

October 7, 2003

Division of Dockets Management  
Food And Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

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RE: Docket No. 2003N-0211

To Whom It May Concern:

The following are comments to the proposed "Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma, dated July 30, 2003.

The proposed changes for the length of storage of non-cellular blood components from the current 12 months at -18°C to two years at -25°C or colder and three months at -18°C will present an economic burden for the hospitals that provide these transfusion products.

These expenses include having settings reformatted on freezers used to store the non-cellular blood components. This will be an enormous cost to the industry because these settings can only be adjusted by the manufacturer of the freezers. An additional expense for many hospitals will be purchasing a new freezer that is capable of maintaining -25°C or colder at all times. This type of freezer will cost approximately \$5,000, which will be very cost-prohibitive for many rural hospitals including ours.

It is important realize that if equipment can not be reformatted or new freezers purchased due to the cost burden, rural hospitals will experience a substantial increase in frozen products that will be outdated. This outdated of products also negatively impacts the financial situation in rural hospitals. In an environment where frozen products are not routinely utilized, except for emergency use, the cost burden may be too much to bear and therefore the product would no longer be available. The patients in rural areas need to have non-cellular blood components available to provide the best care for emergency situations, however, the new requirements may be the impetus to removing these life saving products from the rural hospital inventory.

Our goal to provide the best product at the most efficient price available is in conflict with this proposed change. We request that you to consider our statements before changing the storage requirements for FFP and Cryoprecipitate. The quality of care provided by rural hospitals may be significantly impacted, and negatively so.

Sincerely,

James Carle - Laboratory Manager  
Monroe County Hospital  
6580 165<sup>th</sup> St.  
Albia, IA 52531

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