CBER Master

Section: CBER ADMIN

Welcome

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Welcome to the CBER eSubmitter Electronic Submission Program for Establishments that Collect Whole Blood and Blood Components, including Source Plasma

This software tool automates the submission process for a Biologics Licensing Application. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses, and to allow us to capture data in a more useful, structured, and complete format. These benefits enable CBER to improve the completeness and structure of the the submissions received and allow for an electronic review process. The questions are designed to guide and instruct users on how to compile a thorough submission based on the code of federal regulations (CFR).

For additional information and guidance, please refer to the **CBER Blood Memorandas**, **CBER Guidances, Guidelines, and Points to Consider**, and **Code of Federal Regulations (CFR) - Biologics Related**.
For questions, please contact **CBER_eSubmitter_Program@fda.hhs.gov**.

Are you submitting an investigational or marketing application?	[L]

What Application Type are you submitting?	[L]

What type of product is being licensed?	[L]

CBER 356h

Section: FORM 356h

Introduction

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 &601)

Form Approved: OMB Number 0910-0338

Expiration Date: September 30, 2008

Applicant Information

Date of Submission (MM/DD/YYYY):	[Date]

Applicant Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Firm Name	
Address	
Telephone Number	
Fax Number	
U.S. license number (if previously issued):	

Authorized U.S. Agent

Authorized U.S. Agent Name & Address (If Applicable)	
Contact Name	
Firm Name	
Address	
Telephone Number	
Fax Number	

Product Description

Note:	Specific areas of this form that are not applicable to your submission will be disabled.

New Drug or Antibiotic Application Number, or Biologics License Application Number (if previously issued):	
Information:	If you are submitting a supplement/amendment to an original application, please enter the 6-digit original STN (e.g., 123456). If you are submitting an amendment to a supplement, please enter the 6-digit original STN followed by a slash and the supplement number (e.g., 123456/1234).

Established Name (e.g., Proper name, USP/USAN name):
Proprietary Name (trade name) if any:
Chemical/Biochemical/Blood Product Name (if any):
Code Name (if any):

Dosage Form:	
Strengths:	
Route of Administration:	

(Proposed) Indication(s) For Use:
[Multi-Line Plain Text]

Application Description

Application Type:	[L]
If NDA, identify the appropriate type:	[L]

Information:	If this submission is an ANDA, or 505(b)(2), identify the reference listed drug product that is the basis for the submission.
Name of Drug:	
Holder of Approved Application:	

Type of Submission:	[L]
If Other, please specify:	

Is this a submission of partial application?	[L]
Provide letter date of agreement to partial submission:	

If a supplement, identify the appropriate category:	[L]

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Reason for Submission:
[Multi-Line Plain Text]

Proposed Marketing Status:	[L]
Number of Volumes Submitted:	

Establishment Information

Note:	By indicating that all of your facilities operate under a previously-approved license number, you will not be requested to fill in the establishment details section for each facility. Otherwise, please proceed to the Establishment Details section to enter high-level information for your facilities. Additional details on a new or previously-approved facility will be captured later in the submission.

Does this submission apply to all facilities operating under a previously-approved license number?	( ) Yes ( ) No

Establishment Details

Item: 1 (could contain up to 1000 items with 1 required)

Establishment Information:	
Firm Name	
Address	
Telephone Number	
Fax Number	
FEI	
CFN	
Registration	
Provide the Drug Master File (DMF) number:	

Provide manufacturing steps and/or type of testing conducted at the site (e.g. Final dosage form, Stability testing).
[Multi-Line Plain Text]

Is the site ready for inspection?		[L]
>	When will the site be ready for inspection (MM/YYYY)?	

Cross References

List all related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application.	
Item 1	
Item 2	

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Item 3	

Application Contents

Note:	This section is intended to constitute a check list that should be used to indicate the types of information contained within a particular submission. The CFR references are provided for most items in order to indicate what type of information should be submitted in each section. For further information, the applicant may consult the guidance documents that are available from the Agency.	
This application contains the following items: (check all that apply)		
1.	Index	[ ]
2.	Labeling	[ ]
>	Select one:	[L]
3.	Summary (21 CFR 314.50(c))	[ ]
4.	Chemistry Section	[ ]
A.	Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)	[ ]
B.	Samples (21 CFR 314.50 (e)(1); 21CFR 601.2 (a)) (Submit only upon FDA's request)	[ ]
C.	Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)	[ ]
5.	Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)	[ ]
6.	Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)	[ ]
7.	Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))	[ ]
8.	Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)	[ ]
9.	Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)	[ ]
10.	Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)	[ ]
11.	Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)	[ ]
12.	Case report forms (e.g., 21 CFR 314.50(f)(2); 21 CFR 601.2)	[ ]
13.	Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))	[ ]
14.	A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))	[ ]
15.	Establishment description (21 CFR Part 600, if applicable)	[ ]
16.	Debarment certification (FD&C Act 306 (k)(1))	[ ]
17.	Field copy certification (21 CFR 314.50 (I)(3))	[ ]
18.	User Fee Cover Sheet (Form FDA 3397)	[ ]
19.	Financial Information (21 CFR Part 54)	[ ]
20.	OTHER...	[ ]
>	If Other, please specify:	

Responsible Official or Agent

Responsible Official or Agent:	
Contact Name	
Occupation Title	
Establishment Name	
Address	
Telephone Number	

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

CBER Annual Report

Section: Annual Report

Annual Report Overview

Licensed establishments must submit an Annual Report including minor changes at the establishment. A complete list of requirements can be found in 21 CFR 601.12(d).

Additional clarification on reporting categories can be found in FDA's Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture.

