



June 10, 2011

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

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 2751

Dear Messrs. Randazzo and Jackson:

As part of Invacare Corporation's ongoing Bed Rail Entrapment Awareness Initiative outlined in our letter of May 13, 2011, we are launching a Bed Rail Exchange Program. The intent of this program is to encourage providers and dealers to upgrade their bed rail inventory with the newest bed rail designs that are compliant with the FDA guidelines when used as a system with Invacare beds and mattresses.

We are also taking this opportunity to educate the population of the dangers of bed rail entrapment and opportunities to reduce the risks of entrapment through proper patient assessment, correct configuration and installation, and ongoing maintenance of the complete bed system.

Enclosed please find a draft Bed Rail Exchange Program Launch Letter, draft Bed Rail Selection Chart, and the Bed Rail Entrapment Risk Notification Guide that will be sent to providers and dealers. The program will be initiated by June 30, 2011. We welcome your input on the enclosed documents before sending to our customers.

In addition to the above and related to our discussion of bariatric bed junction box connector issue occurring during installation, Invacare has made the decision to conduct a Field Action of the affected products. As required, an 806 notification will be submitted to the FDA. A copy of that notification will be sent to you.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Blouch", enclosed within a large, hand-drawn oval.

Gerald B. Blouch  
President & Chief Executive Officer  
440-329-6190  
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cc: Ms. Valerie A. Flournoy  
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