Inspections, Compliance, Enforcement, and Criminal Investigations

Med-Mizer, Inc. 7/21/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit. MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2014-DET-13

July 21, 2014

VIA UPS

Mr. Daniel R. Tekulve, President
Med-Mizer, Inc.
80 Commerce Drive
Batesville, Indiana 47006-6700

Dear Mr. Tekulve:

During an inspection of your firm located in Batesville, Indiana, from February 19 through March 7, 2014, an Investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures AC powered, adjustable and bariatric hospital beds. 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 to affect the structure or any function of the body.

This inspection revealed that your firm's bed products 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, the manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received your firm's response, dated March 28, 2014, concerning our Investigator's observations noted on the Form FDA 483 (FDA 483), Inspectional Observations, issued to your firm. We address this response below, in relation to each of the noted violations.

These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action as required by 21CFR 820.100(a). For example, your firm's Corrective and Preventive Action Procedure, MM-P0021 Rev 00, is in draft form and has not been implemented. Additionally, your firm has failed to:

a. Analyze processes, work operations, concessions, quality audit reports, quality records, service records, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems as requires by 21 CFR 820.100(a)(1).

For example: Complaints and non-conformances are the only types of quality data currently maintained by your firm. Complaints, service records, quality records, work operations, and returned product records are not analyzed to identify existing and potential causes of nonconforming product. Also, your firm tracks complaint data on a spreadsheet that contains free form text fields that are not standardized, resulting in an inability to adequately trend the data. For example, when using complaint data from January 1, 2011 to February 19, 2014 to trend for "Description of Failure" for "6090," fourteen complaints are shown. However, the spreadsheet contains several different descriptions of the same part failure that when totaled resulted in a total count of forty complaints related to the inline coupler, part #6090.

b. Identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems as required by 21 CFR 820.100(a)(3). For example, of twenty five closed corrective actions, none of them resulted in the prevention of the cause of the quality issue.

c. Verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device as required by 21 CFR 820.100(a)(4). For example, of twenty five closed corrective actions, none of them were verified to ensure that the action(s) taken were effective.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by formally designated units required by 21 CFR 820.198. Specifically, your firm's Complaint Management System Procedure, MM-P0027, Rev. 01:

a. Fails to require evaluations of complaints to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803 [Medical Device Reporting (MDR)] as required by 21 CFR 198(a)(3). Additionally, your firm's complaint records do not include information required to determine if the event represented an event required to be reported under part 803.

b. Fails to require the review and evaluation of all complaints to determine whether an investigation is necessary, and when no investigation was made, your firm fails to maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate as required by 21 CFR 820.198(b). Twenty five complaints were reviewed where an investigation was not performed; none of the complaints contained the rationale for not investigating and the person responsible for that decision.

c. Fails to require the review, evaluation and investigation, unless such an investigation has already been performed, for a similar complaint, of any complaint involving the possible failure of a device, labeling or packaging to meet any of its specifications as required by 21 CFR 820.198 (c). For example, your firm has received 1,020 complaints of component failures related to models QC, SS, BA, XL, and L80 beds from July 13, 2006 to February 19, 2014 however; of twenty five closed complaints, none included an investigation to determine the root cause of the issue.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

3. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications that includes documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production, as required by 21 CFR 820.70(a).

For example, your firm has not established procedures for the fabrication and assembly of the SS, QC, BA, or PR model beds. Instead, personnel perform these operations based on instructions received by experienced employees and their own previous job experience. There **(b)(4)** weldments that make up your finished bed products, but there are no defined, documented, or implemented procedures for these weldments.

Your firm's response dated March 28, 2014 is not adequate. Your proposed timeline of eight to twelve months for implementation of corrective actions for this observation is not acceptable.

