

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-16

January 8, 1998

Joseph E. Harms, President
Needle & Infusion Technologies, Inc.
390 Scarlett Boulevard
Oldsmar, Florida 34677

Dear Mr. Harms:

We are writing to you because on December 1-5, 1997, FDA Investigator Christine Humphrey collected information that revealed serious regulatory problems involving the Reganes spinal needle and the MICK prostate seed implant needle (Class II and I), for which your firm is the specification developer, manufacturer, and distributor.

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

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 Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to provide documentation relating the Reganes spinal needle and the MICK needle to the validation protocol for the AVID/MSI family of arterial needles, which are also sterilized by the contractor.

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- Failure to establish and maintain contracts or other written agreements that delineate and document the responsibilities of both parties [firm and contract manufacturer(s)] to assure all work affecting quality is met.

The response made by RMS on your behalf dated December 12, 1997 to the List of Observations (FDA 483), Item #2 states that NIT should not be responsible for the contract between AVID/MSI and the sterilization company.

By regulation your firm is ultimately responsible for the quality of all of the devices manufactured and distributed. Your firm does not necessarily have to enter into subcontractor agreements, but your firm should know exactly what those agreements are and assure that the agreement(s) meet your firm's specifications and quality standards for the devices that they handle. Therefore, regardless of what manufacturing process is conducted by a subcontractor, your company is responsible for the finished device that is commercially marketed.

The response also states that the ultimate responsible party for sterilization is AVID/MSI, not NIT. We disagree. NIT's name is on the finished device label and is responsible for conducting finished device testing and release of the product for commercial distribution. In the event that FDA determined that regulatory action was necessary, it would take action against NIT not AVID/MSI.

We strongly urge you to read and understand the responses that your consultant submits on your firm's behalf for FDA's review to ensure their responses are also the responses that you would make and with which you agree. If there are questions concerning the investigator's observations, you should discuss them with us, so that you have a complete understanding of your responsibility with regard to the regulations and can make an appropriate response.

- Failure to conduct post sterilization package integrity testing on the Reganes and MICK needles assuring acceptance criteria is met and documented prior to release.

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- Failure to establish and maintain complete Device Master Records (DMR) and Device History Records (DHR) to assure all specifications and quality assurance requirements are met including component, production process, equipment, and sterilization process parameters.

The response made by RMS on your behalf dated December 12, 1997 to FDA 483, Item #5 states that you disagree that NIT is required to maintain subcontractor's DHR's for each shipment.

By regulation each manufacturer shall maintain DHRs. That is not to say that your firm as the specification developer and manufacturer is required to have on file a copy of each and every DHR generated by your subcontractor, however, you should be receiving, pursuant to your agreement with the contractor, a "Certificate of Conformance" with each lot of device and you should be conducting periodic audits of the contractor's manufacturing facility and procedures to ensure that all required specifications and quality standards are being met for your device.

- Failure to establish and maintain procedures to investigate and control product that does not conform to specified requirements., e.g., there is no record of investigation(s) conducted including review of DHRs located in-house or at the contract facility explaining the occurrence of devices found not to conform to specifications with appropriate corrective and preventive action implemented to assure the nonconformances do not recur.
- Failure to establish and maintain a written MDR procedure to identify, communicate, and evaluate events subject to medical device reporting.
- Failure to follow your own standard operating procedures and/or establish a valid statistical rationale to ensure sampling methods are adequate and documented, e.g., sampling plan requiring C=0 and an AQL of 0.65 for sterile and non-sterile lots of MICK needles was not followed, and written SOPs were not followed covering vendor quality audits.

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You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. 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 Inspectional Observations (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. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite 120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at <http://www.fda.gov>.

A letter signed by Patrick J. Lamb, RMS, Inc. dated December 16, 1997, responding to the Inspectional Observations (FDA 483) issued to you on December 12, 1997, has been received by this office. We have not received any information from you that you have retained RMS to represent you and that RMS will be responding for your firm. Please provide a letter to this office to this effect. Further, the response received promises that some corrections will be completed by January 30, 1998, and others will be completed by February 28, 1998. Please provide updates to this response as corrections are made for our review. Your responses will be reviewed as they are received and an inspection will be scheduled after your consultant certifies to us that all corrections are made to verify your firm's conformance with the Quality System regulations. The response has been made part of your firm's file.

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If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely,

A handwritten signature in cursive script, appearing to read "Edward R. Atkins".

Edward R. Atkins
Acting Director
Florida District