Blood Products Advisory Committee
May 15-16, 2012

Questions for the Committee

Topic I: Safety and effectiveness of the proposed OraQuick® In-Home HIV Test

1. Do the projected benefits of the OraQuick® In-Home HIV Test outweigh the potential risks of false positive and false negative test results?

2. Do the available data provide reasonable assurance that the OraQuick® In-Home HIV Test is safe and effective for its intended use?

3. Please comment on any risk mitigation strategies that should be considered in addition to the current proposed labeling.

Topic II: Evaluation of Potential New Plasma Products Manufactured Following Storage at Room Temperature for up to 24 Hours

(Note: The questions for the committee contained in the FDA issue summary have been revised as follows.)

1. Do the lower Protein S levels detected in the PF24RT24 products in these studies raise safety concerns for transfusions of single units?

    a. If so, what level of Protein S is of concern?
    b. Does the range of Protein S levels observed in the in vitro studies raise concerns?

2. Do the observed levels of Protein S raise additional safety concerns in the setting of current practice to store thawed plasma for up to 5 days in the refrigerator?

3. Given the potential for thrombotic events in the setting of low protein S levels, should any of the following mitigation strategies be considered?

    a. Product labeling that includes:
        i. the in vitro coagulation factor data from the Sponsor's studies
        ii. contraindications for clinical settings associated with higher risk of thrombosis, such as in neonates, liver failure, and patients requiring massive transfusion?

b. A clinical trial program using a staged approach starting with low risk patients and progressing incrementally to higher risk patients as appropriate?

c. Individual unit assays for Protein S for administration to patients at high risk for thrombosis, e.g. neonates undergoing plasma exchange?

4. Please discuss whether any other of the study findings raises concerns.