

**HPC, Apheresis and HPC, Marrow Donor History Questionnaire Materials Version 1.6, December 2016
Chart Detailing Changes from version 1.5, March 2016**

Questionnaire	Change	Rationale
Question 15	Removed	Change in FDA recommendations pertaining to certain RCDAD risk exposure from human derived clotting factor concentrates. ¹
Question 27	Removed	Change in FDA recommendations pertaining to certain RCDAD risk exposure from human derived clotting factor concentrates. ¹
Entire Document	Reformatted question numbers	To accommodate the removal of questions 15 and 27.
Flow Chart	Change	Rationale
Question 15	Removed	Change in FDA recommendations pertaining to certain RCDAD risk exposure from human derived clotting factor concentrates. ¹
Question 27	Removed	Change in FDA recommendations pertaining to certain RCDAD risk exposure from human derived clotting factor concentrates. ¹
Entire Document	Reformatted question numbers	To accommodate the removal of questions 15 and 27.
References	Change	Rationale
FDA Guidance Documents	Added: November HCT/P Guidance	Included the citation for FDA guidance “Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates”

¹ Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates dated November 2016. <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm529537.pdf>