



11/25/97  
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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

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

**WARNING LETTER**

FLA-98-03

October 29, 1997

Tony N. Hanson, President  
Bauer Medical, Inc.  
13191 56th Ct., #160  
Clearwater, Florida 34620

Dear Mr. Hanson:

We are writing to you because on September 25 through October 3, 1997 FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving sterile biopsy needles, which are manufactured and distributed by your firm.

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 Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

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 Quality System Regulation. These violations include, but are not limited to the following:

- Failure to establish and maintain a quality system program, structure, and procedures, e.g., the designation of management with executive responsibility and authority to ensure devices are produced in accordance with established quality standards, and written quality system procedures which document a quality plan, the maintenance of quality system records, including contract reviews, non-conforming product, purchasing controls and an employee training program.
- Failure to validate manufacturing processes ensuring established quality standards are met, e.g., Tyvek pouch seal integrity and the resterilization of devices.

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- Failure to establish and follow change control procedures to ensure conformance to specifications, e.g., three undocumented material changes made to the ACHIEVE and TEMNO devices resulting from customer complaints, change in the use of established sampling plans for seal integrity and in-process testing, and change in the use of the MEDWATCH form to record complaints rather than the specified complaint form.
- Failure to establish and follow sampling plans based on a valid statistical rationale, e.g., the number of samples collected to determine seal integrity depends on the time of day the operation occurs and there is no consideration given to the size of the lot produced.
- Failure to establish and maintain written procedures and records documenting bioburden testing and limits.
- Failure to establish and maintain a complete Device Master Record (DMR) for the ACHIEVE and ACHIEVE COAXIAL biopsy devices, e.g., there are no written procedures for testing of ACHIEVE devices.
- Failure to establish, maintain and document procedures for receiving, reviewing, and evaluating complaints, e.g., complaint files were unavailable because they were being processed.
- Failure to follow your own written procedures, e.g., established procedures for in-process sampling and seal integrity testing are not followed and the designated complaint form used to record complaints was not used in lieu of using the MEDWATCH form.

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 FDA-483, Inspectional Observations, 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.

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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 Quality System Regulation and does not necessarily address other obligations you have under the law. You may obtain general information about all the FDA requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800/638-2041 or through the Internet at <http://www.fda.gov>.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device Quality Systems Regulation (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The initial certifications of audit corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Initial certification by consultant and firm - April 1, 1998
- Subsequent certifications - every 30 days thereafter beginning May 1, 1998 until final certification is achieved.

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

Sincerely,

  
Michael A. Chappell  
Acting Director  
Florida District