U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Encompass Group, LLC 6/2/10

Department of Health and Human Services

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

June 2, 2010

VIA UPS EXPRESS

Mike Spurlock, CEO
Encompass Group, LLC
615 Macon St.
McDonough, GA 30253-3531

WARNING LETTER
(10-ATL-16)

Dear Mr. Spurlock:

During an inspection of your firm located in McDonough, Georgia on December 15, 2009, through December 22, 2009, an investigator from the United States Food and Drug Administration determined that your firm is the specification developer and distributor of the Thermoflect® Hypothermia Prevention Products, including but not limited to blankets, transport Cocoon™, patient gowns, caps, pediatric pants and jackets. 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 t affect the structure or function of the body.

Our inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in tha 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 C.F.R. Part 803 - Medical Device Reporting (MDR) regulation. The significant deviation is as follows:

Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, your firm's MDR procedure which is incorporated into your complaint handling procedure (Complaint Files, number QSR-116, Revision 1, August 29, 2008) does not define processes that will allow your firm to implement timely and effective identification, communication and evaluation of events that may be subject to MDR requirements found in 21 CFR Part 803. Your firm will need to establish and implement a written MDR procedure as required by 21 CFR Part 803.17.

We have reviewed your response and have concluded that its adequacy cannot be determined at this time. You anticipated by April 2010, that the Complaint Procedure, QSR-115, would be rewritten and implemented to specifically address if an event is subject to a MDR requirement and timeliness of reporting the event. In addition, each complaint would be documented to denote, if it is or is not an MDR event. Finally, you stated that your firm would consider preparing a decision tree to help determine an MDR event. However you did not provide documented evidence of this implementation.

You should take prompt action to correct the violation addressed in this letter. Failure to promptly correct this violation 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 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 violation, including an explanation of how you plan to prevent this violation, o similar 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 wi be completed.

In addition, FDA has noted nonconformances with regards to section 501(h) of the Act, 21 U.S.C. § 351(h), due to deficiencies of 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 from Ms. Jea R. Gackowski, Corporate Compliance Officer, dated January 6, 2010, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to Ms. Gackowski (copy enclosed). We address this response below, in relation to each of the noted deviations. These deviations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, your firm opened CAPAs in response to quality audit data which showe the lack of QS regulation training in many departments within your firm. However, the CAPAs do not contain or reference documentation to support complete implementation of the CAPA activities, such as investigating the cause of the nonconformity, identifying the action needed to correct and prevent recurrence, and verification or validation o the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as defined in your firm's Corrective & Preventive Action Procedure QSR-115.

We have reviewed your response and have concluded that it is inadequate. Your firm stated that the CAPA requirements outlined in the regulations and your internal procedure are currently being reviewed and re-evaluated. Your firm also stated by May 2010, you anticipate completing the following:

- Strengthening your current CAPA procedure, QSR-115, to include information that the investigation, implementation, verification, and validation of the CAPA activities are both documented and implemented.

- Review the current strategies for the investigations of nonconformities and update the reports to show all relevant information.

- Improve the overall documentation (Product Quality Reports, Quality Logs, etc.) to show specifics which are needed to support investigation of the nonconformities are being thoroughly documented and completed.

- Implement training initiatives to ensure that employees are trained on CAPA issues.

However, documented evidence of the correction and systemic corrective action was not provided for FDA's review. Further, your firm did not provide evidence demonstrating that you would perform a retrospective review to identify other CAPAs that were not adequately documented.

2. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm's Complaint File Procedure QSR-116, Revision 1, August 29, 2008, does not adequately address procedures for:

a) Processing complaints in a timely manner,
b) Documenting oral complaints upon receipt, and
c) Evaluation of complaints for MDR reporting requirements, under part 803.

We have reviewed your response and have concluded that its adequacy cannot be determined at this time. Your firm stated by May 2010, that you anticipate:

- Strengthening the current program for reporting complaints to ensure that the strategies outlined in the procedures are followed.

- Evaluating the requirements and reports to include those specific actions that are currently not addressed.
- Reviewing the Complaint Handling Procedure, QSR-116, to address the issues noted.
- Initiating training sessions for all appropriate personnel once the procedures and reports are finalized.