4. Failure 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's Product Development Procedure, MM-P0017 Rev. 00, is inadequate.

a. Your firm failed to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, as required by 21 CFR 820.30(c). For example, design inputs are:

i. Ambiguous and do not contain enough information related to intended use and user/patient needs. Specifically, Design Requirement Specification for the M-80 Resident/Sub-Acute Care AC Powered Bed, DRSOO1O, Rev. 00, states "The patient surface can be automatically contoured." However, there are no requirements that specifically state the types of "contours" that need to be achieved, the articulations that would be necessary to achieve those "contours," or the expected load on various sections of the bed when those "contours" are achieved.

ii. Not reviewed, signed and approved before release.

b. Your firm failed to establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, as required by 21 CFR 820.30(d). For example, design outputs are:

i. Not specified in a manner that ensures the device will function properly. Furthermore, measurable or clearly defined acceptance criteria are not established. Specifically, Customer Requirement Specification H-80/L-80 Resident/Sub-Acute Care AC Powered Bed, CRSOO1O, Rev. 00, states Unique Selling Attributes include "Strong Box Frame Construction" and "Reliable Drive System," however there are no specifications mentioned to objectively demonstrate those features.

ii. Not reviewed, signed and approved before release.

c. Your firm failed to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e).

For example: Design reviews are not performed and documented. There are also no procedures governing:

i. The planning and performance of the reviews at appropriate stages of development.

ii. The inclusion of representatives of all functions concerned with the design stage being reviewed, as well as an individual who does not have direct responsibility for the design stage being reviewed.

d. Your firm failed to establish and maintain design verification procedures, as required by 21 CFR 820.30(f). Design verification has not been adequately performed to ensure that the design outputs satisfy the design inputs for the SS, XL, PR, or QC beds. For example:

i. A verification plan was not developed and only two tests were performed which include Electrical Tests and Powder Coating. The Powder Coating test did not have a written/executing protocol with any acceptance criteria. The Electrical Tests involved **(b)(4)**. The purpose of this test could not be traced back to an input requirement and the protocol for the test could not be traced back to a testing standard. These tests were only performed for the XL model. Your firm has not done any testing for the SS, PR, or QC bed lines.

Design inputs for your firm's beds specify they will conform to the voluntary concensus standard IEC and ANSI/ AAMI 60601-1:2005 Standard - Medical Electrical Equipment - part 1: General requirements for basic safety and essential performance. However, you do not have sufficient testing documentation to demonstrate that your beds meet the requirements of that standard. Furthermore, you do not have sufficient documentation to demonstrate that your beds meet your own design requirements. Specifically, you did not perform any reliability testing on your beds to show that they would be capable of operating for the 15 year warranty period.

ii. Design verification was not performed or documented to include the results of the verification, the identification of the design, methods, the date, and the individual performing the verification.

e. Your firm failed to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g).

For example, design validation has not been adequately performed to ensure that the design satisfies the user needs and intended uses for the SS, XL, PR, or QC beds. For example:

i. Risk analyses were not performed to determine if there are any risks to patients or users.

ii. Two tests were performed: Product Transport, and Safety Weight. However, there was no written/executed protocol for the Product Transport test. The Safety Weight test involved **(b)(4)**. The bed did not have casters attached to the bed and the protocol did not specify the positional arrangements of the personnel, the duration of the test, the loading/unloading conditions of the test, or the means for evaluating the bed for adverse impact. These tests were only performed for the XL model. Your firm has not done any testing for the SS, PR, or QC bed lines.

iii. Design validation was not performed or documented to include the results of the verification, the identification of the design, methods, the date, and the individual performing the validation.

f. Your firm failed to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example:

i. Your firm's form ECN #QC00014, dated August 14, 2012, authorized changes that were to strengthen the head width extender for the QC model bed. However, your firm did not

perform any validation testing to show the head width extenders were strengthened and that the changes would not adversely impact the product.

ii. Your firm's form ECN #QC00019, dated February 8, 2013, authorized the modification of the QC model bed frame to incorporate a scale system that would weigh patients on the bed. Your firm did not perform any validation testing to show the scale would accurately and precisely weight patients on the bed.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

5. Failure to validate, with a high degree of assurance and approve according to established procedures, a manufacturing process that cannot be fully verified by subsequent inspection and testing, to ensure the process will continue to meet specifications as required by 21 CFR 820.75(a).

