



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

Warning Letter

FLA-04-33

May 13, 2004

Diane E. Simmons, CEO and President
American Medical Specialties, Inc.
7411 114th Avenue North
Suite 312
Largo, Florida 33773-5127

Dear Mrs. Simmons:

During an inspection of your establishment located in Largo, Florida on March 8-10, 2004, our investigator determined that your establishment is a specification developer of bone fixation pins (K-wires and Steinmann Pins), surgical blades and burs and a distributor of general purpose disinfectants, which 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) [21 U.S.C. 351(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 regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting requirements of 21 CFR Part 803 as follows:

1. Your firm's internal audits failed to verify that the quality system is effective in fulfilling your quality system objectives as required by 21 CFR 820.22. Your firm's internal audits failed to identify and correct numerous deficiencies of the Quality System requirements observed during the present Food and Drug Administration (FDA) inspection (FDA 483, Item #3). In addition, your procedures for quality audits were found incomplete in that the internal audit criteria is not documented. The criteria used as stated by your personnel did not include Purchasing Control, Process Validation, Corrective and Preventative Action, Design Control or Medical Device Reporting (FDA 483, item #9).
2. Your firm's management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure the quality system satisfies the requirements of this part and the established quality policy and objectives as required by 21 CFR 820.20(c).

Specifically, your firm lacks a management review procedure (FDA 483, item #10).

3. Your firm failed to validate and approve processes whose results cannot be fully verified by a subsequent inspection and test according to established procedures as required by 21 CFR 820.75(a). Your firm failed to adequately validate the following operations (FDA 483, item #1):

a) Process validation of sealing process using the [REDACTED] Heat Sealer for medical devices packaged and sent to your contract sterilizer for sterilization.

b) Your sterilization validation (ISO 11137 Method 1) is inadequate because (i) the quarterly bioburden and verification dose audits were not completed since the last FDA inspection in 1996, with the exception of July and November 2002; (ii) your firm used 1994 validation data, despite re-establishing a new bioburden and new verification dose in 1995, to set 2002 verification dose. There was no new sterilization validation (bioburden testing) conducted including changes to the packaging facility which has moved at least three times since 1994; (iii) your firm used blades as worst case device during 2002 quarterly audits, however your firm's comparison of blades and burs showed burs had higher bioburden levels than blades.

c) Several medical devices, such as blades, burs, K-wires, [REDACTED] Pins, are provided non-sterile requiring sterilization by end users. Your firm failed to provide validated sterilization recommendation instructions.

4. Your firm failed to establish and maintain procedures for implementing corrective and preventative action (CAPA) as required by 21 CFR 820.100(a). Your firm has not established any CAPA procedures (FDA 483, item #6).

5. Your firm's investigation of a complaint dated September 2, 2002 reporting the return of three defective burs failed to include the nature and details of the complaint as required in 21 CFR 820.198(e)(5) and failed to include complete results of the investigation as required by 21 CFR 820.198(e)(6). There was no contact with the complainant to determine why the burs were returned as defective or if a patient and medical procedure were involved. An unknown number of burs were reportedly sent for torque testing on the attachment of the hubs however, the results of this testing were not documented as part of the investigation (FDA 483, item #4).

6. Your firm failed to establish and maintain documentation of any evaluation of suppliers and contractors on the basis of their ability to meet requirements, including quality requirements, as required by 21 CFR 820.50(a). Specifically, your firm failed to maintain any evidence that self audit questionnaires were sent to contract manufacturers; no on-site audits have been conducted including at your contract sterilizer; and no written vendor qualification procedure was available (FDA 483, item #2A).

7. Your firm failed 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. Your firm's incoming inspection of K-wires and [REDACTED] pins does not include specifications such as verification of specified material, number of threads per inch, depth of threads, and length of threading (FDA 483, item #2B).

8. Your firm failed to demonstrate that devices are manufactured in accordance with the device master records as required by 21 CFR 820.184(d). Specifically, your firm failed to document visual inspections of the seal integrity after the [REDACTED] pouch sealing process (FDA 483, item #8).

9. Your firm failed to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained as required by 21 CFR 820.72 (a). For example, your firm has not calibrated the temperature sensor on the [REDACTED] Heat Sealer and your firm's micrometer has not been calibrated since August 1995 (FDA 483, item #7).

10. Your firm failed to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30(a). Your firm failed to establish any design control procedure (FDA 483, item #11A).

11. Your firm failed to identify, document, validate/verify, review and approve design changes prior to implementation as required by 21 CFR 820.30(i). Revised labeling included claims that the Instrument Pre-Soak was a high level disinfectant without completion of any design validation or risk analysis and no pre-market notification was submitted to FDA (FDA 483, item #11B).

12. Your firm failed to maintain your written Medical Device Report (MDR) procedures as required by 21 CFR 803.17. For example, your firm's MDR procedure has not been updated and failed to include requirements for baseline reports as required by 21 CFR 803.55 (FDA 483, item #12).

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 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.

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 Quality System/Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been 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 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.

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 (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) 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 Shari H. Shambaugh, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4730.

Sincerely,


Emma R. Singleton
Director, Florida District