



February 26, 1998

WARNING LETTER  
CHI-19-98Chicago District  
300 S. Riverside Plaza, Suite 550 So  
Chicago, Illinois 60606  
Telephone: 312-353-5863CERTIFIED MAIL  
RETURN RECEIPT REQUESTEDMr. Michael Dalton, President  
Norfolk Medical  
7350 N. Ridgeway  
Skokie, IL 60076

Dear Mr. Dalton:

During an inspection of your facility from January 12 to 28, 1998, Investigator Tamara Alicea determined your firm manufactures drug delivery ports. Drug delivery ports are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed 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 manufacturing, packaging, storage, or installation are not in conformance with the Quality System Regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to adequately validate critical manufacturing processes. For example, the packaging validation did not provide assurance that product packaging would consistently provide a sterile barrier after exposure to sterilization stress. Additionally, the validation program did not include a review of packaging validation for product sterilized on your in-house gas sterilizer system.
2. Failure to ensure that measuring equipment is calibrated. Thermocouples used for measurement of the ethylene oxide chamber temperature (during a sterilization validation) were not calibrated.
3. Failure to document the cleaning of manufacturing equipment. The user manual for the [ ] recommends daily cleaning. There is no documentation that this cleaning is being performed.
4. Failure to investigate the cause of nonconformities relating to product processes and the quality system. For example, manufacturing lot [ ] was observed to have [ ] rejections for [ ] and for [ ]. No investigation of these defects was made.

This letter as well as the Inspectional Observations, FORM FDA 483 of January 28, 1998, which was presented to and discussed with you

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at the close of the current inspection, is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to insure that all requirements of the Act, and regulations promulgated thereunder, are being met. The specific violations noted in this letter and in the FDA 483 issued at the closeout of 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 violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge receipt of your response dated February 9, 1998, to our FDA 483. We are concerned by your response regarding the number of rejects in lot [ ]. Your device history record indicates that [ ] devices were processed and [ ] were accepted. Also, there was no justification (given in your response) for the sampling size and no acceptance criteria for the packaging validation. Please respond in writing to these remaining concerns. We do consider your response adequate, but we will need to verify correction by reinspection. Alternatively, you may select an independent consultant to certify to FDA correction of these deficiencies. Please advise us of your decision.

Also, please be advised that previous FDA review without comment of any aspect of your manufacturing operation does not preclude future review and issuance of inspectional observation as necessary. It is your responsibility to ensure that your operation is in compliance with the regulations.

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 awards of contracts. Additionally, no export approval requests will be approved until we verify the indicated correction.

We request that you take prompt action to correct all deviations. Failure to promptly correct 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.

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Please notify this office in writing within 15 working days of receipt of this letter regarding the specific issues we had with your response. Your response should be sent to Stephen D. Eich, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Raymond V. Mlecko". The signature is fluid and cursive, with a large initial "R" and "M".

Raymond V. Mlecko  
District Director