



June 5, 2003

**WARNING LETTER**  
**CHI-16-03**

Chicago District  
550 West Jackson Blvd., 15th Floor  
Chicago, Illinois 60661  
Telephone: 312-353-5863

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Michael Dalton  
President and Chief Executive Officer  
Norfolk Medical Products, Inc.  
7350 North Ridgeway  
Skokie IL 60076

Dear Mr. Dalton:

During the inspection of your firm from February 26 to March 4, 2003, Investigators Jesse Vazquez and James W. Plucinski determined that your firm manufactures subcutaneous needle infusion sets. Subcutaneous needle infusion sets are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to prevent the release of finished medical devices into distribution prior to the completion of activities required in the Device Master Record. For example, your firm's "Production Traveler" failed to document the required Post Sterilization Inspection and Quality Control "OK" stamp for the following dates [21 CFR § 820.80(d)(1)]:  

11/26/02, 11/27/02, 12/2/02, 12/3/02, 12/4/02, 12/5/02, 12/6/02, 12/9/02, 12/11/02, 12/12/02, 12/13/02, 12/16/02, 12/16/02, 12/17/02, 12/18/02, 12/23/02, 12/24/02, 1/2/03, 1/3/02, 1/6/03, 1/7/03, 1/8/03, 1/9/03, 1/10/03, 1/13/03, 1/14/03, 1/15/03, 1/16/03, 1/17/03, 1/20/03, 1/21/03, 1/22/03, 1/23/03, 1/24/03, 1/27/03, 1/28/03, 1/29/03, 1/30/03, and 1/31/03.
2. Failure to prevent the release of finished medical devices into distribution prior to the review of associated data and documentation. For example, the "In-House Sterilization" record was not reviewed, signed, and dated by a designated individual for lot numbers NM301A, NM301B, NM301C, NM301D, NM301E, NM212A, NM212B, NM212C, and NM212D. [21 CFR § 820.80(d)(2)]
3. Failure to establish and maintain procedures for acceptance or rejection of finished device production runs, lots, or batches. For example, your firm did not have procedures for completing the "Product Specifications" document and "Production Traveler" document. [21 CFR § 820.80(d)]

4. Failure to maintain complaint files. For example, the following information was missing from the Norfolk Medical Customer Complaint Form for the investigation into Medical Device Report Number 1450392-2001-00001, dated 10/1/01 [21 § CFR 820.198(a)]:

Complaint number, "Date of Occurrence", "Hospital Address", "Details of Incident", "Lot Number", date complaint was verified with complainant, date the Returned Goods Analysis report was completed, "Reply to Complainant or reason for no reply", "Date of Discussion of whether MDR is necessary", "Date of Discussion of whether notification to competent authority", and if MDR and MEDDEV reports were necessary.

5. Failure to include the dates and results of complaint investigations. For example, the Returned Goods Analysis form for the investigation into Medical Device Report Number 1450392-2001-00001 had no information entered into the "Observations" and "Conclusions" fields. [21 § CFR 820.198(e)(6)]
6. Failure to maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of 21 CFR Part 820, Quality System Regulation. For example, the position of Manager of Clinical and Regulatory Affairs has not been filled since March 2002. According to Norfolk Medical Procedure Customer Complaint Review Policy, dated 2/11/99 [21 § CFR 820.20(b)]:
  - The Manager of Clinical & Regulatory Affairs and President/CEO make up the Customer Complaint Committee.
  - The Customer Complaint Committee is responsible for reviewing complaints, determining what action is required in response to the complaint, assigns complaint action tasks to appropriate personnel and works with the assignee to establish a schedule for completion.
7. Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities. Failure to document training. For example, your firm did not document training of any employee in the "Norfolk Medical Products Inc. Customer Complaint Review Policy" dated 2/11/99. [21 CFR § 820.25(b)]
8. Failure of management with executive responsibility to appoint, and document the appointment of a member of management (management representative) who, irrespective of other responsibilities, shall have established authority for [21 CFR § 820.20(b)(3)]:
  - Ensuring that quality system requirements are effectively established and maintained,
  - Reporting on the performance of the quality system at defined intervals and with sufficient frequency to ensure that the quality system satisfies the requirements of 21 CFR Part 820, Quality System Regulation, and your firm's established quality policy and objectives.
9. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that the quality system satisfies the requirements of 21 CFR Part 820, Quality System Regulation, and your firm's established quality policy and objectives. For example, your firm has not conducted a management review within the past two years. [21 CFR 820.20(c)]

10. Failure to document approval with the date and signature of the individual(s) approving the documents. For example, The "Product Build Specifications" document prepared by the Production Manager, dated 5/1/02, has not been approved, signed, and dated by a designated individual. [21 CFR 820.40(a)]
11. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. [21 CFR § 820.22.]

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 in the Form FDA 483 issued to you 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 violations identified by the Food and Drug Administration (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 that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

We acknowledge receipt of your firm's response, dated March 18, 2003, to the FDA-483. We find the response adequately addresses our concerns. However, we require verification of correction by either FDA inspection or by a third party auditor's written verification.

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

Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 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 Michael Lang, Compliance Officer. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,

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Arlyn H. Baumgarten  
District Director