Enter the Start Date of your reporting period for this annual report submission (MM/DD/YYYY):	[Date]
Enter the End Date of your reporting period for this annual report submission (MM/DD/YYYY):	[Date]

Provide a list of licensed products.	
Licensed Product 1	
Licensed Product 2	
Licensed Product 3	

Attach a list of facilities (including Registration Numbers) and mobile collection vehicles.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach an organizational chart of your establishment.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Have minor changes occurred in the reporting year pertaining to manufacturing, quality control, facilities, and/or responsible personnel?		( ) Yes ( ) No
>	Indicate all area(s) in which changes are being reported in this submission.	
	[ ] Product Manufacturing and Procedural Changes [ ] Pre-existing Antibodies Collection Program(s) Implementation or Discontinuation [ ] Equipment Changes [ ] Contractor Changes [ ] Facility Changes [ ] Other	

Have FDA guidances been implemented in the reporting period for this annual report submission?	( ) Yes ( ) No

Product Manufacturing and Procedural Changes

CBER Annual Report

Indicate which of the following product manufacturing and/or procedural changes are being reported in this submission.
[ ] Donor Suitability and/or Administration of Donor Questionnaires [ ] Blood Collection [ ] Informed Consent [ ] Product Manufacturing [ ] Quarantine and Disposition [ ] Quality Control Methods [ ] Blood Sets [ ] Other

Donor Suitability and/or Administration of Donor Questionnaires

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Blood Collection

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Informed Consent

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Product Manufacturing

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quarantine and Disposition

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control Methods

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Blood Sets

Indicate which of the following changes pertaining to blood sets are being reported in this submission.
[ ] Collection Sets [ ] Leuko-Reduction Filters [ ] Other

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other Product Manufacturing and/or Procedural Changes

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Pre-Existing Antibodies Collection Program Implementation/Discontinuation

Licensed Source Plasma facilities must follow the FDA's Guidance for Industry: Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies.

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Equipment Changes

Indicate which of the following equipment changes are being reported in this submission.
[ ] Automated Apheresis Equipment Software [ ] Equipment/Test Methods [ ] New Equipment

[ ] Other

Automated Apheresis Equipment Software

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Equipment/Test Methods

Indicate the equipment/test method changes that are being reported in this submission:
[ ] Irradiator [ ] Infectious Disease Screening [ ] Total Protein or Protein Electropheresis [ ] Vital Sign and Hgb/Hct Testing [ ] Other

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

New Equipment

Indicate the new equipment that is being reported in this submission:
[ ] Blood Establishment Computer System for Maintaining Donor Data (Must Be 510k Approved) [ ] Automated Equipment for Donor Samples (ABO/Rh, Antibody Screen, Infectious Disease Markers) [ ] Sterile Docking Devices [ ] Other

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other Equipment Changes

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

CBER Annual Report

Contractor Changes

Indicate which of the following contractor changes are being reported in this submission.
[ ] Contract Testing Lab for QC Tests [ ] Temporary Use of Backup Contractor for Manufacturing Steps [ ] Contractor for Blood Collection or QA Activities [ ] Other

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Facility Changes

Indicate which of the following facility changes are being reported in this submission.
[ ] Add/Delete Mobile Collection Vehicle [ ] Change on "DBA" Name [ ] Open/Close/Relocation of Auxiliary Facilities [ ] Other

Provide an explanation of changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other

Provide an explanation of any other changes and attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

FDA Guidances Implemented

List or attach FDA guidances implemented by the firm, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

CBER Amendment

Section: Amendment

1.0 Amendment Responses and Supporting Information

Item: 1 (could contain up to 100 items with 1 required)

Enter the details of your response and/or reason for an amendment to a pending submission.
[Multi-Line Plain Text]

Enter or attach the response and supporting information.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Complete

Package Files for Submission

Information:	Once you have ensured that all required questions are populated and all applicable documents have been attached within the submission, please begin the packaging process of your submission by selecting "Output" > "Package Files for Submission" or clicking the Package icon from the top toolbar. Specific directions for packaging your submission can be found in the eSubmitter User Manual.

BLA Core Questions

Section: Core Questions

Submission Contents

Are you requesting approval for a merger and/or acquisition?	( ) Yes ( ) No

Are you requesting approval for a new comparability protocol?	( ) Yes ( ) No

Are you requesting approval for a manufacturing modification independent of a specific product?	( ) Yes ( ) No
Warning:	If you are requesting approval for a modification that is specific to a product (e.g., Irradiated Red Blood Cells), please select 'No' and then indicate that you are requesting licensure for a product below.
>	Select the applicable manufacturing modfication(s).
	[ ] Irradiation [ ] Leukocyte Reduction

Are you requesting licensure for a product and/or a manufacturing modification?	( ) Yes ( ) No

Are you requesting approval for a process?	( ) Yes ( ) No
>	Select the process(es) for which you are requesting approval.
	[ ] Alternative Procedures [ ] Computer-Assisted Interactive Donor History [ ] Sterile Connecting Devices [ ] Autologous Donations [ ] Other

Are you requesting approval for a revised label of a previously approved product and/or Circular of Information?	( ) Yes ( ) No
>	Select the type of label.
	[ ] Revised Label of a Previously Approved Product [ ] Circular of Information
>	Select the previously approved product(s) for which a revised label is being submitted.

	[ ] Whole Blood [ ] Red Blood Cells (Automated) [ ] Red Blood Cells [ ] Platelets Pheresis [ ] Platelets [ ] Plasma (Automated) [ ] Plasma (includes PF24; Plasma, Cryoprecipitate Reduced) [ ] Fresh Frozen Plasma (Automated) [ ] Fresh Frozen Plasma [ ] Liquid Plasma [ ] Source Leukocytes [ ] Cryoprecipitated AHF [ ] Pooled Cryoprecipitated AHF

Products Included in Blood & Blood Components BLA/BLS

Select the product(s) being applied for under this BLA/BLS submission from the following list of traditional blood and blood component products.
[ ] Source Plasma [ ] Whole Blood [ ] Red Blood Cells [ ] Platelets [ ] Plasma [ ] Fresh Frozen Plasma [ ] Liquid Plasma [ ] Source Leukocytes [ ] Cryoprecipitated AHF

Source Plasma

Is this submission for Source Plasma that is collected every 28 days or less frequently (Infrequent Plasma Program)?	( ) Yes ( ) No

Whole Blood

Select the appropriate description for your submission.
( ) Product Approval Request ( ) Modification for a Previously Approved Product

Select the collection method for the product.
( ) Manual

Select the product(s) to which this submission applies.	
Product 1	
Product 2	

BLA Core Questions

Product 3	

Select the manufacturing modification(s), if applicable.	
Modification 1	
Modification 2	
Modification 3	

Red Blood Cells

Select the appropriate description for your submission.
( ) Product Approval Request ( ) Modification for a Previously Approved Product

Select the collection method for the product.
( ) Manual ( ) Automated

Select the instrument(s) being used for collection.	
Instrument 1	
Instrument 2	
Instrument 3	
Message:	Note: If your instrument is not listed, contact CBER for instructions on properly completing your submission.

