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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
60 Eighth Street, NE
Atlanta, GA 30309

Telephone: 404/253-1161
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January 24, 2008

**VIA FEDERAL EXPRESS**

Paul D. Meringola, CEO
Medical Action Industries
800 Prime Place
Hauppauge, NY 11788

**WARNING LETTER**
(08-ATL-04)

Dear Mr. Meringola:

During an inspection of your firm located in Arden, North Carolina on September 25 through October 9, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures a variety of medical procedure trays and kits. 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.

The 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, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R), Part 820. We received a response dated October 18, 2007 from Ms. Robin K. Blankenbaker, Director of Quality Assurance and Regulatory Affairs, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to Ms. Blankenbaker at the close of the inspection. We also received a second undated response, which we will reference as the December response. We address these responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to fully validate and document a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). Specifically,

A) No software validation or verification was available for the [redacted] planning [redacted] system which is used for managing inventory, distribution of inventory, scheduling, engineering change orders, recalls, complaints, reworks, device master records, product return, procurement, production and sales processes. You provided some documented "scenarios"; however there was no protocol or summary included with those scenarios and no evidence that the tasks listed in the scenarios were ever performed.

We have reviewed your response received by the Atlanta District office on October 22, 2007 and have concluded that it is inadequate in that while you indicate that you have performed the [redacted] software verification, no documentation was provided. Documentation provided in your December response is incomplete and does not fully address software verification. While various printouts of output testing were provided, there was no protocol one could follow to assess what your testing is actually accomplishing.

B) You did not perform bioburden determination in the 2005 ethylene oxide (EO) validation study as specified in your protocol. The validation for the EO sterilization process was conducted in May 2005 in order to [redacted]. As part of protocol # 797040273, your firm was to perform a bioburden evaluation study. The investigator was informed that the bioburden study was not done. The protocol emphasized the need to perform annual review of bioburden trends to ensure the continued appropriateness of the biological indicator.

Both your October and December responses are inadequate. Your December response provided a comparison of the 2004 and the 2007 bioburden data which was done on 10/18/07, after the completion of our inspection, on your highest bioburden (surgical gowns). Information provided in your December response shows that while bioburden for the surgical gowns was done in 2004, sterility testing done in 2005 (no documentation provided), there was no other bioburden data for the surgical gowns for 2006. The 2007 bioburden data for the surgical gowns was conducted after our inspection. Additionally your corrective action to this observation did not indicate that your firm was making a commitment to perform routine bioburden testing of the surgical gowns.

C) You have not performed product functionality and/or packaging integrity testing on post-sterilized products to assure conformance with product specifications. You received customer complaints of liquids dry in packages, failing seals, and incorrect kit assembly. According to the sterilization validation protocol # 17-05-002, your firm was to conduct functionality and/or packaging integrity testing on the post-sterilized products to assure conformance to specification. You did not conduct a formal study to assess product functionality and/or package integrity. You provided our investigator with a document showing that one case out of a [redacted] pallet load was visually checked. The document was incomplete and did not have enough information to show what was checked. You did not conduct any QA inspections prior to the release of the lot and also no inspections are done post sterilization of the lot.

We reviewed your October response and determined that it was incomplete in that you did not provide any evidence of product functionality or package integrity testing. Your December response was inadequate in that no statistical rationale was provided for packaging evaluations. You did not specifically indicate how you were going to address product functionality.

2. Failure to review, evaluate, and investigate where necessary complaints involving the possible failure of a device to meet any of its specifications, as required by 21 CFR 820.198(c). Specifically, customer complaint #20000667 dated 8/6/07 indicated that Laceration Kits (Product #57877) were gamma sterilized and resulted in rusty instruments and discolored medicine cups. The lots in inventory were placed on hold. Your firm's investigation into this matter indicated that the needles cannot be gamma sterilized. You subsequently re-sterilized the affected lots which were still in inventory

by EO sterilization. This action was taken by your firm's product family coordinator who is an administrative support person. Information in the complaint file indicated that the sales representative will work with the customer to determine the disposition of the product already in the field. As of the start of our inspection, your firm did not have any documentation of customer contact or your firm's response to the customer. During the inspection, our investigator asked whether other customers were affected and was told that only one customer had received the affected product.

Your responses are inadequate in that you did not identify a root cause for the discolored medicine cups and rusty instruments. While your October response indicates that this was an isolated case, your December response indicates that your firm received one other complaint for rust on instruments in 2007.

3. Failure to establish and document corrective and preventive action activities, including analysis of sources of quality data, investigations of causes of nonconformities, verification and validation of corrective actions, and the implementation of corrective and preventive actions, as required by 21 CFR 820.100. You have not established a formal corrective and preventive action system. You received at least 5 confirmed complaints on Lot TL6090201 of Alcohol Prep Pads which had an "unpleasant odor". You did not determine a root cause for these complaints. A Supplier Corrective Action Report (SCAR) was to be sent to the vendor, however, the complaint record shows that no SCAR was sent and that the supplier had indicated to you that they received a batch of "funny smelling" isopropyl alcohol. No formal investigation was made to determine whether the alcohol was within specifications and if impurities were present.

