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To: ~~Arthur~~ DEB
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FEI 1031452
~~FACTS 45038~~
FACTS 64880

September 8, 2010

ERS 9/9/2010

Ms. Emma R. Singleton
District Director
United States Food and Drug Administration
Department of Health and Human Services
District Office
555 Winderly Place, Suite 200
Maitland, FL 32751

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COMPLIANCE

Dear Ms. Singleton,

Please accept this response to the FDA-483 that was issued at the conclusion of a recent inspection of Invacare's Sanford Florida manufacturing (1031452) facility. The inspection was conducted by Mr. Richard K. Vogel and Andrea H. Norwood who are both Investigators from the local FDA district office in Maitland, Florida.

It is important to note that Mr. Vogel advised that a response from Invacare was required within fifteen (15) business days. As such, this response includes actions or direction planned rather than specific actions already documented as in place.

The observations listed within the 483 are summarized below and then followed by Invacare response.

Observation 1:

The observation stated: "Firm failed to take adequate corrective action in response to reports of entrapment involving Invacare medical beds sometimes resulting in death", "failed to implement...to models in the field...design changes implemented in 2007", and that the "Firm fails to take preventative action to ICCI bed systems after its own risk assessments completed in May 2009 and July 2010 indicate an increased risk of entrapment".

Response 1:

The design changes referenced are the same as those referenced in the last inspection of this facility occurring in February of 2009; namely Change Request Numbers 0745051 and 0745055. As reported earlier, these Change Requests were opened in July 2007 in recognition of the CDRH publication "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment" published in March 2006. The document identifies that the guidelines are "Nonbinding Recommendations", "Do not bind the FDA or the public", "do not establish legally enforceable responsibilities" and that the word "should" within the context of the document "means that something is suggested or recommended, but not required". Regardless of these points, Invacare recognized the value of the work and made the business decision that new bed packages or "systems" offered by the firm as bundled, purchasable as single line invoice items would meet those guidelines. These changes were consistent with guidance that was published by the Hospital Bed Safety Workgroup (HBSW) "Clinical Guidance For The Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Setting". Each change is described as follows:

- 0745051- The purpose of the change was to modify the existing full length rail mounting location to ultimately provide that a new Invacare "bed system" as defined within the guidance document, when delivered to a customer and measured with the appropriate evaluation tool would meet the newly established dimensional entrapment guidelines for zones 1-4 prior to being placed into service.
- 0745055- This change was in response to an internal marketing suggestion for product enhancement. The mattress deck, onto which the foam mattress is placed, is constructed of chain link metal that is interconnected. The mattress deck is connected at its circumference to the rigid metal bed frame by means of multiple helical springs. Installation instruction sheets for optional bed rails indicate, by spring

number, where the rail mounting bracket is to be installed on the bed frame rail. This change was to provide a different color spring (black compared to silver) as an extra visual indicator to the installer as to the location where the rail is to be mounted. This was also covered in the instructions for use that was supplied with the rails. Contrary to the observation, the change described was not to correct any design or labeling deficiency or any malfunction. Rather it was to provide a marketing product enhancement that was consistent with the recently published guidelines.

Attached as Exhibit A are copies of Change Request numbers 0745051 and 0745055

In addition, to increase awareness to our customers and users regarding entrapment, Invacare has taken the following actions over several years:

- Starting in 2002, Invacare included copies of a brochure entitled "A Guide to Bed Safety" published by the HBSW in 2002 with our rail and bed products. This was well before the publication from the FDA referenced above;
- Updated IFU's to provide links to the FDA publication and other information regarding entrapment risks;
- Updated our corporate web site to include links to the FDA information;
- Added on-product labeling to our bed rail products highlighting entrapment risks; and
- Published customer educational articles regarding entrapment that were included within Invacare's quarterly customer mailing, "Invacare Update".

These above actions were incremental in nature and were not to correct any identified product defect or malfunction. Several attempts were made to explain the above actions during the audit, however inspector Vogel refused to review any evidence of the above actions or even discuss them. He commented that he was not aware of the CDRH publication "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment" published in March 2006, would not discuss it or even review a copy of the document when Invacare provided it during the inspection.

Both the CDRH and HBSW documents address that not all patients are at risk for entrapment and that evaluation of legacy equipment, including determination regarding its ultimate suitability for any given patient, requires the involvement of the equipment provider as well as those directly involved with patient care. Invacare continues to assert that product in the field, when properly selected, installed, maintained and used is safe and effective for its intended use. As such, Invacare believes that no field action to address legacy product is indicated.

