

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

Docket number **2004D-0343**
Draft Guidance for Industry and FDA Staff - Hospital Bed System Dimensional
Guidance to Reduce Entrapment

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We would also like to thank you for the opportunity to comment on the FDA draft guidance for hospital bed system dimensional guidance to reduce entrapment. We understand the intention of the document, to minimize the potential of patient entrapment in a hospital bed. We also feel that the statement will focus too much attention on proactive testing of existing beds with little or no actual risk reduction. Our understanding is that the pilot testing of existing beds has revealed that most of the beds tested will not meet these dimensional limitations. So the extensive time and effort that would be required to determine that our 375 existing hospital beds will not pass is wasted with no risk reduction.

We feel that the FDA should revise the draft to clearly identify existing (legacy) beds as not being inherently unsafe even though they do not meet the new dimensional limits established in the document. The focus on dimensional limits must be on new beds manufactured after the implementation of the document.

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