

Inspections, Compliance, Enforcement, and Criminal Investigations

Amsino Medical USA 4/3/09



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
New Orleans District
404 BNA Drive
Building 200 -Suite 500
Nashville, TN 37217
Telephone: (615)
366-7801
FAX: (615) 366-7802

April 3, 2009

WARNING LETTER NO. 2009-NOL-07

FEDERAL EXPRESS Delivery Signature Requested

Timir Patel, Chairman and CEO
MRP Incorporated, LLC
dba Amsino USA
7319 Meadow Woods Way
Clarksville, Maryland 21029

Dear Mr. Patel:

During an inspection of your firm, located at 5209 Linbar Drive, Suite

640, Nashville, Tennessee on September 30, October 1, 14, 15, 17, 20 and 24, 2008, investigators from the United States Food and Drug Administration (FDA) determined your firm manufactures sodium chloride and heparin catheter lock-flush solutions. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed these devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C., Section 351(h)), because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation do not conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations, Part 820 (21 CFR 820). We received a response letter, with enclosures from **(b) (7) (c)**, dated November 4, 2008, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (483) issued to **(b) (7) (c)**. We received a response update, dated February 10, 2009, from **(b) (7) (c)** which supplied additional information and updated versions of some documents. We address the responses below, in relation to each of the noted violations. The violations include, but are not limited to, the following:

1. Failure to adequately establish and maintain procedures for implementing corrective and preventive action including requirements for investigating the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, your firm failed to investigate the possible root causes for the production of air-filled syringes identified by your firm on August 8, 2008.

The adequacy of your response dated February 10, 2009, cannot be determined at this time. Although your firm has provided an updated; **(b) (4)** document **(b) (4)**, your firm has not determined the root cause of the empty syringes.

2. Failure to adequately ensure all corrective and preventive action activities required under 21 CFR 820.100, and their results, are documented, as required by 21 CFR 820.100(b).

For example, your firm failed to complete a (b)(4) **for changes to the which your firm reprogrammed on August 9-10, 2008. This software was placed** into production by your firm on August 11, 2008.

Your response to this observation appears to be adequate.

3. Failure to adequately validate computer software for its intended use according to an established protocol, as required by 21 CFR 820.70(i).

For example, your firm failed to provide documentation detailing the validation of the **(b)(4)** and **(b)(4)** prior to production use. **(b)(4)** on both systems were reprogrammed on August 9-10, 2008, and utilized in production on August 11, 2008. The validation was not completed until October 6, 2008.

Your response to this observation appears to be adequate.

4. Failure to adequately establish and maintain acceptance procedures, where appropriate, to ensure specified requirements for in-process product are met, as required by 21 CFR 820.80(c).

For example, your firm discards syringes containing air, but does not have an acceptance limit for the type or quantity of discards . Additionally, your firm was aware it was producing syringes containing air and had difficulties detecting the air-filled syringes.

The adequacy of your response dated February 10, 2009, cannot be determined at this time. Though you provided a syringe weight study for monitoring the filling process and a written standard operating procedure for monitoring weights of syringes through the use of control charts, you failed to provide evidence of your implementation of the written procedures you developed for the use of control charts and scrap rates, in process acceptance, and intervention decisions. We will confirm you have implemented these procedures during our next inspection.

5. Failure to adequately establish procedures for identifying

training needs and ensure all personnel are trained to adequately perform their assigned responsibilities and the training is documented, as required by 21 CFR 820.25(b).

For example:

A. Your firm fails to document on the job training.

B. The training documentation provided by your firm is inadequate, as it is not specific enough to evaluate the competency, proficiency and comprehensiveness of the firm's training program.

The adequacy of your response dated February 10, 2009, can not be determined at this time as you failed to provide documented evidence demonstrating those employees were trained.

6. Failure to establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks, as required by 21 CFR 820.20(b)(1).

For example:

A. Your firm's procedures list corporate entities, positions, and individuals which are not part of the firm's current corporate structure for quality.

B. Your firm failed to list second shift quality personnel, their positions, and to whom they report within the corporate quality structure.

C. Your firm's procedures fail to list the current individuals with responsibility and authority of management review.

Your response to this observation appears to be adequate.

You should take prompt action to correct the violations addressed in this letter for which you have not already provided an adequate response. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money

penalties. Also, federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations for which you have not already provided an adequate response, including an explanation of how you plan to prevent these violations, or similar violations, from recurring. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. 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 Mr. Mark W. Rivero at the above address. If you have any questions about the content of this letter please contact Mr. Rivero at (504) 219-8818, extension 103.

This letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the 483, issued at the closeout of the inspection, may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

/S/

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: 483 dated October 24, 2008

cc: **(b) (7) (C)**

Amsino Medical USA, Inc.

5209 Linbar Drive, Suite 640

Nashville, Tennessee 37211