Lastly and contrary to the observational statement, Invacare did not any conduct "risk assessments" in May 2009 or July 2010 "indicating increased risk of entrapment" with versions of Invacare beds.

Moving forward, Invacare continues to examine entrapment risks and is considering adding additional instruction regarding relative body size as it may relate to increased entrapment risk. While there are no contraindications regarding pediatric use of Invacare beds and that proper patient assessment including proper equipment selection would address this concern, we recognize that the FDA published guidelines were based on international anthropometric data for the population at greatest risk for entrapment and that they may not have taken into consideration patients with a body size below the low range of data used as part of their evaluation and subsequent publication. Invacare believes that adding the "Key Body Part Dimensions" as described within the FDA's guidance document to our instructions for use may aid our customers in the evaluation of patients regarding entrapment risk.

Observation 2:

"Complaints involving the possible failure of a device and labeling to meet any of its specifications were not evaluated where necessary." Multiple Invacare complaint investigations were then listed as supporting evidence. These complaints were categorized by the auditor as "Entrapment Issue", "Potential Fire Issue" and "Other Issues".

Response 2:

Invacare agrees that documentation of attempts to gather information should be improved. We are reviewing our current complaint investigation process and are exploring solutions that would document and define "Critical Information" requirements and the attempts to gather this information, whether or not the information is ultimately provided by our customers. We expect to have a documented process in place by October 15, 2010.

It is important to note that many of our customers, including HME providers and care facilities, refuse to provide user/patient details and/or reports due to fear of HIPAA violations or litigation. In light of this reality, Invacare attempts to have product returned for analysis whenever possible. We rely on these evaluations to establish or eliminate device malfunction. When product designed and manufactured by Invacare is identified as malfunctioning, an appropriate risk assessment is conducted. When product is returned and found to function normally to specification, we document the complaint as such. Speculation as to "most likely root cause" is generally not performed. These speculative, "what if" scenarios are part of the risk assessment process that occurs as part of product development activities. If complaint information identifies a malfunction involving a hazard or failure not originally considered then the risk assessment document would be revised to capture the "new" hazard and any resulting mitigating action taken.

Addressing the categories listed by the auditor:

Entrapment –

- Several times the auditor cited "Failure to determine if a patient's size related to a higher risk of entrapment...if the bed's dimensions put a patient at higher risk". As stated in our response to Observation 1 above, Invacare is reviewing the "body size" issue as it relates to entrapment and will update the agency regarding any action taken by October 15, 2010.
- Invacare does not make product recommendations for any given patient. Those decisions are the responsibility of the health care facility and/or medical professionals who are familiar with the patient's unique medical condition and requirements. Invacare's current Home Care instructions for beds contain the following statements:

ACCESSORIES WARNING

Invacare products are specifically designed and manufactured for use in conjunction with Invacare accessories. Accessories designed by other manufacturers have not been tested by Invacare and are not recommended for use with Invacare products.

ENTRAPMENT WARNING

Proper patient assessment and monitoring, and proper maintenance and use of equipment is required to reduce the risk of entrapment. Variations in bed rail dimensions, and mattress thickness, size or density could increase the risk of entrapment. Visit the FDA website at <http://www.fda.gov> to learn about the risks of entrapment. Review "A Guide to Bed Safety", published by the Hospital Bed Safety Workgroup, located at www.invacare.com. Use the link located under each bed rail product entry to access this bed safety guide. Refer to the owner's manuals for beds and rails for additional product and safety information. After any adjustments, repair or service and before use, make sure all attaching hardware is tightened securely. Assist rails with dimensions different from the original equipment supplied or specified by the bed manufacturer may not be interchangeable and may result in entrapment or other injury.

Invacare recognizes the concerns raised regarding the use of non-Invacare products and is examining whether these WARNINGS are communicated consistently by Invacare Continuing Care (ICC) and the Home Care business units and/or if additional statements are required. In response please see observation 3 response below regarding risk assessment.

Potential Fire Issue –

Complaint files 2267, 2837, 2850, 3599, 3660, 3790, 4470, 4894, 4948 and 5208 involved Bariatric beds. The controller for these beds consists of an electronic circuit board imbedded in a solid plastic compound that is used in electronic applications. During production the circuit board is slid into a solid plastic outer case into which a liquid plastic compound is poured. When the liquid cures, the circuit board is completely encased in a solid black plastic. Disassembly for further analysis is not possible.