Select the product(s) to which this submission applies.	
Product 1	
Product 2	
Product 3	

Do you have a comparability protocol for the Red Blood Cell product(s) selected above and/or manufactured on the indicated instrument?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	
>	Do you have any revised procedures, labels, or information to submit to the FDA for approval?	( ) Yes ( ) No
>	Are you submitting for additional manufacturing facilities under your comparability protocol?	( ) Yes ( ) No

Select the manufacturing modification(s) for this product, if applicable.	
Modification 1	

BLA Core Questions

Modification 2	
Modification 3	

Platelets

Select the appropriate description for your submission.
( ) Product Approval Request ( ) Modification for a Previously Approved Product

Select the collection method for the product.
( ) Manual ( ) Automated

Select the instrument(s) being used for collection.	
Instrument 1	
Instrument 2	
Instrument 3	
Message:	Note: If your instrument is not listed, contact CBER for instructions on properly completing your submission.

Select the product(s) to which this submission applies.	
Product 1	
Product 2	
Product 3	

Do you have a comparability protocol for the Platelet product(s) selected above and/or manufactured on the indicated instrument?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	
>	Do you have any revised procedures, labels, or information to submit to the FDA for approval?	( ) Yes ( ) No
>	Are you submitting for additional manufacturing facilities under your comparability protocol?	( ) Yes ( ) No

Select the manufacturing modification(s) for this product, if applicable.	
Modification 1	
Modification 2	
Modification 3	

Plasma

BLA Core Questions

Select the appropriate description for your submission.
( ) Product Approval Request ( ) Modification for a Previously Approved Product

Select the collection method for the product.
( ) Manual ( ) Automated

Select the instrument(s) being used for collection.	
Instrument 1	
Instrument 2	
Instrument 3	
Message:	Note: If your instrument is not listed, contact CBER for instructions on properly completing your submission.

Select the product(s) to which this submission applies.	
Product 1	
Product 2	
Product 3	

Do you have a comparability protocol for the Plasma product(s) selected above and/or manufactured on the indicated instrument?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	
>	Do you have any revised procedures, labels, or information to submit to the FDA for approval?	( ) Yes ( ) No
>	Are you submitting for additional manufacturing facilities under your comparability protocol?	( ) Yes ( ) No

Select the manufacturing modification(s) for this product, if applicable.	
Modification 1	
Modification 2	
Modification 3	

Fresh Frozen Plasma

Select the appropriate description for your submission.
( ) Product Approval Request ( ) Modification for a Previously Approved Product

BLA Core Questions

Select the collection method for the product.
( ) Manual ( ) Automated

Select the instrument(s) being used for collection.	
Instrument 1	
Instrument 2	
Instrument 3	
Message:	Note: If your instrument is not listed, contact CBER for instructions on properly completing your submission.

Select the product(s) to which this submission applies.	
Product 1	
Product 2	
Product 3	

Do you have a comparability protocol for the Fresh Frozen Plasma product(s) selected above and/or manufactured on the indicated instrument?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	
>	Do you have any revised procedures, labels, or information to submit to the FDA for approval?	( ) Yes ( ) No
>	Are you submitting for additional manufacturing facilities under your comparability protocol?	( ) Yes ( ) No

Select the manufacturing modification(s) for this product, if applicable.	
Modification 1	
Modification 2	
Modification 3	

Liquid Plasma

Select the appropriate description for your submission.
( ) Product Approval Request ( ) Modification for a Previously Approved Product

Select the collection method for the product.
( ) Manual

Select the product(s) to which this submission applies.

BLA Core Questions

Product 1	
Product 2	
Product 3	

Select the manufacturing modification(s) for this product, if applicable.	
Modification 1	
Modification 2	
Modification 3	

Source Leukocytes

Select the appropriate description for your submission.
( ) Product Approval Request ( ) Modification for a Previously Approved Product

Select the collection method for the product.
( ) Manual ( ) Automated

Select the instrument(s) being used for collection.	
Instrument 1	
Instrument 2	
Instrument 3	
Message:	Note: If your instrument is not listed, contact CBER for instructions on properly completing your submission.

Select the product(s) to which this submission applies.	
Product 1	
Product 2	
Product 3	

Cryoprecipitated AHF

Select the product(s) to which this submission applies.	
Product 1	
Product 2	
Product 3	

Is your establishment thawing Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF for transfusion?	( ) Yes ( ) No

BLA Core Questions

Summary of Facility and Establishment Information

Note:	Original applications should include a summary sufficient for the reader to obtain a good general understanding of the data and information in the application. Supplements filed under the requirements of 21 CFR 601.12 do not require a summary; however, a summary in the cover letter is useful. The following core questions are intended to assist you in formulating the submission summary. These questions will ensure that your summary is complete and accurate.

Does your facility utilize an outside test laboratory(ies)?	( ) Yes ( ) No
Is this submission for a new outside test laboratory(ies) ONLY?	( ) Yes ( ) No
Warning:	Note: If you are submitting an application for a new outside test laboratory(ies) ONLY, please answer 'No' to all questions within the "Submission Contents" section to ensure that inapplicable sections are disabled.

Does this submission include a new facility that is requesting licensure to manufacture blood products?	( ) Yes ( ) No
Warning:	For Whole Blood and Blood Products: A new license may require a pre-license inspection by CBER. Please contact your consumer safety officer to schedule the inspection.

