Questions for March 2001 BPAC

Diversion of initial blood collection to a separate bag to decrease bacterial contamination of final blood product.

1. Are the FDA's proposed criteria for the design of the collection system adequate to assure the safe diversion of the initial volume of blood with possible reduction of bacterial contamination?
   The criteria include:
   a) closed system
   b) diverted blood is separated from final blood product by unidirectional flow
   c) volume of diverted blood is sufficient
      i) for all required testing
      ii) to potentially reduce bacterial contamination

2. For products that meet FDA's approval criteria, do the available European studies provide sufficient data to support the claim that diversion of initial 30 cc of blood significantly reduces the bacterial contamination of the final blood product?

3. If the studies are not adequate, what kind of studies performed in the US would be needed for such a claim?