For example: your firm's **(b)(4)**, utilized to weld your retractable hospital bed devices, have not been validated.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

6. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, and is not released into distribution until the activities required in the Device Master Record (DMR) are completed, the associated data and documentation is reviewed, the release is authorized by the signature of a designated individual, and the authorization is dated, as required by 21 CFR 820.80(d).

For example, your firm's Final Inspection/Test Work Instructions for Beds Procedure, MM-W000l Rev.00, and Final Inspection/Test Work Instructions for BA8000 are inadequate.

a. Neither of the procedures specifies the acceptance criteria for each test that will be performed and the "MED-MIZER, INC., Control Sheets" do not include acceptance criteria for each test or visual inspection. Tests include "welds," "labeling," and "contour w/ weight applied," but there are no specifications listed for these tests/attributes and there are no acceptance criteria listed.

b. For bed Model SS803A, Serial Numbers **(b)(4)**, final inspection personnel checked off that the electrical test "Leakage current less than **(b)(4)** ", passed despite the final inspections failing to include the utilization of electrical measurement equipment.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

7. Failure to establish and maintain procedures to control product that does not conform to specified requirements as required by 21 CFR 820.90.

Your firm's Inspection and Control of Non-Conforming Product Instructions Procedure, MM-W0023 Rev.00, is inadequate.

a. There are no requirements for the evaluation of non-conformances to determine if an investigation is necessary as required by 21 CFR 820.90(a). For example, of twenty five non-conformances reviewed, none had documented evaluations.

b. The procedure fails to include that the documentation for the distribution of non-conforming product shall include the justification for the use of non-conforming product and the signature of the individual(s) authorizing the use. For example, non-conformances with a "Use as is" disposition are not reviewed and approved before use and no justification is provided when assigning a "Use as

is" disposition. Of twenty five non-conformances reviewed, seven were assigned a "Use as is" disposition; however, none of them included a justification and the signature of the individual authorizing use of the nonconforming product.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

8. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications and to ensure rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, are documented in the DHR as required by 21 CFR 820.90(b) (2). For example:

a. There are no defined, documented, or implemented procedures for controlling rework of nonconforming product. However, from July 21, 2006 to February 19, 2014, your firm has performed rework three hundred ninety three times and a review of rework documentation from three rework operations revealed they were:

i. Performed without written procedures that included retesting and reevaluation of the product after rework to ensure the device met its approved specifications.

ii. There was no documentation of a determination of any adverse effects from the rework upon the product.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

9. 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.

For example, Purchasing Control Procedure, MM-P0025 Rev. 00, requires supplier evaluations to be completed; however, your firm has not established procedures for how to evaluate suppliers to determine if they are capable of supplying conforming goods and have not completed any supplier evaluations. In addition:

a. Your firm has failed to establish and maintain records of acceptable suppliers, contractors, and consultants, as required by 21 CFR 820.50(a)(3).

b. Your firm failed to maintain purchasing documents that include an agreement that your suppliers, contractors, and consultants agree to notify your firm of changes in the product or service so that your firm can determine whether the changes affect the quality of the finished device, as required by 21 CFR 820.50(a)(3)(b).

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

10. Failure to establish and maintain procedures for acceptance of incoming product that includes inspection, testing, or verification of its conformance to specified requirements, as required by 21 CFR 820.80(b). For example, your firm's Receiving Inspection Work Instructions, MM-W0026 Rev.00, is inadequate in that it requires all components and materials received to undergo a document review where part numbers, part descriptions, and quantity are visually verified for conformance to the part specifications listed on the Bill of Materials; however, critical components are not inspected, tested or verified to meet specifications.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

11. Failure to establish and maintain procedures to ensure that Device History Records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR), as required by 21 CFR 820.184.

a. Your firm's DHRs do not include or refer to the location of the acceptance records that demonstrate the device is manufactured in accordance with the DMR, as required by 21 CFR 820.184(d). For example:

i. Despite your firm's Med-Mizer SS/CC Control Sheet including spaces for the final tester to check, pass or fail, for items such as "welds," "Hi/Low W/ Weight Applied," and "Contour W/ Weight Applied," the control sheet does not indicate the specifications for those tests.

ii. Your firm does not document the in-process fabrication of components and the completion of sub-assemblies by personnel.

b. Your firm does not include the primary identification label and labeling used for each production unit as required by 21 CFR 820.184(e).

