



December 20, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20852

Re: Comments on Docket Number 2004D-0343; Draft Guidance on Hospital Bed System Dimensional Guidance to Reduce Entrapment

Dear Sir or Madam:

Sunrise Medical Inc., a manufacturer of homecare and extended care medical device products that includes hospital bed systems, respectfully submits these comments to the Food and Drug Administration (FDA) in response to 69 Federal Register Notice 52907 (August 30, 2004) requesting comments on the Agency's draft guidance document *Hospital Bed System Dimensional Guidance to Reduce Entrapment*.

I. Introduction

Sunrise Medical is a manufacturer of hospital bed systems. Along with other industry members, Sunrise has participated in the Hospital Bed Safety Workgroup (HBSW) since its inception to help develop ways to mitigate the risk of bed entrapment. We recognize that the potential for serious patient injuries and death from hospital bed entrapments is a serious public health issue that can be mitigated by:

1. Developing workable dimensional guidance for hospital bed systems that would reduce the risk of patient entrapment; and
2. Providing validated test methods and tools that further complement and support standards such as IEC 60601-2-38, ISO 14971 and others.

To this end, and as HBSW discussions have suggested, it is extremely important for the purpose of the proposed Guidance document that a validated test method and/or tool be available to implement dimensional criteria.

II. Comments

Sunrise is fully aware and mindful that FDA's "marching orders", in their simplest form, constitute ensuring that medical device manufacturers shall design and manufacture devices that are first and foremost safe and effective. The efforts put forth by the HBSW

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Sunrise Medical North American Headquarters
7477 East Dry Creek Parkway
Longmont, Colorado, 80503

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have resulted in meaningful recommendations that could be implemented to mitigate entrapment risk. The collaboration among workgroup members fits nicely with the Corrective and Preventive Action requirement found in FDA's Quality System Regulation. Sunrise considers this a productive "Preventive" action effort.

III. Conclusion

In the interest of time and so as not to repeat what has previously been submitted, Sunrise hereby respectfully submits its support of comments provided by AdvaMed, the Advanced Medical Technology Association, dated December 17, 2004.

Sunrise hopes that these comments will be considered as part of FDA's "Least Burdensome Approach" which provides a process for industry and others to submit comments for addressing issues, in this case, the reduction of hospital bed entrapment.

We appreciate the opportunity to offer comments and look forward helping the Agency in any way we can to address this issue.

Respectfully,

A handwritten signature in black ink that reads "Joseph E. Olsavsky".

Joseph E. Olsavsky
Director - Regulatory Affairs

Sunrise Medical
100 DeVilbiss Drive
Somerset PA 15501