



# **Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma**

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# Regulation Changes

- Direct Final Rule and Companion Proposed Rule will publish 8/16/07.
- Changes considered to be non-controversial.
- Rule designed to amend regulations to make them more consistent with current practices.
- If no significant adverse comments are received the rule will become effective 2/16/08.

# Platelet Regulation Changes

- 610.53 Dating Periods –Platelets:
  - 72 hours from the time of collection of the source blood, providing labeling recommends storage at 20 to 24° C, between 1 and 6° C, or as specified in the directions for the blood collecting, processing, and storage system approved for such use by the Director, CBER

# Platelet Regulation Changes

- 640.20(b) Source
  - The source material for Platelets is plasma which may be obtained by whole blood collection or by plateletpheresis.
    - “By plasmapheresis” has been removed

# Platelet Regulation Changes

- 640.21 Suitability of donors
  - (b) Plasmapheresis removed.
  - (c) Plateletpheresis donors must meet the criteria for suitability as prescribed in 640.3 and 640.63(c)(6), or as described in an approved biologics license application (BLA) or an approved supplement to a BLA. Informed consent must be obtained as prescribed in 640.61.
    - **Codifies 110 lb weight**
    - **Ensures that registered facilities are held to the same standards as licensed facilities**

# Platelet Regulation Changes

- 640.22 Collection of Source Material
  - (b) Plasmapheresis removed
  - (c) If plateletpheresis is used, the procedure for collection must be as prescribed in 640.62, 640.64 (except paragraph (c)), and 640.65. or as described in an approved biologics license application (BLA) or an approved supplement to a BLA.
    - **Ensures that registered facilities are held to the same standards as licensed facilities**

# Platelet Regulation Changes

- 640.25(b)(2)
  - Amended by changing the requirement for the pH at the end of the storage period to be not less than 6.2.

# Platelet Regulation Changes

- The DFR will be posted tomorrow at the following website:
  - <http://www.fda.gov/cber/blood/bldrule.htm>