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

12. Failure to establish procedures for identifying training needs, ensure that all personnel are trained to adequately perform their assigned responsibilities and that training is documented, as required by 21 CFR 820.25(b). For example:

a. Your firm does not maintain documentation that demonstrates the training needs of your employees have been identified.

b. Your firm does not maintain documentation demonstrating training has been given to meet the employees' training needs.

c. Of eleven employees training records requested, no training records were available or provided by your firm's officials.

Your firm's response dated March 28, 2014 is not adequate as it did not include documentation or evidence of the corrections, corrective actions, or consideration of systemic corrective actions.

Our inspection also revealed that your firm's Model SS Hospital Beds 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 806 – Medical Devices; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

Failure to submit a written Report of Correction or Removal to FDA for a medical device correction or removal conducted to reduce a risk to health posed by a device, or remedy a violation of the act caused by the device which may present a risk to health, as required by 21 CFR Part 806.10.

For example, your firm made a decision in June 2008 to implement a field correction due to an insufficient weld on its Model SS Hospital Beds. The correction involved placing a **(b)(4)**. On August 18, 2008 your firm made a decision to replace twenty five beds with new beds which would allow the factory to repair twenty five beds at a time until all of the remaining beds met the manufacturing specifications. This correction and removal activity spanned to at least five facilities and impacted approximately one hundred twenty four beds. Your firm did not submit a written report to FDA of the correction and removal as required by 21 CFR 806.

We reviewed your firm's response dated March 28, 2014, and it appears to be adequate. Your firm stated, "Med-Mizer will be conducting a voluntary recall due to a correction that was not reported to FDA." Med-Mizer has contacted the Detroit District Recall Coordinator to begin the process. Currently Med-Mizer is evaluating the extent of the recall. Med-Mizer will be continuing forward on this voluntary recall and will notify us of their progress. A Report of Correction or Removal was submitted to FDA on April 21, 2014. An Urgent Medical Device Recall letter dated April 18, 2014, was sent to all affected customers about the insufficient weld.

Our inspection also revealed that your firm's AC-Powered Adjustable Hospital Bed is 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 regarding the devices that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 Medical Device Reporting. Significant deviations include, but are not limited to:

1. Failure to develop, maintain and implement written MDR procedures as required by 21 CFR 803.17. For example:

During the inspection of your firm, your firm acknowledged that you did not have an MDR procedure.

2. Failure to submit an MDR to the FDA no later than thirty calendar days the day your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that you market may have caused or contributed to a death as required by 21 CFR 803.50(a)(1). For example:

Your firm was aware of a complaint in which a patient was in bed in a low position and tried to exit the bed, and when doing so, the patient's head became positioned between the mattress and the side rail. Air was displaced in the mattress and the mattress refilled causing the patient's head to go between the mattress and side rail. The patient died. Your firm became aware of the event on October 27, 2009 and did not file an MDR.

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the Reportability Review Team by email at ReportabilityReviewTeam@fda.hhs.gov

Your firm 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 the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of 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 violations 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 device have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

We request that you submit your revised plan for corrective actions based on this correspondence in writing, within fifteen (15) business days from the date you receive this letter, to the following

address:

Food and Drug Administration
Detroit District Office
300 River Place, Suite 5900
Detroit, Michigan 48207

If you have any questions about the content of this letter, please contact: CDR Kimberly Martin at (317) 226-6500 ext. 116.

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

Sincerely,
/S/
Paige E. Shelborne
Acting District Director
Detroit District Office

Page Last Updated: 07/28/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Accessibility Contact FDA Careers FDA Basics FOIA No Fear Act Site Map Transparency Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of Health & Human Services

Links on this page: