CMS 145512
SNR

FEI 1031452

January 11, 2011

Mr. Ronnie E. Jackson
Director of Compliance
United States Food and Drug Administration
Department of Health and Human Services
District Office
555 Winderley Place, Suite 200
Maitland, FL 32751

RECEIVED

JAN 12 2011

COMPLIANCE

Re: Warning Letter; FLA-11-10: Sanford, Florida

Dear Mr. Jackson:

Please accept this response to the FDA's Warning Letter, dated December 15, 2010, that was addressed to Invacare's Chairman of the Board and Chief Executive Officer, Mr. A. Malachi Mixon, III. Invacare received the warning letter on December 21, 2010.

Before addressing the specifics within the letter, I would like to advise you that while Mr. Mixon remains Invacare's Chairman of the Board, I was appointed the President and Chief Executive Officer by the Board of Directors, effective January 1, 2011.

Attached you will find the response to the warning letter issued to our manufacturing facility in Sanford, Florida. In addition to the attached response, Invacare has responded to two FDA 483's on January 11, 2011, related to our corporate headquarters at One Invacare Way, Elyria, Ohio and our Taylor Street manufacturing facility in Elyria, Ohio.

I recognize the urgent need to address each and every one of FDA's concerns. I have taken personal responsibility to see that Invacare does that in a timely and permanent manner. We are looking at Quality System Regulation compliance on a company-wide, systematic basis.

I have put together an internal team of regulatory, quality, engineering, and manufacturing personnel who will report directly to me on our response and our corrective actions. Further, recognizing the need to address these concerns and implement effective and permanent change, we have contracted with (b) (4) an independent firm staffed with industry experts who have substantial experience in quality systems management and regulatory compliance matters in the medical device industry, including specific experience within the FDA itself. (b) (4) will be involved in developing and reviewing any proposed quality system changes as well as participating in verifying effectiveness of implemented changes. (b) (4) will also provide assistance in the design of permanent solutions to procedures and systems, third party independent assessment, validation of system changes, and overall project management of the quality system improvements. I am confident that adding (b) (4) as part of the process will ensure that we address these issues completely and appropriately, in a timely manner.

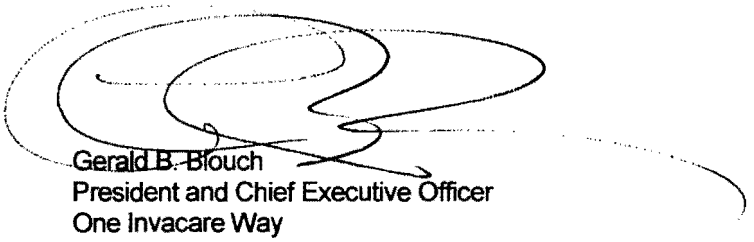
Over the past year, under my leadership, we also have taken action independent of the FDA inspections to improve our quality and corrective action systems. Specifically, we began programs that are resourced to target system level improvement. Examples include an electronic CAPA and adverse event management system (b) (4) and our quality Functional Excellence program that utilizes an (b) (4) platform to improve our quality, engineering, and regulatory training capabilities to our global associates.

As we move forward to correct these issues appropriately, we commit to providing the FDA with formal follow-up reports regarding our activities at a minimum on the following dates: February 18, 2011, March 18, 2011 and June 10, 2011. Our current expectation is to complete close out of the issues identified in the warning letter by June 10, 2011, and will update our progress on our timeline during our follow-up reports. We will provide quarterly updates thereafter, if necessary, until all corrective actions have been completed.

In closing, I want to assure you that I and the rest of my management team at Invacare take these issues seriously and that we are committed to provide the resources necessary to make the appropriate changes. We believe that our actions taken already and those planned in the near future will correct the compliance issues observed.

If you should have further questions or concerns please contact me directly.

