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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
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November 29, 2007

WARNING LETTER
CIN-08-33808-05

VIA FEDERAL EXPRESS

Mr. Donald L. Sullivan
CFO/Acting CEO
E Med Future, Inc.
34 South Clay Street, Suite D
Millersburg, Ohio 44654

Dear Mr. Sullivan:

During an inspection of your firm located in Millersburg, Ohio, on July 9 through 25, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is the manufacturer (specification developer) for needle disintegration devices (NeedleZap). 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 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 (CFR), Part 820. We received a response from you dated August 7, 2007, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (FDA 483), that was issued to you. We address your 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 a quality system that is appropriate for the specific medical devices designed or manufactured and that meets the requirements of 21 CFR part 820, as required by 21 CFR 820.5.

   For example, for the last two years, your firm has not implemented any of your quality procedures, effectively operating without any quality system.

Your response to this observation appears adequate. We will verify this corrective action during a future inspection of your firm.

2. Failure to establish management controls as required by 21 CFR §820.20. For example:

   For the last two years, your firm has not implemented your complaint procedure, corrective and preventive action procedure, nonconformance procedures, and any other quality procedures, in violation of the requirement of 21 CFR §820.20(e) that each manufacturer establish quality system procedures and instructions.

   Since June of 2006, your firm has not appointed a management representative to ensure that quality system requirements are effectively established and maintained in accordance with the requirements of part 820, and to report on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR §820.20(b)(3).

   No management reviews have been conducted since May of 2005 although your management review procedures state that such reviews will be conducted, at a minimum, every 12 months. [21 CFR §820.20(c)]

   Your response to this observation appears adequate. Please update us on the progress of your corrective action regarding this observation. We will verify your corrective action at a future inspection of your firm.

3. Failure to implement corrective and preventive action procedures, including procedures for analyzing complaints, returned product, and other sources of quality data to identify existing and potential causes of nonforming product or other quality problems, and failure to document all corrective and preventive action activities and results, as required by 21 CFR §820.100.

   For example, your firm has been reworking approximately 15% of the NeedleZap devices received from your contract manufacturer, because of "an issue with posts that were cracking in the NeedleZap case". Additionally, you have had many units returned from customers due to broken posts, no charge, "needlewaste" in electrodes, and bad battery. Your firm has not determined the root cause of these nonconformances, no corrective actions have been documented, and no trending and analysis of this data has been performed.

   We have reviewed your response to this observation and have concluded that it is inadequate, because neither the Response Letter, nor your newly drafted CAPA procedure (attached to the Response Letter), address how the quality data will be analyzed, including what statistical techniques will be used to analyze the quality data. Under 21 CFR 820.100(a)(1), you must use appropriate statistical methodology where necessary to detect recurring quality problems. See also 21 CFR 820.250 (requiring procedures for identifying valid statistical techniques.)

4. Failure to implement procedures for receiving, reviewing, and evaluating complaints by a formally designated unit; failure to review, evaluate, and where required, investigate, complaints; and failure to maintain appropriate records of investigation, as required by 21 CFR 820.198.

   For example, you have had over 50 devices returned to your firm through your return material authorization (RMA) system since 2006. More than 30 of these devices were returned due to broken posts, no charge, "needlewaste" in electrodes, and bad battery. None of these returns have been evaluated to determine if they meet the definition of a complaint and no failure investigations of these devices have been conducted.

   We have reviewed your response to this observation and have concluded that it is inadequate. Neither the new Product Complaint form, nor the Complaint Handling and Medical Device Reporting procedure (attached to the Response Letter), addresses documenting your reply (if any) to the complainant, as required by 21 CFR 820.198(e). Also, please send an update on the progress of your evaluation of determining if the RMAs received in the last 18 months are complaints.

5. Failure to implement your written procedure to control product that does not conform to specified requirements, including failure to properly identify, segregate and disposition nonconforming product, as required by 21 CFR §820.90.

   For example, the FDA investigator observed nonconforming NeedleZap devices throughout your firm that were not clearly identified or dispositioned. Additionally, he found nonconforming devices on a shelf that were ready for shipment.

6. Failure to establish and maintain rework procedures, including failure to document rework and retesting that is performed on finished devices, as required by 21 CFR §820.90(b)(2).

