evaluation of complaints to determine whether an investigation is necessary as required by 21 CFR 820.198(b). For example, there is no documentation that complaints associated with PolyVue contact lenses are investigated to determine the root cause of the product defects.
10. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization as required by 21 CFR 820.20. For example, management with executive responsibility has not maintained an adequate organizational structure to ensure that devices are produced according to the specifications and parameters set forth in the device master record.

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The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We acknowledge receipt of your January 30, 2003, response to the FDA-483. We are unable to evaluate the effectiveness of your response, as no supporting documents were included.

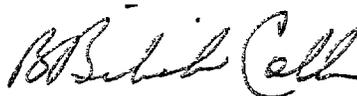
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are corrected. Also, no requests for Certificates to Foreign Governments will be approved 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 FDA initiating regulatory action without further informal notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Mr. Warwick at (303) 236-3054.

Sincerely,



B. Belinda Collins  
District Director

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