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CMS

April 29, 2011

Mr. Ronnie Jackson
Director, Compliance Branch
U.S. Department of Health & Human Services
U.S. Food and Drug Administration
Florida District Office
555 Winderley Place, Suite 200
Maitland, FL 32751

Mr. Salvatore Randazzo
Compliance Officer
U.S. Department of Health & Human Services
U.S. Food and Drug Administration
Florida District Office
555 Winderley Place, Suite 200
Maitland, FL 32751

Dear Messrs. Jackson and Randazzo:

Thank you for taking the time to meet with me and my team on Monday, April 25, 2011. We appreciate your time and feedback concerning our activities to implement systemic corrective actions at Invacare.

As we discussed at the meeting, Invacare is committed to maintaining sustainable compliance with FDA regulations. Since Ms. Flournoy requested at our meeting that Invacare provide FDA with an action plan by mid-May, we are sending her a courtesy copy of this letter. Based upon the conversation, we are evaluating a number of additional initiatives and proposals that are focused on patient safety. Those actions which are summarized below align with our analysis of our adverse events history. We will consider additional actions between now and the submission of a more detailed report to you by May 13, 2011.

Proposed actions are as follows:

1. We are in the process of distributing entrapment guidelines to all Invacare bed customers, and we are exploring other means for communicating the entrapment guidelines to the homecare industry.

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2. We will produce a DVD training on entrapment risk avoidance to be distributed to customers and other interested parties.
3. We will evaluate how Invacare can sponsor entrapment risk seminars and training at homecare industry events and at large national homecare dealer accounts.
4. We will also work on publishing articles in the homecare trade press and trade journals to create more awareness of entrapment risk.
5. We will promote to homecare providers the use of the FDA recommended bed safety entrapment kit for use during configuration and installation of homecare beds.
6. We will follow up on the two specific incidents referred to in our meeting (MDR #2010-00088 and Medwatch #158283722-2011-001) and provide more details concerning those complaint investigations and the relevant results.
7. We will review our procedures for complaint investigation and documentation for complaints that are involved in litigation.
8. As we discussed this week, Invacare's bariatric bed is subject to malfunction due to improper connection of the power plug during installation. This fault condition renders the product inoperable. While there have been no injuries or fires attributable to this condition, we are analyzing potential technical design changes and additional labeling and training to address this issue.
9. Finally, and most significantly, we will conduct a field action to replace legacy Invacare bed rails which conform to the FDA Dimensional Guidelines to Reduce Entrapment, published March 2006. We understand that such an action would be well received by the FDA, and we wish to demonstrate our sincere commitment to taking all reasonably available actions within our control to reduce entrapment risk. It is our expectation that such a field improvement action on the legacy product will not be subject to the Part 806 reporting requirements.

We are completing an analysis of all adverse events involving bed products going back to 2004 which may highlight the need for additional measures which we would include in our mid-May submission. All of the actions described above are in addition to the implementation of the process improvements described in our response(s) to the Warning Letter. We trust that the actions described in this letter, which we intend to discuss in our mid-May report to the Agency are consistent with your requests at our April 25 meeting. We will contact the Agency to confirm our expectations are aligned with those of the FDA. If appropriate, we would welcome the opportunity to meet directly with the Agency to answer any questions about the proposed submission.

We believe there are significant industry challenges to reducing bed rail entrapment risk in homecare due to the complex structure of the homecare market. The bed system installed in the home is configured by a homecare dealer, which owns the components, based upon a patient assessment or in some cases a prescription. Manufacturers like Invacare lack control over the bed products after they are sold into the homecare dealer market. We would invite the opportunity to discuss potential industry wide solutions for minimizing the unique entrapment risks associated with the homecare market.

Sincerely,

Gerald B. Blouch
President and Chief Executive Officer

GBB:djh

cc: Ms. Valerie A. Flournoy
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