All of these complaints occurred during initial setup of the bed by the HME provider within the end user's home. Invacare identified the likely cause of these complaints as incorrect connection of the motor cables to the controller during this setup. The connectors on both the motor cables and bed controller are plastic, square

shaped, four conductor types that are purchased as catalog items from a producer of electrical interconnect products. Proper orientation during connection of the cables is provided by geometric features within the plastic contact housing of the connector that provide a keyed, one-way interface between any two mating pairs. While keyed as described, the connectors can be forced to "mate" in the incorrect orientation by ignoring the assembly instructions and physically forcing the connection. Mis-mating of a connector pair results in a short circuit condition when the bed's control pendant is first activated. This short circuit will open a thin conductive copper trace on the circuit board, effectively acting like a fuse, rendering the device inoperative. This condition is likely accompanied by an odor and/or a popping noise as the trace opens. None of the above complaints resulted in any fire or external damage.

Recognizing the 483 finding, Invacare will document a risk assessment specific to this condition and submit it to your office by October 15, 2010.

Invacare has received additional information from the facility regarding complaint 4894 indicating the user was transported to the hospital as a precaution to be "checked out" and that no serious injury occurred. The facility would not provide a copy of any internal reports including medical records or those of the local responding fire department. A copy of Invacare's complaint record is attached as Exhibit B showing the recent update.

The remaining complaints are as follows:

- 4521 - No product defect has been alleged to date. History has shown that bed fires can be the result of user smoking or exposure to a fire unrelated to the product. Invacare is attempting to have the product evaluated by a cause and origin fire expert. Invacare will update the agency when and if that analysis occurs.
- 2598 – Involved an APP pump and pad that Invacare distributes. While failure of the device was confirmed, no external or internal damage of any kind was observed on the returned device. In addition, Invacare has determined that this is an isolated incident. Considering these points we have concluded that further analysis including root cause analysis by the manufacturer is not indicated. We have notified the manufacturer regarding this malfunction and have included a copy of that notification as Exhibit C.
- 2837 – Customer has not returned product as Invacare had previously requested. Nature of complaint suggests misconnection as described above.
- 4352 – Involved a MA85 low air mattress pump that Invacare distributes. Returned device was examined with no external damage present. In addition there is no complaint history regarding this product. Considering these points further root cause analysis by the manufacturer was not deemed necessary. We have notified the manufacturer regarding this device failure and have included a copy of that notification as Exhibit D.

Other Issues:

As indicated above, Invacare agrees that improvement on how investigations are documented especially with regard to information that Invacare requests but is not provided or is denied is desired. However, many complaints involve product that has been in a provider's rental fleet for years, the history of which is unknown, or the provider has little or no information regarding the specific product that was in use. Short of malfunctions that are identified during returned product analysis, hypothesizing on potential root cause in the absence of any specific failure trend or information regarding the product involved does not seem to be indicated.

Observation 3:

Risk analysis is incomplete.

Response 3:

All of the 483 points cited involve entrapment risk. Invacare conducts risk assessment activities as part of the product development process and as part the complaint handling process when malfunctions are identified.

While the guidance documents do not mandate design requirements for manufacturers and are clear in stating that they "may not reduce entrapment in all populations", as described above in response to observation 1,

Invacare has been proactive in addressing bed rail entrapment risks even before the publication of the FDA's guidance document in March 2006.

As the FDA guidance document points out, "not all patients are at risk for entrapment and not all hospital beds pose a risk of entrapment." Invacare continues to assert that vulnerable patients must be identified and assessed regarding their increased potential for rail entrapment and that this assessment must be performed by medical professionals familiar with the unique medical requirements of the patient and that this assessment must be part of the equipment selection process.

However recognizing the questions raised, Invacare will conduct a risk assessment regarding bed rail entrapment with the intent of determining if there are areas of concern that are not currently addressed, such as patient size, or if existing labeling can be augmented in some way. We anticipate that this review will be completed by October 30, 2010.

Observation 4:

- A) (b) (4) Test provided by bed control box supplier "does not substantiate statement by Invacare that because of flame rated potting material there is no risk of fire presented to the user."
- B) Firm's purchasing control for bariatric control (junction) box is inadequate in that only one audit of this supplier was documented in 2001.

Response 4:

- A) Invacare agrees that (b) (4) tested and rated materials are not an assurance that there is "no risk of fire". However, polymeric materials that are able to pass this testing and obtain a (b) (4) rating have a measured reduction in their flammability when exposed to a small open flame or radiant heat source. While Invacare has observed electronic failures of bariatric bed controllers, none of these failures have been confirmed as causing any fire. Properties of this material are attached as Exhibit E. The potential for fire will also be addressed in the risk assessment discussed as part of Response 2 above.
- B) The acceptance of the supplier was in accordance with Invacare's supplier requirements that were in effect at the time of the audit. We had audited the supplier in 1998 and again in 2001. That assessment is attached as Exhibit F. Invacare is unaware of any requirement to audit suppliers annually.