   For example, your firm is examining all NeedleZap devices received from your contract manufacturer and has reworked about 15% of these devices due to issues with the post cracking in the case and wrong screws being used. This rework and any retesting are not documented. You also do not have a written procedure on how to perform the rework and the retesting that must be performed.

   We have reviewed your response to this observation and have concluded that it is inadequate, because it does not include a written rework procedure and does not address how rework will be documented.

7. Failure to implement procedures for calibration, including failure to perform calibration on testing equipment, as required by 21 CFR §820.72(b).

   For example, the multimeter used to test the NeedleZap after rework is performed has not been calibrated. Additionally, your written calibration procedure, which requires all equipment to bear a calibration label and be calibrated at a maximum of 12-months interval, is not being followed.

   Your written response is inadequate, because it does not specifically address the calibration of the multimeter. It only states that all procedures will be completely revised.

8. Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities; and failure to implement your training procedure, as required by 21 CFR §820.25(b).

   For example, there is no documentation of any training of any current employees with regard to their assigned responsibilities, although your training procedures require documentation of training. In addition, an employee assigned to receive customer calls on problems with the NeedleZap indicated that she in fact has received no training on how to perform her assigned tasks, including documenting customer complaints.

   Your written response is inadequate, because it does not specifically address training. It only states that all procedures will be completely revised.

9. Failure to conduct quality audits; and failure to implement audit procedures to assure that the quality system is in compliance with the established quality systems requirements and to determine the effectiveness of the Quality Systems, as required by 21 CFR §820.22.

   For example, you have not performed quality audits for two years.

   Your response states that an audit of your firm would be completed by September 30, 2007. Please inform us if the audit has been completed, and if not, when it will be completed.

The inspection also revealed that your NeedleZap 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 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:

1. Failure to submit an MDR to FDA within 30 days of receiving information that reasonably suggest that your marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR §803.50(a)(2).

   For example, in February of 2005, your firm received a copy of a Voluntary MedWatch report from a doctor, which described the nurse being stuck by a needle that had "worked its way out of a side seam" of a NeedleZap device. It further states that many of the patients treated with these needles have HCV and HIV; and that the nurse was evaluated and treated for high risk exposure. You did not report this to FDA within 30 days as a malfunction MDR.

   Your response to this observation appears adequate, and subsequent to the date of the inspection, your firm submitted MDRs on this event to FDA. Your response also states that you are reviewing all NeedleZap return material authorizations (RMAs) for the last 18 months, and are evaluating these RMAs to determine if they are reportable under 21 CFR Part 803, Medical Device Reporting. Please update us on the progress and findings of this review.

2. Failure to conduct an investigation of each MDR event and evaluate the cause(s) of the event, as required by 21 CFR §803.50(b)(3).

   For example, there is no evidence to show that you conducted a failure investigation on the complaint (T0002) involving the nurse who picked up a NeedleZap unit and was stuck by a needle protruding from the side of the device. This type of event is considered a malfunction. Also, a telephone conversation documented in the complaint file states, "Action taken to the new units would not have the same problem." It is unclear what, if any, actions were taken. According to your MDR reporting procedures, it states that "serious event/incidents and near incidents shall be investigated and reported as appropriate." Each manufacturer is responsible for conducting an investigation of each event and evaluating the cause of the event. If it is determined that an event is not reportable, the decision must be documented as described in 21 CFR §803.18.

   This observation was mad after the FDA 483 was issued. Your response did not address why a failure investigation for this complaint was not conducted.

   Although E-Med Future, Inc. has MDR reporting procedures, it was noted that some aspects of the procedure are incomplete or obsolete. For example:

   MDR report and respective time frame are not addressed, i.e., Supplement MDR reports, 21 CFR §803.56.

   The procedures do not contain a specific definition and procedure for addressing MDR reportable malfunctions. You could address this by defining "near incident" as including an MDR reportable malfunction or by adding a separate definition/procedure for MDR malfunctions.

   Item #6.8.2 of your procedures addresses the submission of Annual Reports to FDA. As a result of statutory changes enacted in 1997, MDR regulations no longer require submission of annual certifications of the number of MDRs filed. We recommend that you thoroughly review your MDR procedures to ensure that they will promote compliance with the requirements of 21 CFR part 803.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in the initiation of regulatory action without further notice. This may include, but is 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 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 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, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrective actions 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 timeframe within which the corrections will be completed.

Your response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may forward a facsimile to her at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by the 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 action to correct the violations and to bring your products into compliance.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District