

Jan. 4. 2007 2:26AM

**Mount  
Sinai**

The Mount Sinai Medical Center

One Gu. No. 1594, y Plac. 2  
New York, NY 10029-6574

The Mount Sinai Hospital  
Mount Sinai School of Medicine

Food and Drug Administration  
Central Document Room (CDR)  
5901-B Ammendale Road  
Beltsville, MD 20705-1266  
FAX (301) 827-6870

Re: Docket No. 2005N-0403 and RIN 0910-AA49.

Dear Sir/Madam,

The proposed rule was clearly not written with hematopoietic progenitor cell (HPC) products in mind. Since each HPC product is unique it will require that each transplant program apply to the FDA for an identifying number for each unit of stem cells collected peripherally and from umbilical cords before release.

Due to the biological nature of HPC products, which are typically infused within hours of collection/manufacturing and expiration time is short. In many cases, unrelated HPC products are received from collection centers located not only in different parts of the country but from overseas, and time used for manufacturing is one of the most important factors in preservation of HPC potency. Therefore there is no reasonable opportunity for the collection facility or processing laboratory to attain an identifier code within minutes of collection/receipt 24 hours a day, seven days a week. I am convinced that that the implementation of the NDC system for HPC products would not be in the best interest of the patients.

On the other hand, the ISBT 128 Standard that was voluntarily created to identify and track cells from the time of collection through manufacturing, storage, transport and ultimately patient infusion could be successfully used for HPC products.

Sincerely,



Yelena Sinitsyn, MS  
Supervisor  
Stem Cell lab Mount Sinai MC  
One G.Levy Place Box 1024  
New York, NY 10029  
Phone: 212.241.0001  
Fax: 212.876.5994

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