Does your establishment utilize an off-site storage facility(ies)?		( ) Yes ( ) No
Does your establishment have a license number for your requested blood product(s)?		( ) Yes ( ) No
>	Will you be utilizing the same SOPs in all of your facilities?	( ) Yes ( ) No ( ) Not Applicable

New Facility

Summary Information for a New Facility

Enter information for the authorized official.	
Contact Name	
Occupation Title	
Email Address	

Enter address of the new facility.	
Establishment Name	

BLA Core Questions

Address	
Telephone Number	
Fax Number	

Enter the registration number.	
Attach a copy of the registration form [FDA 2830], if available.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Enter the date the facility started collecting donors (MM/DD/YYYY).	[Date]

Select the facility's collection programs (select all that apply).	[ ] Injectables [ ] Noninjectables [ ] Research Use Only

Enter collection instrument(s) used at this facility.			
Item	Instrument Type	Number of Instruments	Software Version
Item 1		Item 2	

Is a computer system used at the facility?		( ) Yes ( ) No
>	Enter the name of the software.	
>	Is the software 510(k) cleared?	( ) Yes ( ) No
>	Enter the 510(k) number, if available.	
>	Explain why your software is not 510(k) cleared.	
	[Multi-Line Plain Text]	

Do you have a physician substitute program currently approved?		( ) Yes ( ) No
>	Are you applying for a physician substitute program?	( ) Yes ( ) No

Enter a description of medical oversight at the facility.
[Multi-Line Plain Text]

Enter a description of the quality program.
[Multi-Line Plain Text]

BLA Core Questions

Attach the floor plan of the facility (optional).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Previously-Approved Facility

Summary Information for a Previously-Approved Facility

Is this submission for all facilities?	( ) Yes ( ) No
Note:	If this submission does not apply to all facilities, applicable addresses will be collected at a later point in the submission process.

Enter information for the authorized official. [QUESTION TYPE NOT YET IMPLEMENTED: CONTACT COMPLEX]

Enter the license number.	

Select the intended use(s) of the product (select all that apply).	[ ] Injectables [ ] Noninjectables [ ] Research Use Only

Do you have a physician substitute program currently approved?		( ) Yes ( ) No
>	Are you applying for a physician substitute program?	( ) Yes ( ) No

Facility Addresses

Item: 1 (could contain up to 1000 items with 1 required)

Enter address of the facility.	
Facility Name	
Address	
Telephone Number	
Fax Number	

Enter the registration number.	

Section: Establishment Description

Part I. Organization and Personnel

BLA Core Questions

Description of Manufacturing Organization	
If this is a new or revised application, summarize the general characteristics of the organization. Provide an organizational diagram showing reporting authorities, complete with descriptive job titles. The diagram should be sufficient for someone unfamiliar with your organization to recognize the interrelationships of the major functional units.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Part II. Physical Plant and Major Equipment

Item: 1 (could contain up to 1000 items with 1 required)

Stop:	Do not submit physical plant information with this application. Physical plant information will be reviewed upon inspection for compliance with the CFR [21 CFR 211 & 606] and with cGMP.

Major equipment used in the manufacture of blood and blood components:
[Multi-Line Plain Text]

Include model numbers, version numbers, and number of units for the specified equipment.			
Item	Model Number	Version Number	Number of Units
Item 1		Item 2	

Provide a description of the equipment used and pertinent notes, e.g., special chambers used on apheresis equipment. Attach any supporting documentation, if applicable.	
[Multi-Line Plain Text]	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Part III. Quality Assurance

Note:	Depending on the size and organization of the applicant's manufacturing operation, the make-up of the staff performing these duties can vary greatly and still successfully accomplish the FDA recommended QA functions. Provide a summary of your QA program. The summary need not be extensive, but should address the following topics when applicable to your operations:

Do you have a previously approved quality assurance program?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	

Reporting Responsibility
This section of the quality assurance summary shall include the following: 1. Who performs the quality assurance functions and how these functions are integrated into the manufacturing process. 2. To whom the quality assurance unit (those performing quality assurance functions) reports. 3. The quality assurance unit's position and relationship in the general organizational structure relative to other organizational units.

BLA Core Questions

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Oversight	
This section of the quality assurance summary shall include the facets of the manufacturing process which are included in the quality assurance unit's oversight, such as those directly under the applicant's control, contracted processes, materials and supplies, laboratory testing for tests of record, and laboratory testing for in-process controls.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Authorities	
This section of the quality assurance summary shall include those individuals with the authority to act, to report, or to recommend.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Training and Assessment of Personnel	
This section of the quality assurance summary shall include the quality assurance unit's role in performing or reviewing the training and assessment of personnel in all aspects of the manufacturing process.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Competency Evaluation	
This section of the quality assurance summary shall include the quality assurance unit's activity in performing or reviewing competency evaluations of personnel in all aspects of the manufacturing process.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Proficiency Testing	
This section of the quality assurance summary shall include the quality assurance unit's activity in performing or reviewing proficiency evaluations of personnel in all aspects of the manufacturing process.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Systems Validation
This section of the quality assurance summary shall include the following:

BLA Core Questions

1. The general requirements and/or recommendations for process and computer validation, if applicable. 2. How the quality assurance unit monitors conformance with its validation requirements and/or recommendations.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Problem Investigation and Resolution	
This section of the quality assurance summary shall include the following: 1. The system for collecting problem reports. 2. The approach to problem analysis and trend analysis. 3. The plan to ascertain the effectiveness of implemented changes and corrections.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Audits	
This section of the quality assurance summary shall include the following: 1. The system for designing audits and collecting data. 2. The approach to analyzing audit data. 3. The plan to ascertain the effectiveness of implemented changes and corrections.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Section: Mergers and Acquisitions

Mergers and Acquisitions

Merger	
Note:	A merger of two or more licensed manufacturers results in the formation of a new legal entity which will require the issuance of a new U.S. License. The new U.S. License holder should provide statements which address the following issues: the managerial structure, reporting responsibilities, QA oversight, any changes to the physical plant or equipment and/or manufacturing procedures. Unless the participants in the merger were using matched manufacturing SOP, the information described in the Chemistry Manufacturing and Controls (CMC) section should also be included in the merger submission.

Does this application include a merger?	( ) Yes ( ) No

Attach any files that pertain to the merger, if necessary.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

BLA Core Questions

Acquisition	
Note:	1. An acquisition occurs when one U.S. License holder purchases a facility that was previously operating under a different U.S. License. The license of the previous U.S. License holder will be revised to delete the facility and the license of the U.S. License holder acquiring the facility will be supplemented to include the acquired facility. The U.S. License holder acquiring the facility should include a statement that describes how the new facility will be incorporated into their manufacturing organization. The following issues should be addressed: SOP to be used at new facility, changes in staff or equipment, disposition of product remaining at the facility which was collected under the previous U.S. License, responsibility for donor deferral and look-back procedures for testing done under the previous U.S. License, and any change in contracting facilities (e.g. outside testing laboratory). That is, the supplement sent to FDA would include elements described in both the CMC section and the Establishment Description section. 2. An acquisition may also occur when an applicant who currently holds no U.S. License purchases a facility that was previously operated under a U.S. License, but does not purchase the entire license. The license of the previous U.S. License holder will be revised to delete the facility and the new owner must apply to be licensed as a new applicant. All of the information in this guidance should be included in support of the application. 3. An acquisition may also occur when a new BLA is established by acquiring already established licensed centers.

