

Steps to Consider for Hospitals that wish to transfuse 6 or 7 Day SDP Platelets in Plasma

In order to extend platelet dating past 5 days (6 to 7 days), a hospital must:

1. Be registered with the FDA as a Blood Establishment **and**
2. Test for bacterial contamination using a test designated – i.e., cleared by FDA and labeled – as a “Safety Measure.” Currently only the Verax Platelet PGD Test meets the definition of a “safety measure” test.

A. Blood Establishment Registration

Register with FDA or amend a current registration by completing the online form at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM082389.pdf>

If a problem is encountered with online registration, download and print a paper copy of the registration form. Instructions for completing the form can be found at:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm>

Follow the Instructions for Completing Blood Establishment Registration Form FDA 2830.

1. The Draft Guidance dated December 2014 recommends that “you note you are performing bacterial detection testing on platelet products in the “Other” field in the Products section” of the form.
2. If using a paper copy, the Reporting Official must sign and date the form and send to the address indicated on page 3 of the Instructions.
3. FDA will send the establishment’s reporting official a validated form once the registration has been updated.

Note: If a facility is a licensed establishment, SOPs and labeling must be submitted to FDA for review and approval via a License Amendment.

Direct registration questions to: Blood Registration Coordinator, 240-402-8360 or contact by email at bloodregis@fda.hhs.gov

B. Additional Considerations

1. SDPs must be in plasma and, for now, in a Fresenius (Fenwal) or Terumo manufactured platelet bag.
2. Platelet PGD testing must be performed within 24 hours of transfusion. Note that this is consistent with PGD labeling.
3. Interstate shipment is not allowed but tested platelets may be shipped intrastate.