Regards,



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cc: Anthony C. LaPlaca, Sr. Vice President & General Counsel
Jeffrey Craigo, Vice President, Global Quality
Ronald J. Clines, Director, Regulatory Affairs

January 11, 2011

Mr. Ronnie E. Jackson, Director of Compliance
United States Food and Drug Administration
Maitland, FL

Response to FDA Warning Letter regarding Invacare Corporation Sanford, FL Facility

This response is attached to a letter from Gerald B. Blouch, Invacare President and Chief Executive Officer, addressed to the FDA which forms a part of this response.

Below is a summary of each item listed in the FDA warning letter, followed by Invacare's response. Where appropriate we have broken the response down into several sections that communicate what Invacare's immediate, short term actions will be followed by a more detailed analysis of what we have identified as the root cause and our long term plans to address it.

We commit to providing the FDA with formal follow-up reports regarding our activities at a minimum on the following dates: February 18, 2011, March 18, 2011 and June 10, 2011. Our current expectation is to complete close out of the issues identified in the warning letter by June 10, 2011, and will update our progress on our time line during our follow-up reports. We will provide quarterly updates thereafter, if necessary, until all corrective actions have been completed.

The following responses address the specific items of the warning letter:

Item 1:
Failure to establish and maintain adequate procedures to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems and to employ appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 CFR 820.100(a)(l).

The FDA determined that our response was inadequate in that our procedure, Procedure BB14-00, does not clearly identify the requirements for analyzing complaints or discuss what statistical methodology will be utilized to detect recurring problems which is a requirement under 21 CFR 820.100(a)(l). In addition the firm has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

Response:
We recognize that our procedure for complaint handling must be improved corporate wide to maintain consistent standards for analyzing complaints which include statistical analysis of complaints from all possible sources and include a process for appropriate and documented corrective action.

Root Cause Determination:
No corporate procedure specific to statistical techniques was used in various areas across the business. Actions need to be risk based, assess all applicable sources and include trigger points for action. While Invacare recognizes that these trigger points may be different from product line to product line, we agree that they need to be defined and statistically based.

Preventative Measures / Systemic Long Term Correction:
1) Create new corporate procedure that defines the statistical methods used. Facility specific procedures, such as BB14-001, will be revised to be in alignment with this new procedure as

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appropriate. Revised procedures will be provided as part of the February follow-up. Training records on this procedure will be provided as part of the March follow-up.
2) Improve current trending used for Adverse Event complaints and other sources of quality data. Identify improved means to trend Adverse Event complaints especially those involving "key words" such as "fire, smoke, heat, hot and burnt," malfunctions and reportable events. The methods to be employed will be provided as part of the March follow-up. Long term system changes will be reviewed, validated, and audited by (b) (4) and we will update on the expected completion by our June follow-up.

Item 2:
Failure to establish and maintain adequate procedures to 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).

Invacare's response dated September 8, 2010, was determined by the FDA as not adequate. Invacare stated that moving forward it would take actions to increase awareness to customers and users regarding entrapment and is considering adding additional instruction regarding body size as it may relate to increased entrapment. However Invacare's response did not discuss or provide any evidence of its process for identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems. In addition Invacare has not performed any systemic corrective actions to ensure that all necessary data sources are appropriately analyzed and evaluated.

Response:
As discussed with the inspectors on site at the Sanford facility, Invacare does recognize that the documentation of our risk assessment activities must be improved. We recognize the need to improve our Corporate risk assessment procedure and apply it consistently throughout our facilities.

Root Cause Determination:
Invacare's Corporate complaint system does not document that potential user risk was considered, if a formal risk assessment is required or if an existing risk assessment requires review or updating as part of the investigation process. In the current process, risk assessment is performed when a device malfunction or manufacturing process issue is discovered. Risk assessment activities conducted as part of complaint investigation lack specific thresholds that trigger overall product risk update or the potential to update the MDR reporting decision process.