Does this application include an acquisition?	( ) Yes ( ) No

Attach any files that pertain to the acquisition, if necessary.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

Section: Outside Test Laboratories

Outside Test Laboratories

Item: 1 (could contain up to 1000 items with 1 required)

Has outside test laboratory been previously approved for use in your establishment?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	
>	Would you like to add additional tests for this previously-approved laboratory?	( ) Yes ( ) No

If the outside laboratory has not been previously approved according to the guidelines of the Clinical Laboratory Improvement Act of 1988 (CLIA), please submit the appropriate information below to request approval.	
>	Name and address of laboratory or NAT pooling facility.

BLA Core Questions

	Establishment Name	
	Address	
	Telephone Number	
	Fax Number	

>	Registration number of the laboratory or NAT pooling facility.	

Select any tests or services which this outside test laboratory will be performing.	
Test or Service Performed 1	
Test or Service Performed 2	
Test or Service Performed 3	

Add any additional comments below.
[Multi-Line Plain Text]

Section: Off-Site Storage

Off-Site Storage

Item: 1 (could contain up to 1000 items with 1 required)

Enter the establishment name and address.	
Establishment Name	
Address	
Telephone Number	
Fax Number	

Has this off-site facility been previously approved by the FDA for storage of your products?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	

>	Registration number of the off-site storage facility.	

Does your firm keep a written agreement with the off-site storage facility?	( ) Yes ( ) No

Describe the method of transportation to the off-site storage facility and how proper temperature in maintained during transportation.
[Multi-Line Plain Text]

Section: Debarment Certification

BLA Core Questions

Debarment Certification

Information:	Section 306(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a(k)), as amended by the Generic Drug Enforcement Act of 1992 (GDEA), requires that drug product applicants certify that they did not and will not use in any capacity the services of any debarred persons in connection with a drug product application.

Please sign and attach a debarment certification statement.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Enter any additional information about your debarment certification statement, if necessary.
[Multi-Line Plain Text]

Section: Comparability Protocol

Comparability Protocol

Note:	In addition to the information submitted in a prior approval supplement (PAS), your approval request for a new Comparability Protocol must include the following information.

Attach a description of the planned manufacturing change.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach the implementation plan.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach the criteria for acceptance of product prepared under changed conditions.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach the training program.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach the quality assurance program, including the quality control testing plan.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Would you like to request a reduced reporting category (CBE-30) for particular changes in the Comparability Protocol [21 CFR 601.12(e)]?	( ) Yes ( ) No

BLA Core Questions

Section: Complete

Package Files for Submission

Note:	Once you have ensured that all required questions are populated and all applicable documents have been attached within the submission, please begin the packaging process of your submission by selecting "Output" > "Package Files for Submission" or clicking the Package icon from the top toolbar. Specific directions for packaging your submission can be found in the eSubmitter User Manual.

BLA Source Plasma

Section: Summary

Source Plasma Donor Types

The following is a list of traditional donor types for Source Plasma. Select the applicable donor types being applied for under this BLA/BLS submission.

Normal Donor	( ) Yes ( ) No
Vaccine Immunization Program	( ) Yes ( ) No
Red Blood Cell Immunization Program	( ) Yes ( ) No
Donor with a Pre-Existing Disease-Associated Antibody (IgG only)	( ) Yes ( ) No
Donor in a Disease State with an Antibody (IgG and/or IgM)	( ) Yes ( ) No
Donor with a High-Risk Status	( ) Yes ( ) No
Donor Participating in an IND Study	( ) Yes ( ) No

Donor Type Specifics

Note:	The following section(s) are intended to verify that the summary contains the appropriate information for applicable donor types.

Normal

Enter a detailed explanation of the current request for your facility.
[Multi-Line Plain Text]

Vaccine Immunization Program

Vaccine Immunization Program Summary Details

Enter the approved immunization program(s) you are requesting.	
Item 1	
Item 2	
Item 3	
If Other, enter program.	

BLA Source Plasma

Enter the existing IND program(s) you are requesting.	
Item 1	
Item 2	
Item 3	
If Other, enter program.	

Are you requesting a previously approved program under your license number?	( ) Yes ( ) No
> Enter your FDA-assigned number (STN) for the approval.	

Describe the medical oversight for the program.
[Multi-Line Plain Text]

Are you following a licensed vaccine package insert?	( ) Yes ( ) No

IND Warning

Stop:	If you are not following the package insert immunization schedule, please contact CSO and submit as an IND.

Red Blood Cell Immunization Program

Red Blood Cell Immunization Program Summary Details

Note:	Implementation of a Red Blood Cell Immunization Program or new manufacturing facility will require a pre-license/pre-approval inspection by CBER. Please contact your consumer safety officer to schedule the inspection.

Warning:	If an outside testing facility (contractor) is performing any testing, an outside test lab supplement to the BLA is required.

Whole Blood and/or Red Blood Cell Supply/Collection

Whole Blood and/or Red Blood Cell Supply/Collection for Red Blood Cell Immunization Program

Who supplies/collects Whole Blood and/or Red Blood Cells for the Red Blood Cell Immunization program?	( ) Outside Facility ( ) Submitter

Enter information for each outside facility (not under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which collects/supplys Whole Blood and/or Red Blood Cells for the Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

BLA Source Plasma

Enter information for each in-house facility (operating under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which collects/supplys Whole Blood and/or Red Blood Cells for the Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Are the cells collected from donors who have been tested and qualified according to the FDA memorandum to licensed establishments performing Red Blood Cell immunizations, "Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma Donors" (March 14, 1995)?	( ) Yes ( ) No
>	Explain why this best practice is not followed.
	[Multi-Line Plain Text]

Is the donor's eligibility determined according to FDA regulations and recommendations?	( ) Yes ( ) No
>	Explain why this best practice is not followed.
	[Multi-Line Plain Text]