We reviewed your October response which indicates that you now have a new procedure for CAPA documentation. The CAPA system in place during our inspection was not robust enough to capture all CAPA activities. We will review the adequacy of your new CAPA procedure during our next inspection.

4. Failure to establish and implement sampling plans based on a valid statistical rationale, as required by 21 CFR 820.250(b). You did not have a rationale for the number of packages which are visually inspected every [redacted] hours on the [redacted] packaging machines. Out of [redacted] IV kits reviewed under work order #21470, a total of 6 packages were evaluated. There were no additional inspections or evaluations performed on these packages either pre or post sterilization before the work order was released.

Your October response indicated that all packaging machines have been validated. This was not the case during our inspection. You indicated that according to your sampling procedure, [redacted] from each cavity of the die is visually inspected and tensile strength testing is done at the start of each work order and, at a minimum every [redacted] hours. Our investigator noted that in some cases tensile strength testing is done and in some cases only visual inspection is done. You still have not provided a rationale/justification for your sampling.

5. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). You have not established procedures for identifying, segregating, and handling non-conforming products.

Your response indicates that your firm now has a written procedure for addressing non-conforming product. This response appears adequate and will be evaluated during our next inspection.

6. Failure to ensure that all employees have the necessary training and experience to perform their jobs, as required by 21 CFR 820.25 (b). Specifically employees who manage, perform, and assess work affecting quality have not been adequately trained as members of your firm's quality unit. Quality Assurance employees have not performed effectively in conducting complaint investigations, corrective/preventive action activities, design activities, internal audits, risk analysis and/or document reviews. You ran out of existing safety pins for the circumcision tray and a larger safety pin was substituted. You received at least two customer reports of excessive bleeding. The change to the larger safety pin was made by the Product Family Coordinator (PFC). The product authorization form was not signed and did not proceed through the change process. Other examples of inadequate employee training are the failure to implement adequate corrective and preventive actions to complaints of crystallizing alcohol in kits and a complaint of weak seals.

Your October response is inadequate in that there were no commitments to improve employee training. Your December response appears adequate. We will evaluate the adequacy and effectiveness of your employee training during our next inspection.

7. Failure to conduct management review at defined intervals, as required by 21 CFR 820.20 (c). Specifically, you have not conducted management reviews [redacted] of 2007 as per your SOP # 1-QA-0107 (Management Review). There were no management review attendance documents available to show the quality system's review for this year.

Your October response appears adequate and will be evaluated during our next inspection.

8. Failure to conduct quality audits to verify that the quality system is effective in fulfilling the quality system objectives, as required by 21 CFR 820.22. You had not audited several key areas of your quality system such as environmental controls, acceptance activities, sterilization, labeling and packaging, storage, and distribution. In addition, your procedures for quality audits were not complete in that they did not include an audit frequency.

Your October response is inadequate in that audits of the subsystems identified in the first 3 quarters of 2007 indicate the due dates with no documentation that such audits were conducted. Your December response still indicates that many of the QSR areas to be audited have not been audited.

Our inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803-Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited, to the following:

Failure to develop, maintain, and implement written MDR procedures to provide for: (1) Timely and effective identification, communication , and evaluation of events that may be subject to MDR requirements; and (2) A standardized review process or procedure for determining when an event meets the criteria for reporting under 21 CFR Part 803, as required by 21 CFR 803.17(a). You had not established MDR procedures and there is no internal system which provides for a standardized review process for determining when an event meets the criteria for reporting. Complaint #200000300 in which an x-ray detectable sponge reportedly disintegrated while in the patient, and complaint #200000447 which indicated that two patients experienced redness, erythemia and blisters at their central line placement site from the use of the new [redacted] dressing were not investigated.

Your responses are inadequate in that you made no attempt to get additional patient information with respect to these complaints. There is no documentation to show any contact with the health care providers or patients to obtain additional information about these complaints.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations 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 money penalties. Also, 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, 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, including an explanation of how you plan to prevent these violations from occurring again. 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. Please send your response to Serene N. Ackall, Compliance Officer at 60 Eighth Street, NE, Atlanta, GA 30309. If you have any questions about the content of this letter please contact Serene N. Ackall at 404-253-1296.

Finally, you should know that 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 Inspectional Observations, Form FDA 483 (FDA 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,

Mary Woleske

Mary H. Woleske
District Director

Cc: Ms. Robin K. Blankenbaker
Director of Quality Assurance and Regulatory Affairs
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Arden, NC 28704-9302