Short Term Corrective Action:
Invacare will revise the procedure "Risk Assessment for Product Malfunctions and Quality Issues" (CP14-013) and the associated form (fm14013a) to ensure risk feed back into the design process. Copies of the revised procedure and form will be provided as part of the March follow-up.

Occurrence Prevention / Systemic Corrective Action:
Review the (b) (4) complaint system and identify areas for process improvement including risk assessment or other actions that may be required. As indicated in item 1 above, Invacare is creating a Corporate procedure specific to statistical techniques that will address data sources and define trigger points for other action. Summary of this review will be provided as part of the March follow-up. Specific changes to be made to the (b) (4) system and a time line for validation and implementation will be provided as part of the June follow-up. Long term system changes will be reviewed, validated, and audited by (b) (4) and we will update on the expected completion by our June follow-up.

Item 3:
Failure to maintain an adequate record of the investigation including the dates and results of the investigation, as required by 21 CFR 820.198(e).

FDA determined that Invacare's response dated September 8, 2010, is not adequate. Invacare stated that it would review the current complaint investigation process and although not specified, is exploring solutions that would document and define "Critical Information" requirements and the attempts to gather this information. Invacare stated that these corrective actions would be completed by October 15, 2010. Invacare has not provided any evidence of implementation of changes to the current investigation process. Invacare also stated that it would document a risk assessment specifically to the potential fire issue and will submit it to FDA by October 15, 2010. Invacare did not mention how it will ensure that the dates and results of complaint investigations are adequate. Additionally, Invacare did not discuss how it will conduct a systemic corrective action that involves re-assessing all complaints to ensure that the investigations were adequately completed and documented.

Response:
Invacare recognizes the need to improve our complaint handling process. We need to improve the timeliness and documentation of critical information requests and their result.

Root Cause Determination:
Inadequate documentation regarding the minimum information that should be requested / attempted to be obtained as part of the investigation. When information is not available or not provided, there is no documentation indicating that it was requested or that it was not available / or denied. Complaint handling system does not define these data types or require acknowledgement that an attempt was made to obtain the information.

Short Term Corrective Action:
1) The consumer incident reporting form, fm14002b, that is used to communicate complaints to Corporate Regulatory Affairs was modified to provide increased visibility of the information required to be obtained as part of the complaint receipt process. A copy of the revised form is enclosed (b) (4)
2) Additionally, we have enclosed a revised risk assessment regarding the "potential fire issue" (b) (4)

Preventative Measures - Systemic Long Term Correction:
1) Invacare will review all risk assessments performed by Regulatory Affairs in response to reportable event complaints or other complaints and determine if other "design considerations" should be added to Invacare's Product Design Inputs, Risk Assessment and Control Plan, form fm04013c. This will provide for consideration of these identified risks as part of new product development activity. A summary regarding this activity will be provided as part of our March follow-up.
2) Invacare will review the (b) (4) complaint system and identify areas for improvement. Specific attention will be given to documenting the dates of follow-up attempts, the information requested and the results of that follow-up. A summary of this review will be provided as part of the March follow up. Specific changes to be made to the system including a time line for their validation and implementation will be provided as part of the June follow-up.
3) Develop an eLearning training module specific to complaint handling. The progress on this activity will be provided as part of the June follow-up.
4) Invacare will review complaint files received over a two year period that involve claims of possible bed rail entrapment or where malfunctions are suggested by the presence of key words such as fire, smoke, flame, etc. thereby suggesting the potential for fire. Invacare will examine these files to determine if the complaint investigation was adequately investigated and documented. A summary regarding complaints received between July 1, 2010 and December 31, 2010 will be provided as part of our March follow-up. The remaining 18 months will be provided as part of the June follow-up.

Item 4:
Failure to establish and maintain adequate procedures for validating the device design in order to ensure that devices conform to defined user needs and intended uses, and perform risk analysis where appropriate, as required by 21 CFR 820.30(g).