Are records pertaining to the Whole Blood and/or Red Blood Cell donors readily accessible to the Source Plasma facility in the event of any adverse complication occurring in the recipient of the Red Blood Cell immunogen?	( ) Yes ( ) No
>	Explain why this best practice is not followed.
	[Multi-Line Plain Text]

Glycerolizing/Deglycerolizing, Sterility Testing

Glycerolizing/Deglycerolizing for Red Blood Cell Immunization Program

Who is doing glycerolization and deglycerolization for the Red Blood Cell Immunization program?	( ) Outside Facility ( ) Submitter

Enter information for each outside facility (not under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which performs glycerolization/deglycerolization for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Enter information for each in-house facility (operating under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which performs glycerolization/deglycerolization for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

BLA Source Plasma

Are the glycerolized Red Blood Cells stored at the facility which is performing the glycerolization and deglycerolization?	( ) Yes ( ) No
> Explain why this best practice is not followed.	
[Multi-Line Plain Text]	

How are the glycerolized Red Blood Cells stored?	[ ] Whole Red Blood Cell Units [ ] Pedi-bags [ ] Vials

How is the outside facility preparing the deglycerolized Red Blood Cell aliquots?
[Multi-Line Plain Text]

Is the expiration date of the deglycerolized Red Blood Cells 24 hours?		( ) Yes ( ) No
>	Provide expiration date.	
>	Submit sterility testing for ten (10) lots if you are requesting to extend the expiration date.	
	File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

How is the outside facility supplying deglycerolized Red Blood Cells to your center?	[ ] Pedi-bags [ ] Vials

What are the shipping procedures for the deglycerolized Red Blood Cells?
[Multi-Line Plain Text]

Do you have a previously approved Red Blood Cell Immunization program at another facility under your license number?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	

Sterility Testing for Red Blood Cell Immunization Program

Who is performing sterility testing for the Red Blood Cell Immunization program?	( ) Outside Facility ( ) Submitter

Enter information for each outside facility (not under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which performs sterility testing for Red Blood Cell Immunization program.

Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Enter information for each in-house facility (operating under your license)--including facility name; registration and/or

license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which performs sterility testing for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Qualification and Selection of Donors

Qualification (Pedigreeing) of Red Blood Cell Donors for Red Blood Cell Immunization Program

Who is responsible for pedigreeing Red Blood Cell donors?	( ) Outside Facility ( ) Submitter

Enter information for each outside facility (not under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which performs qualification (pedigreeing) of Red Blood Cell donors for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Enter information for each in-house facility (operating under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which performs qualification (pedigreeing) of Red Blood Cell donors for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Does the facility follow all recommendations contained in the "Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma Donors," (March 14, 1995) memorandum?	( ) Yes ( ) No

>	Explain why this best practice is not followed.
	[Multi-Line Plain Text]

Selection of Source Plasma Donors for Red Blood Cell Immunization Program

Who selects Source Plasma donors to participate in the Red Blood Cell Immunization program?	( ) Outside Facility ( ) Submitter

Enter information for each outside facility (not under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which performs selection of Source Plasma donors for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Enter information for each in-house facility (operating under your license)--including facility name, registration and/or license number ("Reg/Lic No."), and previously-approved FDA-assigned number ("FDA No."), if applicable--which

BLA Source Plasma

performs selection of Source Plasma donors for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Selecting Red Blood Cells for Source Plasma Donors for Red Blood Cell Immunization Program	
Who selects and/or matches Red Blood Cells for Source Plasma donors?	( ) Outside Facility ( ) Submitter

Enter information for each outside facility (not under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which selects Red Blood Cells for Source Plasma donors for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Enter information for each in-house facility (operating under your license)--including facility name; registration and/or license number ("Reg/Lic No."); and previously-approved FDA-assigned number ("FDA No."), if applicable--which selects Red Blood Cells for Source Plasma donors for Red Blood Cell Immunization program.			
Item	Facility Name	Reg./Lic. No.	FDA No.
Item 1		Item 2	

Does the medical director at the facility approve the selection of Red Blood Cells for Source Plasma donors?		( ) Yes ( ) No
>	Explain why this best practice is not followed.	
	[Multi-Line Plain Text]	

Infectious Disease Testing

Item: 1 (could contain up to 100 items with 1 required)

Who is performing the infectious disease testing of the Red Blood Cell donors?		( ) Outside Facility ( ) Submitter
Enter the name of the facility.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	
>	Enter the FDA-approved number of the facility, if applicable.	

Note:	If the testing laboratories have not been previously approved by FDA, please be sure to complete Outside Test Lab section.

BLA Source Plasma

Donor Phenotyping and Antibody Testing

Red Blood Cell and Source Plasma Donor Phenotyping for Red Blood Cell Immunization Program

Who is performing the Red Blood Cell phenotyping and antibody testing of the Red Blood Cell and Source Plasma donors?	( ) Outside Facility ( ) Submitter

Enter the name of the facility.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	
>	Enter the FDA-approved number of the facility, if applicable.	

Enter the antigens for which Red Blood Cell and Source Plasma donors are being tested at the facility.
[Multi-Line Plain Text]

Source Plasma Donor Antibody Tests (Screening, Identification, and Titer) for Red Blood Cell Immunization Program

Regarding antibody testing, are the antibody screen, identification, and titer all performed at the same facility?	( ) Yes ( ) No

Enter the name of the facility that performs all antibody testing.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	
>	Enter the FDA-approved number of the facility, if applicable.	

Enter the name of the facility that performs the antibody screen and identification.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	
>	Enter the FDA-approved number of the facility, if applicable.	

Enter the name of the facility that performs and monitors the antibody titer.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	
>	Enter the FDA-approved number of the facility, if applicable.	

Prescribing and Administering Injections

Prescribing Red Blood Cell Injections for Red Blood Cell Immunization Program

BLA Source Plasma

Who prescribes the Red Blood Cell injections?	( ) Outside Facility ( ) Submitter

Enter the name of the facility.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	
>	Enter the FDA-approved number of the facility, if applicable.	

Is the volume (dose) and schedule (frequency) consistent with FDA guidance?		( ) Yes ( ) No
>	Explain why this best practice is not followed.	
	[Multi-Line Plain Text]	

Red Blood Cell Injection of the Source Plasma Donor for Red Blood Cell Immunization Program

Who injects the Red Blood Cells into the Source Plasma donors?	( ) Outside Facility ( ) Submitter

Enter the name of the facility.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	
>	Enter the FDA-approved number of the facility, if applicable.	

