

Dating Period For Storage of Red Blood Cells, Frozen (12/4/87)

DATE: December 4, 1987

FROM: Director, Office of Biologics Research and Review

SUBJECT: Extension of Dating Period For Storage of Red Blood
Cells, Frozen

TO: All Registered Blood Establishments

The Office of Biologics Research and Review (OBRR) has evaluated submitted data and has approved storage of Red Blood Cells, Frozen for a maximum of ten years when prepared by certain methods. This extension of dating applies to red blood cells prepared with high glycerol methods (40% glycerol) and stored at -65 degree celsius or lower. Red blood cells already in storage may be stored for ten years if the above requirements are met and appropriate testing for anti-HIV has been performed.

Establishments wishing to extend the dating to ten years should appropriately revise their Standard Operating Procedure(s). For registered establishments, such revisions need not be submitted to OBRR, but should be available for routine inspection. Establishments holding licenses for Red Blood Cells, Frozen are required to submit notification of the change in the dating period. The information submitted should include the method used and samples of any modifications to the label and the circular of information.

Please note that the storage period after thawing has not been changed. Red Blood Cells, Frozen must be used within 24 hours of thawing and deglycerolization.

If there are questions regarding this extension of the dating period for Red Blood Cells, Frozen, please call Mrs. Mary Gustafson, (301)443-5433 or Dr. Joseph Fratantoni (301)496-2577.

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