The FDA determined that Invacare's response dated September 8, 2010, was not adequate. Invacare stated that it would conduct a risk assessment regarding bed rail entrapment with the intent of determining if the areas of concern that are not currently addressed, such as patient size, or if existing labeling can be augmented in some way. Invacare stated that these activities will be completed by October 30, 2010; however, it has not provided any evidence of implementation of this corrective action. Invacare's response did not address other issues associated with the mattresses or bed rails or how, according to its procedure, CPO4- 013, information obtained from production or post-production activities that suggests the existing risk assessment may not reflect current information will be assessed to determine if a need exists to modify the existing risk assessment. Additionally, Invacare did not discuss how it will conduct a systemic corrective action that includes a retrospective review and reevaluation of other types of complaints to ensure that the risk analysis has been appropriately updated.

Response:
As indicated in item 2 above, Invacare recognizes that our Corporate complaint system does not document that potential user risk was considered, if a formal risk assessment is required or if an existing risk assessment requires review or updating as part of the investigation process. In the current process, risk assessment is performed when a device malfunction or manufacturing process issue is discovered. Risk assessment activities conducted as part of complaint investigation lack specific thresholds that trigger overall product risk update at the design level or the potential to update the MDR reporting decision process.

Related Product / System Containment:
1) Invacare will review all risk assessments performed by Regulatory Affairs over the past two years in response to complaints and determine if other design considerations should be added to Invacare's Product Design Inputs, Risk Assessment and Control Plan, fm04013c. This will provide for consideration of these identified risks as part of new product development activity. A summary of this activity will be provided as part of the March follow-up.
2) Review procedure "Risk Assessment for Product Malfunctions and Quality Issues" (CP14-013) and associated form (fm14013a) to provide for enhanced risk feed back into the design process. Copies of revised procedures and forms will be provided as part of the March follow-up.
3) Invacare will review complaint files received over a two year period that involve claims of possible bed rail entrapment or where malfunctions are suggested by the presence of key words such as fire, smoke, flame, etc. thereby suggesting the potential for fire. Invacare will examine these files to determine if the complaint investigation was adequately investigated and documented. A summary regarding complaints received between July 1, 2010 and December 31, 2010 will be provided as part of our March follow-up. The remaining 18 months will be provided as part of the June follow-up.

Invacare continues to support the FDA's position as stated within the "Practice Hospital Bed Safety" publication that was published in June 2009 that stated that "not all patients are at risk for entrapment, and not all hospital beds pose an entrapment risk" and that "...health care facilities, as well as patient caregivers, are urged to take a careful look at hospital beds. They need to determine if there are large openings that present an entrapment risk" for particular patients and "to take steps to minimize this risk".

Recognizing that manufacturers must provide adequate instructions for use, which may include patient use that may be contraindicated, Invacare has conducted a risk assessment regarding patient size or other factors that may impact a patient's risk of entrapment. A copy of that assessment is enclosed (b) (4) As a result of that assessment, Invacare has developed language specific to "body size" and other conditions where the use of the product may be contraindicated. Enclosed is a copy of the approved

language that will be added to all of Invacare's bed product lines moving forward [redacted] We will make this available on our corporate web site and explore other ways of sharing this information with our existing customers.

Occurrence Prevention / Systemic Corrective Action:
We will review the [redacted] complaint system and identify areas for process improvement including risk assessment or other actions that may be required. As indicated in item 1 above, Invacare is creating a Corporate procedure specific to statistical techniques that will address data sources and define trigger points for other action. Summary of this review will be provided as part of the March follow-up. Specific changes to be made to the [redacted] system and a time line for validation and implementation will be provided as part of the June follow-up. Long term system changes will be reviewed, validated and audited by [redacted] This will be supplied as part of our March follow-up.

In addition we will update the corporate Product Design Input, Risk Assessment and Control plan, form fm04013c, to add "small patient body size" as a specific design consideration. This will provide for consideration of this potential risk as part of any new product development activity. A copy of the revised form will be part of the March follow-up.