Source Plasma Collection

Item: 1 (could contain up to 100 items with 1 required)

Enter the name of the facility.		
>	Enter the registration number of the facility.	
>	Enter the license number of the facility, if applicable.	

Has the requesting facility requested a variance to collect Source Plasms from donors who have been immunized in the previous 12 months? Note: If the collecting facility can obtain documentation that the immunizing cells were from a pedigree donor, then they do not need a variance.		( ) Yes ( ) No
>	Explain why this best practice is not followed.	
	[Multi-Line Plain Text]	

Does the Source Plasma meet the product standards in the CFR?	( ) Yes

	( ) No
>	Explain why this best practice is not followed.
	[Multi-Line Plain Text]

Donor with a Pre-Existing Disease-Associated Antibody (IgG only)

Donor with a Pre-Existing Disease-Associated Antibody (IgG only) Summary Details

Note:	Programs for the collection of plasma containing IgM antibodies are considered disease state programs and require review and approval as a prior approval supplement, under 21 CFR 601.12(a).

Note:	If the patient is HBV, HCV, and/or HIV positive/reactive, please refer to the "High Risk" Memorandum, linked below.

Guideline for Collection of Blood and Blood Products from Donor with Positive Tests for Infectious Disease Markers ("High-Risk Donors"), 26 October 1989.

Is there a previously submitted disease-associated antibody program at another facility under the license number?		( ) Yes ( ) No
>	If yes, enter the date of submission.	[Date]

Indicate the disease-associated* antibodies that you would like approved in this submission. *HLA, RBC, and Platelet are non-disease associated pre-existing antibodies that may be included in this program.	
Item 1	
Item 2	
Item 3	
If Other, enter antibody.	

Is the SP collected only from otherwise suitable donors who meet all the required/recommended donor suitability criteria that pertain to normal SP donors?		( ) Yes ( ) No
>	Explain why this best practice is not followed.	
	[Multi-Line Plain Text]	

Is the donor informed that his/her plasma is being collected because it contains a specific antibody?		( ) Yes ( ) No
>	Explain why this best practice is not followed.	
	[Multi-Line Plain Text]	

Is the donor informed that the level of his/her antibody will be monitored periodically in order to determine that he/she may continue participating in this program?		( ) Yes ( ) No
>	Explain why this best practice is not followed.	

	[Multi-Line Plain Text]

Is the plasma collected from donors in a convalescent state of the disease, if applicable, and not during acute illness (Note: the primary indicator for this is the presence of IgG antibody)?	( ) Yes ( ) No ( ) Not Applicable
>	Explain why this best practice is not followed.
	[Multi-Line Plain Text]

Is a donor with pre-existing red blood cell antibodies verified to not currently be participating in an immunization program and has not been immunized, either deliberately or by transfusion, within the previous 12 months?	( ) Yes ( ) No ( ) Not Applicable
>	Explain why this best practice is not followed.
	[Multi-Line Plain Text]

Donor in a Disease State with an Antibody (IgG and/or IgM)

Donor in a Disease State with an Antibody (IgG and/or IgM) Summary Details

Note:	Disease state donors are individuals who may have chronic illness, be recovering or be recovered from their illness, but are otherwise in good enough health to allow donation. These donors have been tested and found to possess or lack a specific trait, protein, or antibody. The antibodies can be either IgG or IgM. The plasma collected from these donors is usually used in the manufacture of non-injectable or in-vitro diagnostic products, such as controls for test kits.

Note:	If the patient is HBV, HCV, and/or HIV positive/reactive, please refer to the "High Risk" Memorandum, linked below.
Guideline for Collection of Blood and Blood Products from Donor with Positive Tests for Infectious Disease Markers ("High-Risk Donors"), 26 October 1989.	

Do you have a previously approved disease state wtih an antibody program at another facility under your license number?		( ) Yes ( ) No
>	Enter the FDA-assigned number (STN).	

Select the specific autoimmune disease state conditions with IgG antibodies to be collected.	
Item 1	
Item 2	
Item 3	

>	If Other, enter disease state.	

Select the specific autoimmune disease state conditions with IgM antibodies to be collected.	
Item 1	

Item 2		
Item 3		
>	If Other, enter disease state.	

Select the specific hematologic/oncologic disease state conditions with IgG antibodies to be collected.		
Item 1		
Item 2		
Item 3		
>	If Other, enter disease state.	

Select the specific hematologic/oncologic disease state conditions with IgM antibodies to be collected.		
Item 1		
Item 2		
Item 3		
>	If Other, enter disease state.	

Select the specific infectious disease state conditions with IgG antibodies to be collected.		
Item 1		
Item 2		
Item 3		
>	If Other, enter disease state.	

Select the specific infectious disease state conditions with IgM antibodies to be collected.		
Item 1		
Item 2		
Item 3		
>	If Other, enter disease state.	

Select the specific allergic disease state conditions to be collected.		
Item 1		
Item 2		
Item 3		
>	If Other, enter disease state.	
>	Define specific allergies.	
	[Multi-Line Plain Text]	

What is the rationale for the collection of product from these donors (i.e., describe the desired property in the SP being

harvested)?
[Multi-Line Plain Text]

What is the intended use of the product (e.g., for manufacture into non-injectable products)?
[Multi-Line Plain Text]

Donor with a High-Risk Status

Donor with a High-Risk Status Summary Details

Do you have a previously approved high-risk status program at another facility under your license number?	( ) Yes ( ) No
> Enter the FDA-assigned number (STN).	

List the specific positive marker and disease condition being collected. For example, HIV I/II virus, Hepatitis B virus, Hepatitis C virus, and/or Hepatitis A virus (IgM).
[Multi-Line Plain Text]

If applicable, list the other risk factors being collected. For example, risk factors for HIV-1 infection (donors with certain high risk factors may need to be approved as a variance).
[Multi-Line Plain Text]

List the rationale for the collection.
[Multi-Line Plain Text]

List the intended use of the product (e.g., for manufacture into noninjectable products).
[Multi-Line Plain Text]

Donor Participating in an IND Study

Donor Participating in an IND Study Summary Details

Please submit IND number.	