Observation 5:

Design Validation did not ensure the device conforms to defined user needs and intended use. Specifically that Invacare's user / owner manuals are "clear enough to communicate that use of non-Invacare mattresses could lead to higher risk of death of patient via entrapment".

Response 5:

Invacare has not established or stated that use of non-Invacare products could lead to increased entrapment risk. Our position is that Invacare products are specifically designed and manufactured for use in conjunction with Invacare accessories. We have not tested, nor do we plan to test, other manufacturers' products when used with Invacare products. In addition, Invacare cannot attest to the testing performed by other manufacturers on their products when they are used in combination with Invacare products. As such, our statement has been that "Accessories designed by other manufacturers have not been tested by Invacare and are therefore not recommended for use with Invacare products". An example of this statement from our IVC Series Bed User manual is attached as Exhibit G.

Observation 6:

Personnel do not have the necessary training to perform their jobs. Specifically that "training of regulatory affairs personnel, consumer affairs personnel, territory business managers (sales reps) and customer service

personnel fails to assure that they have the knowledge necessary to attempt to obtain all pertinent information from complainants in order to complete adequate investigation of complaint regarding entrapment and potential fire issues related to their medical beds.”

Response 6:

Complaint “investigation” is driven by Regulatory Affairs and Consumer Affairs. As explained to the auditor, the majority of complaints are received by Invacare’s Customer Service phone center. These associates are effectively on the front line regarding complaint intake. As such, these associates are provided documented training as to the nature of complaints and the regulatory requirements for the firm. Given that the Customer Service staff may not all be technically knowledgeable about all of Invacare’s various product lines, our complaint handling procedure (CP14-002) provides that when a customer service representative receives a complaint, they gather whatever information is immediately available, with the primary goal of documenting contact information so a follow up can be made. This information is forwarded to Consumer Affairs via the Consumer Incident Reporting form, fm14002. Consumer Affairs then follows up with the complainant to gather any missing information. Training records for the Customer Service staff and Consumer Affairs were provided during the audit.

Copies of CP14-002, fm14002, Customer Service training records, Consumer Affairs training records and Regulatory Affairs training records are presented again as Exhibits H, I, J, K and L respectively. Sales staff was presented an over view of these requirements in a sales meeting that occurred earlier this year. Copies of the PowerPoint presentation regarding this subject are attached as Exhibit M.

Invacare agrees that training of the sales staff should be documented. As such we will review how new sales associates are “On Boarded” to the organization and how we can improve that training documentation. We anticipate an update regarding this initiative by October 15, 2010.

Observation 7:

Customer Service Training: Training regarding Complaint Handling procedures and requirements was missing for four associates. Training for five associates occurred after they had already taken complaint calls.

Response 7:

As indicated in other sections, the main goal of the Customer Service representative is to document whatever information is immediately available, document contact information so a follow up call can be made and to then forward that information to Consumer Affairs who then will follow up. In the examples cited the associate acted correctly and forwarded the information. No information was lost or mishandled in the process.

Recognizing the observation and the requirement to document training before activities are performed, Invacare will review the training of the current Customer Service staff. Training will be provided as required and documented. In addition, the on-boarding process for new customer service staff will be reviewed to ensure that new associates in the future have documented training in place prior to processing calls of this type. We anticipate these activities will be completed by October 15, 2010.

Observation 8:

MDR Report not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests a marketed device may have caused or contributed to a death or serious injury. Specifically, “Complaint #4234 dated 02/17/10 which references that there was an alleged death of patient and entrapment with Invacare bed between the bottom of the bed rail and the top of the mattress.”

Response 8:

As the observation documents, Invacare’s investigation involved contacting the health care facility. An appropriately responsible person within the facility advised Invacare that they had reviewed the coroner’s report and that the death was attributed to a heart attack and the patient was “entrapped” post mortem. The facility further reported that the rail had not malfunctioned and that the bed was back in service with no issues. Based on this reliable information Invacare’s position continues to be that the bed / rail did not malfunction and that reporting as an MDR was not required. While this is in conflict with observational finding, Invacare filed the

MDR however it was not submitted as a "Malfunction". Attached as Exhibit N is a copy of MDR 1525712-2010-00128

Invacare recently contacted the facility involved with the complaint and again requested a copy of the coroner's report. This request was promptly refused as before. A copy of the complaint investigation record documenting this activity is attached as Exhibit O.