Item 5:
Failure to establish adequate procedures for identifying training needs for ensuring that all personnel are trained to adequately perform their assigned responsibilities and for documenting training, as required by 21 CFR 820.25(b).

FDA determined that the adequacy of Invacare's response could not be determined at the time of the issuance of the warning letter. Invacare stated that it was reviewing the training of the current Customer Service Staff and was providing additional training as needed. Additionally, the on-boarding process for new customer service staff was reviewed to ensure that new associates in the future have documented training in place prior to processing calls of this type. These activities were expected to be completed by October 15, 2010; however, Invacare has not provided any evidence of implementation of these corrective actions. FDA also indicated that Invacare failed to review previous complaint history or FDA MDR databases in accordance with Invacare procedures with the intention of identifying possibly related incident and trends.

Response:
The training issue identified involved a Customer Service employee located at the corporate office. While Invacare did complete training of the Customer Service employees, Invacare concurs that those activities were not documented.

Short Term Containment:
Training was completed for all Customer Service Staff. Those training records are enclosed [redacted]

Root Cause Determination:
Employee on-boarding process at the corporate level is poorly defined regarding training requirements and those documentation requirements.

Occurrence Prevention / Systemic Corrective Action:
Identify and implement a web based training system corporate wide with initial focus on customer facing employees. This will ensure that training requirements for new employees are properly identified and that training activities are completed prior to the employee performing the activity. Results of initial solution search and proposed plan will be part of the March follow-up. A specific solution and time line will be provided as part of the June follow-up.
In addition we will conduct a review of previous complaint history and existing FDA databases and provide an update as part of our March follow-up.

Item 6:
Failure to report to the FDA no later than 30 calendar days after the day that you become aware of information, from any source, that reasonably suggests that a device that you market has malfunctioned and this device or a similar device that you market 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). Invacare's response dated September 8, 2010, did not address this charge because it was not on the FDA 483 issued to you at the end of the inspection.

Response:
The FDA's position is that any complaint that contains a "key word", by its very nature regardless of the product involved, suggests that potential and therefore meets the "may cause" element within the regulation. Invacare understands the FDA's position and its justification. As such, going forward Invacare will take "key word" usage into consideration when making MDR decisions.

Related Product / System Containment: Invacare has reviewed the two complaint files referenced in the warning letter, 2850 and 4470, and has filed MDRs. Copies are enclosed (b) (4) Invacare will also review all complaints over the past 2 years which reference a "key word" for an MDR decision that is in line with the "may have caused…" requirement. Invacare will provide a summary report covering complaints received between July 1, 2010 – December 31, 2010 and copies of any MDRs that resulted in filing as part of this review in the February follow-up. We will follow with the remaining 18 months (January 1, 2009 – June 30, 2010) in the March follow-up.

Root Cause Determination: Risk of malfunction is not presumed until confirmed during analysis. Invacare should report based on the claim as received (including any analysis performed within the 30 days of complaint notification) and provide follow up MDRs if additional information or analysis indicates that that the original assessment was inaccurate or incomplete.

Short Term Corrective Action: Review "Adverse Event File Handling and MDR Reporting" (RAWI-14-003) as well as the Complaint Handling and Medical Device Reporting / Vigilance Reporting procedure (CP14-002) and the "Preliminary Product Evaluation" procedure (CP14-011) and update with training as appropriate. Revised procedures will be provided as part of the February follow-up.

Occurrence Prevention / Systemic Corrective Action: 1) Investigate potential to update (b) (4) workflow to identify "critical" or "key word" complaints on entry in a manner that would prioritize complaint review and filing decisions. 2) Review (b) (4) complaint handling process with regard to how risk analysis ties back into the MDR decision and other areas. Summary of initial reviews of these activities will be provided as part of the March follow up. Specific changes identified for the (b) (4) system and a time line for validation and go-live will be provided as part of the June follow-up. Long term system changes will be reviewed and audited by (b) (4)