



December 9, 1999

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

8789 '99 DEC 17 89:26

Re: Docket 98N-0673

Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Direct Final Rule and Companion Document to the Direct Final Rule

To Whom It May Concern:

Please accept the following comments relating to Docket 98N-0673, "Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma; Direct Final Rule and Companion Document to the Direct Final Rule". We believe these comments to be substantial and a major departure from current regulations and accepted industry standards.

640.23(a)

The rationale for considering ABO/Rh testing valid for three months in plateletpheresis donors is not clear. Since donors do not change their blood types, the only reason to ever retest the blood type is to confirm that the samples were obtained from the correct donor. If it is not important to do this at each donation, why would it be important to ever repeat it? It would make more sense to state that further typing need not be done once two identical typings were on record. Also, why single out plateletpheresis donors for this exemption?

640.62

The requirement that a physician be physically present within fifteen minutes is unreasonable and unworkable.

- There is no reason to apply a stricter criterion to plasma donors (or any apheresis donors) than for other blood donation. Adverse effects experienced during apheresis donation are less frequent than for whole blood donation and are very unusual.
- Plasma collections are routinely performed at satellite centers and on mobile collection units, making it entirely impractical to have such physician proximity.
- Most establishments have gained some form of variance to this requirement allowing for local hospital agreements or the use of physician substitutes, therefore this statute is not reflective of current industry practice.
- Cardiovascular and other emergencies are much better handled by experienced emergency response teams than by blood establishment physicians.

98N-0673

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If any requirement must be retained, it should permit such collections if a physician or an emergency response team is available within the fifteen minute period. This would be adequate coverage for the patient and is feasible virtually anywhere.

640.4(g)(2)

Allowance should be made for collection of the samples for laboratory testing within 24 hours of the collection of the component in some circumstances. This is particular important for the collection of granulocytes since, for reasons of cell viability, granulocytes must be transfused as soon as possible after collection. If the sample for testing is drawn at the beginning of the collection, cell integrity would be severely compromised if transfusion were delayed for completion of testing (12-24 hours).

640.61

The requirement that donor informed consent be delivered personally by a physician, applicable to Source Plasma, Plasma (640.31(b)), and Platelets (640.21(b)), is unnecessary, unreasonable, and unworkable. There is no reason to single out these types of collection for this requirement. These collections are accomplished in many blood centers at satellite and mobile collection sites, and physicians are not usually present at these sites. Informed consent can be provided by responsible personnel under the guidance of a blood establishment physician, as with all other blood component collections.

Sincerely,

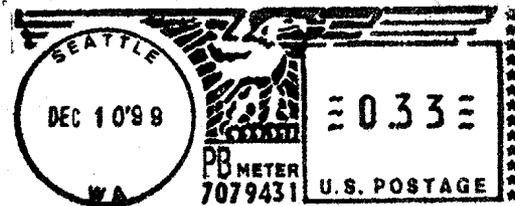


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