



May 13, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
Attn: Joan Todd
P.O. Box 3002
Rockville, Maryland 20847

RE: Report Number MW5016196

Dear Ms. Todd:

This letter is a follow-up to Invacare's letter submitted to FDA on June 28, 2010 in response to a letter dated June 9, 2010 received from the agency regarding the above-referenced Invacare complaint file.

Your letter requested the following information:

- 1) *Determine the root cause for the entrapment and any contributing factors.*
- 2) *Identify the zone of entrapment (see FDA Guidance on Hospital Bed Entrapment) in which the child was caught. Was any entrapment zone testing performed with the bed as delivered and set-up in the patient's home?*
- 3) *Is there a history of entrapment with this particular rail design? Is the side rail mounted to the bed frame or does it rest between the mattress support platform and mattress? What type of mattress was used with the bed frame and did it meet the specifications for the bed?*

1.) In response to item 1, this incident is the subject of a pending litigation case, and the root cause is still unknown, although our inspection of the bed, rails and cross braces ruled out any defect with the referenced products. According to plaintiff's counsel, the patient's mother disassembled the bed after the accident and placed it in a shed. The mattress was discarded and unavailable for inspection. At the time of Invacare's product inspection, the bed appeared to be in working order. Both rails had a warning label regarding placement of the rails and cross braces. Upon delivery of the product by the home care provider, the family signed paperwork indicating that the family received education on use of the product. Additionally, the (b) (4) was involved with caring for this patient and identified the need for "bumpers" on the bed, which were ultimately provided to the family. The bumpers were in the home at the time of the Invacare inspection, however it is unclear whether the bumpers were used on the bed.

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2.) In response to item 2, the plaintiff (decedent's family) alleges in court filings that the child was caught between the horizontal bars. This describes entrapment zone 1 (within the rail).

3.) In response to item 3, since 2001, Invacare has received two entrapment-related complaints with this particular rail model with average yearly sales of (b) (4) rails of the same model in the same time period. The rail involved in this complaint (Invacare Reduced Gap Full - Length Bed Rail, Product ID: 6629) attaches to two metal cross braces that are secured to the bed frame's mattress deck. Once installed, the mattress is placed on top of the mattress deck (support platform). As noted above, the mattress was discarded and was unavailable for inspection. As such, at this time, mattress type, condition, and suitability for the bed frame is unknown.

If you should have further questions, please contact me as indicated below.

Kind Regards,



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