As stated above, Invacare believes that our original reporting decision was in accordance with the requirements of 21 CFR, part 803. If the FDA continues to support the observational finding, Invacare requests that the FDA provide the regulation citation supporting this position.

Observation 9:

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction were to recur. Specifically, "Firm received complaint #4250 dated 02/19/10 which references a patient who was in an Invacare bed who reached down to get something off the floor and when he tried to sit back up he was prevented because his neck was resting under the rail. He did not have enough strength to back away from the bar, staff had to assist him and he allegedly received a neck injury. Firm failed to report a malfunction MDR to the FDA".

Response 9:

This complaint involved an Invacare Continuing Care Arro 171 bed equipped with Assist Rails, referred to as "enabler" rails by the facility. These rails feature the ability to be placed into one of three positions by pulling a release knob and then rotating the rail about a pivot point. The positions are described as follows:

- 1) Transfer - Rail completely rotated up towards headboard of bed to allow for easy transfer into the bed from a wheel chair.
- 2) Assist - Rail rotated up at a 90 degree, vertical angle to provide the user with stability and a handhold as they get into or out of the bed
- 3) Guard - Rail in a horizontal position to provide protection against inadvertently rolling out of bed.

In this complaint, it is stated that the user was reaching to pick something up off the floor. This indicates that the rail was in the "assist" position and the user was in fact sitting on the edge of the bed. When the user went to "sit back up" he was prevented because the back of his neck was hitting the hand hold portion of the rail. This is not consistent with Zone 4 entrapment as illustrated within the FDA's guidance document "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment". As the document illustrates, Zone 4 entrapment involves entrapment of the user's neck between the compressed mattress and the end of the bed rail. This is not what happened in this incident.

As such, Invacare's original position was that the rail in this incident did not malfunction and that no serious injury occurred. Therefore MDR reporting was not required. During the audit the inspector indicated that "you should have filed an MDR". As such, attached as Exhibit P, Invacare has included a copy of MDR 125712-2010-00132. Prior to filing the MDR, Invacare again contacted the facility which confirmed that their characterization of the event was not a malfunction of the product and that the product is still in use with this particular patient.

As stated above, Invacare believes that our original reporting decision was in accordance with the requirements of 21 CFR, part 803. If the FDA continues to support the observational finding, Invacare requests that the FDA provide the regulation citation supporting this position.

Observation 10:

Procedures for corrective and preventative action have not been adequately established. Specifically:

- A) "Firm fails to analyze MDRs, adverse events or product complaints during trend analysis by problem codes such as entrapment or potential fire hazards."

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- B) CAPA CP14-008 Invacare Corporate Corrective and Preventative Procedure does not require all corrective actions be verified and/or validated as effective prior to implementation and that they do not adversely affect the finished device.

Response 10:

- A) Invacare trends complaints of this type during Product Safety Committee meetings which are held on a quarterly basis at a minimum. Historically, Invacare has trended complaints by product type for many years. Invacare currently trends complaints by product categories, product type, MDR type, MDR by product type and root cause code analysis. Due to the highly confidential nature of the trending reports and the potentially prejudicial effect of disclosure under a FOI request, we have not enclosed the data. If appropriate assurances can be given to prevent disclosure of the material, we can discuss ways of allowing review of the data.

The "problem codes" referred to in the observation are codes assigned based entirely on the allegation as initially received by our Customer Service staff. Often times this initial allegation, when followed up on by Consumer Affairs, is not accurate. In addition, analysis of returned product also indicates that the initial allegation was inaccurate or did not occur. For these reasons the trending is based on the items described.

Invacare disagrees with the position that we are not trending complaints. Recognizing the concern, however, we are investigating ways of improving trending of more serious allegations such as entrapment and fire risk. We anticipate having a preliminary trending scheme developed and reviewed at the November 2010, Safety Committee meeting.

- B) As a matter of practice the facility audited does require that all corrective actions be verified and/or validated as effective prior to implementation and that they do not adversely affect the finished device. Reviewing the Florida Operation Procedure BB14-001, "Corrective and Preventative Action" and the corporate procedure CP14-008, "Corporate Corrective and Preventative Action Procedure", Invacare agrees that clarifications to the procedure documents regarding "prior to implementation" and that proposed actions "do not adversely affect the finished device" are appropriate. As such, attached as Exhibit Q are draft revisions of these procedures that will be implemented once training is documented.

Invacare believes the actions taken or planned will address your concerns and demonstrate the firm's commitment to meeting the regulations as a medical device manufacturer / distributor as defined under 21 CFR. If you should have any immediate questions prior to receiving an update, please contact me directly as indicated below.

Regards,



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