Update Summary
Blood Products Advisory Committee
October 22, 2004

Topic: **Comments to Docket 2004D-0198 re: Draft Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components (April 2004)**

Background

Before each donation, potential blood and plasma donors are asked questions about their medical history and high-risk behavior. These questions help to determine if the donation process will be safe for the donor and if the donated products will be safe for the recipient. FDA has required or recommended that certain information be obtained about donors' health history in our regulations or guidance documents.

Historically, blood centers were responsible for developing their own questions. The first uniform questionnaire was developed by AABB in the 1950s. As the number of infectious diseases and other problems associated with blood transfusions increased, the number of questions and complexity of the questionnaire increased. A multi-organizational task force was formed to evaluate, revise and streamline the AABB uniform donor questionnaire. The FDA is a liaison to this task force. The task force and the FDA discussed the new questionnaire at four BPAC meetings (September 5, 2000, June 14, 2001, June 13, 2002, and December 11, 2003).

The task force submitted the revised questionnaire and accompanying materials (user brochure, medication deferral list and donor education materials) to the FDA for review. The FDA completed the review of the full-length questionnaire and published a draft guidance document recognizing it as an acceptable tool for collecting donor information in order to determine eligibility to donate consistent with FDA requirements and recommendations.

Information to be presented to the BPAC

The purpose of the presentation is to update the BPAC on the status of the guidance document. Specifically, the presenter will:

- ?? Summarize the comments sent to the docket for this guidance
- ?? Describe FDA's current thinking in response to the comments
- ?? Describe FDA's plans to complete and publish a final guidance document

At least nine sets of comments have been submitted to the docket from large and small blood centers, industry organizations, and a vendor for a computer-administered questionnaire. The following is a summary of the four comments that were posted to

docket for viewing at the time this issue summary was prepared. The presenter will include all available comments during the update presentation.

- ?? All respondents appreciated FDA's recognition of the new questionnaire and that it may be self-administered.
- ?? Most respondents appreciated the proposed 21 CFR 601.12 reporting categories for licensed blood establishments implementing the new questionnaire and materials.
- ?? Some wanted FDA to more strongly endorse the new questionnaire.
- ?? Some were concerned that FDA stated it was acceptable for blood establishments to eliminate non-FDA required/recommended questions.
- ?? Most requested an expedited FDA review and acceptance of the task force's abbreviated donor questionnaire.
- ?? Some asked for clarification about using the new questionnaire "without modifications." For example, they wanted to know if a different format could be used to present the information on the materials.
- ?? Many comments were submitted asking about clarifications and revisions of the task force's materials themselves. These comments are not relevant to regulatory considerations and will be forwarded to the task force for their consideration.
- ?? One comment asked that FDA reexamine its rationale for some of the current donor eligibility regulations.

Because the FDA regards this topic as an update item, there will be no charge to the BPAC and no questions presented. However, the committee members will have an opportunity to ask questions of the presenter.