However, your firm did not provide any documented evidence of this implementation.

3. Failure to establish and maintain adequate complaint handling procedures for the review and evaluation of all complaints to determine whether an investigation is necessary, as required by 21 CFR 820.198(b). For example, you firm's Complaint Files Procedure, QSR-116, Revision 1, August 29, 2008, does not include reviewing and evaluating all complaints to determine whether an investigation is necessary or when no investigation is made, maintaining a record that includes the reason for not investigating and the name of the individual responsible for that decision.

We have reviewed your response and have concluded that its adequacy cannot be determined at this time. Your firm stated by May 2010, that you anticipate:

- Strengthening the current program for reporting complaints to ensure that the strategies outlined in the procedures are followed.
- Evaluating the requirements and reports to include those specific actions that are currently not addressed.
- Reviewing the Complaint Handling Procedure, QSR-116, to address the issues noted.
- Initiating training sessions will be for all appropriate personnel once the procedures and reports are finalized.

However, your firm did not provide any documented evidence of this implementation.

4. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, Section 4.2 of your firm's procedure, Non-conforming Product, number QSR-114, August 29, 2008, requires documentation of information relating to nonconformances of finished devices that will form your nonconforming report. The procedure requires the documentation of those responsible for the investigation and follow-up and a corrective action. Additionally the procedure stated that all information regarding disposition and corrective action shall be recorded. Although the rejection log contained a record of the information as specified in the procedure, it did not adequately include or reference an investigation int the nonconformance or a corrective action. The corrective action plan only stated, "notify Supervisor of issue".

We have reviewed your response and have concluded that its adequacy cannot be determined at this time. Your firm stated that you are re-evaluating the procedure, and by April 2010, anticipated enhancing the reports to provide the documentation needed to support that the evaluation and investigation are appropriately performed. Your firm also stated that you are performing the investigations and have the documentation to support the practice and procedures. However, your firm did not provide any documentation demonstrating implementation of the procedures or evidence showing that an evaluation and investigations are adequately performed.

5. Failure 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, Section 4.8 of your firm's Design Control Procedure QSR-105 states, "Each division will establish a procedure to ensure that design changes will be governed by approval from the departments that will be affected by the change as well as the Quality department." However the procedure does not adequately address or reference procedures for the identification, documentation, validation or where appropriate verification, review, and approval o design changes before their implementation, as required by the Quality System regulation for design changes.

We have reviewed your response and have concluded that its adequacy cannot be determined at this time. Your firm stated by May 2010, you anticipate updating the Design Control procedures, QSR #105, to detail the process and/or reference the supporting documentation (i.e. other procedures, process approval forms, flow charts, etc.) that are currently followed during the design change. However, your firm did not provide documented evidence of the correction or systemic corrective action.

6. Failure to maintain adequate device master records (DMRs) which shall include or refer to the location of packagin and labeling specifications, including methods and processes used, as required by 21 CFR 820.181(d). For example, the Device Master Record for the **(b)(4)** Series did not include or reference the labeling procedures or specifications

We have reviewed your response and have concluded that its adequacy cannot be determined at this time. Your firm stated that by February 2010, all device master records (DMRs) would be reviewed and you would determine the DMRs that need to be corrected. Additionally, by April 2010, you anticipated updating all of the specifications, which includes labeling information. Further, once your firm identifies all of the medical devices that need to be changed, you will update the records to ensure that the type of label and its format are clearly defined in the record's documentation. However your firm did not provide documentation and evidence of implementation.

7. Failure to establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of 21 CFR Part 820 such as appointing, and documenting such appointment of, a member of management who, irrespective of other responsibilities shall have established authority over and responsibility for: ensuring that the quality system requirements are effectively established and effectively maintained in accordance with this part; and reporting on the performance of the quality system to management wit executive responsibility for review, as required by 21 CFR 820.20(b)(3)(i). For example, your firm did not have a documented management representative.

Documentation of the management representative was created and provided prior to the close of inspection.

Your response should be sent to Serene N. Ackall, Compliance Officer. If you have any questions about the content of this letter, please contact Ms. Ackall at 404-253-1296 or fax at 404-253-1201.

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 th 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/

John R. Gridley, Director
Atlanta District

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