



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NOV 22 2004

Janet E. Trunzo  
Advanced Medical Technology Association (AdvaMed)  
1200 G Street N.W., Suite 400  
Washington, DC 20005-3814

Re: Docket No. 2004D-0343

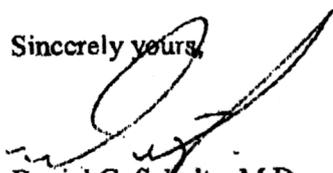
Dear Ms. Trunzo,

This is in response to your request for an extension of the comment period on the draft guidance document entitled "Hospital Bed System Dimensional Guidance to Reduce Entrapment," published in the *Federal Register* of August 30, 2004 (69 FR 52907). You requested an extension of 30 days.

Under 21 CFR 10.115 (g) (5) you can comment on a document at any time. Therefore, an extension of the comment period is not necessary. We established the November 29, 2004, deadline to simplify preparation of a final guidance. If you submit your comments within 30 days as you suggested in your letter, please be assured that we will consider them in the preparation of a final guidance.

FDA is placing a copy of this letter in the docket for this notice of availability. If you have any questions about this letter, please contact Joseph M. Sheehan at 301-827-2974.

Sincerely yours,



Daniel G. Schultz, M.D.  
Director

Center for Devices and Radiological Health