QUESTIONS TO THE COMMITTEE

TOPIC I:

1.) Is the kinetic comparison (timed sampling spiking study) an appropriate design of an equivalency demonstration between culture-based and rapid test devices?

2.) What should be the minimum sensitivity in CFU/mL for detection of a contaminated platelet unit at time of release?

3.) FDA proposes three tiers of data requirements respectively to validate a Quality Control indication, an indication for Adjunctive Use as a Release Test; and a scheme appropriate to support clearance of these devices for the stated indications?

TOPIC II:

1.) Do BPAC members agree that bacterial testing of 500 consecutive collections is appropriate for validation of the aseptic process?

    a. If not, what sample size and acceptance criterion does BPAC suggest?

2.) Do BPAC members agree that the information presented on the duration of effect of platelet function inhibition and half-life of the drug, support limiting collection to 5 days from the last dose of aspirin (ASA) or aspirin containing drugs, and 3 days from the last dose of non-steroidal anti-inflammatory drugs (NSAIDS)?

    a. If not, please comment on deferral periods that would be more appropriate.

3.) Do the BPAC members agree that the proposed recommendations on donation frequency, interval between donations, and number of components collected pper year are appropriate to protect the safety of the donor pending the availability of additional safety data on larger annual volumes of collection?

    a. If not, please comment on limits that would be more appropriate.

TOPIC III:

1.) Does the Committee concur with FDA's proposed criteria for test performance (analytical and clinical sensitivity and specificity) for home-use HIV test kits?

2.) Does the Committee concur with FDA's proposal for the Phase II study?

3.) For Phase III studies, which of the options presented does the committee recommend?

QUESTIONS TO THE COMMITTEE (CONT'D)

4.) Does the Committee concur with FDA's proposed content for informational materials provided with home-use HIV test kits and the steps that should be taken to validate the adequacy of those informational materials to communicate or provide pathways to adequately address issues including:

   a. Accuracy of testing
   b. Correct test interpretation
   c. The importance of supplemental testing for confirmation of positive results
   d. Management of psychological and social issues
   e. Medical referral

5.) If the Committee does not concur with any of the proposals in Questions 1-4, what additional information/modification would be needed to support approval of a home-use HIV test kit?