Describe the rationale for collecting donors under the IND program.
[Multi-Line Plain Text]

Additional Summary Information

Please add any additional comments and summary information.
[Multi-Line Plain Text]

BLA Source Plasma

Section: Labeling

Labeling

Are you submitting new or revised labels as part of the submission?	( ) Yes ( ) No
A previously approved label(s) or Instruction Circular (e.g. "Circular of Information") is being used without change. Provide the FDA-assigned number(s) (STN) to reference the previously approved label(s).	
Item 1	
Item 2	
Item 3	

Part I. Transmittal of Labels and Circulars

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

TRANSMITTAL OF LABELS AND CIRCULARS

Form Approved: OMB Number 0910-0338

Expiration Date: September 30, 2008

CHECK ONE:	( ) Draft ( ) Final (in distribution)

Note:	NOTE: No license may be granted unless this completed submittal form has been received (U.S. Public Health Service Act, Section 351; the Federal Food, Drug, and Cosmetic Act, Section 502; and Title 21 U.S. Code of Federal Regulations, Part 600).

MANUFACTURER NAME AND RETURN ADDRESS	
Establishment Name	
Address	
Registration	

LICENSE NO.	
PRODUCT NAME	
[Multi-Line Plain Text]	

Part II. Labeling Details and Comments

LABELING DETAILS

BLA Source Plasma

LABEL TYPE CODE	[ ] Container
> If OTHER, please specify	

REPLACES PREVIOUS LABEL	
REVIEW AND REVISION NO.	
DATE	[Date]

SUBMISSION REASONS (Check all that apply)	[ ] New Product [ ] New Indication [ ] Other (Specify)
> If OTHER, please specify	

SELECT IF THIS LABELING IS IN SUPPORT OF:	( ) Application ( ) Supplement ( ) Part of an Annual Report
> Associated BLA/PLA No.	

COMMENTS (Include any Manuf. ID number, description or revision no. of label being replaced.)
[Multi-Line Plain Text]

Source Plasma Donor Type Specifics

Note:	The following section(s) are intended to verify that labeling contains the appropriate information for applicable donor types.

Normal

Item: 1 (could contain up to 100 items with 1 required)

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?	( ) Yes

BLA Source Plasma

		( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
	> Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Is the expiration date less than or equal to ten years?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

BLA Source Plasma

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Does this label include an infectious disease test statement?	( ) Yes ( ) No
> Please enter the infectious disease test statement.	
[Multi-Line Plain Text]	
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Does the product test positive for communicable disease agents?	( ) Yes ( ) No
> Is biohazard labeling included?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Vaccine Immunization Program

Item: 1 (could contain up to 100 items with 1 required)

BLA Source Plasma

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Is the expiration date less than or equal to ten years?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label include an infectious disease test statement?	( ) Yes ( ) No
>	Please enter the infectious disease test statement.
	[Multi-Line Plain Text]
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?	( ) Yes ( ) No
>	Is biohazard labeling included? ( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.

BLA Source Plasma

	[Multi-Line Plain Text]

Is the name of the licensed vaccine listed on this label?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Immunization Program

Select the products that you are requesting in this submission:		
>	Whole Blood and/or Red Blood Cells for Further Manufacturing	( ) Yes ( ) No
>	Glycerolized Immunogen Red Blood Cells	( ) Yes ( ) No
>	Aliquots of Deglycerolized Immunogen Red Blood Cells	( ) Yes ( ) No
>	Syringe(s) with Deglycerolized Immunogen Red Blood Cells	( ) Yes ( ) No

Source Plasma Labels

Item: 1 (could contain up to 100 items with 1 required)

Red Blood Cell Immunization Program Labeling Details

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.

	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Is the expiration date less than or equal to ten years?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label include an infectious disease test statement?	( ) Yes ( ) No
>	Please enter the infectious disease test statement.
	[Multi-Line Plain Text]
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?	( ) Yes ( ) No
>	Is biohazard labeling included? ( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is Source Plasma label for immunized plasma included?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on the label.
	[Multi-Line Plain Text]

Is the immunogen Red Blood Cell antigen listed on this label?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the immunogen Red Blood Cell antibody listed on this label?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other Applicable Labels

Whole Blood and/or Red Blood Cells for Further Manufacturing

Do you have a previously-approved label for Whole Blood and/or Red Blood Cells for further manufacturing into immunogen Red Blood Cells?	( ) Yes ( ) No
> Enter the previously-approved FDA-assigned number (STN).	

Is the label for Whole Blood and/or Red Blood Cells for further manufacturing into immunogen Red Blood Cells included?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach label(s) for Whole Blood and/or Red Blood Cells for further manufacturing into immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Glycerolized Red Blood Cells

Do you have a previously-approved label for glycerolized immunogen Red Blood Cells?	( ) Yes ( ) No
> Enter the previously-approved FDA-assigned number (STN).	

Is the label for glycerolized immunogen Red Blood Cells included?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.

	[Multi-Line Plain Text]

Attach label(s) for glycerolized immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Aliquots of Deglycerolized Immunogen Red Blood Cells		
Do you have a previously-approved label for aliquots of deglycerolized immunogen Red Blood Cells?		( ) Yes ( ) No
>	Enter the previously-approved FDA-assigned number (STN).	

Is the label for aliquots of deglycerolized immunogen Red Blood Cells included?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Attach label(s) for aliquots of deglycerolized immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Syringes with Deglycerolized Immunogen Red Blood Cells		
Do you have a previously-approved label for syringes of deglycerolized immunogen Red Blood Cells?		( ) Yes ( ) No
>	Enter the previously-approved FDA-assigned number (STN).	

Will immunogen Red Blood Cells be temporarily stored in syringe (at 1-6C) for a period of time prior to injection? Answering "No" implies Red Blood Cells will be immediately injected.		( ) Yes ( ) No
>	Is the label for the syringe with deglycerolized immunogen Red Blood Cells to be stored at 1-6 C included?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Attach label(s) for syringes of deglycerolized immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor with a Pre-Existing Disease-Associated Antibody (IgG only)

BLA Source Plasma

Item: 1 (could contain up to 100 items with 1 required)

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?	( ) Yes ( ) No
> Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the name and address of the manufacturer on submitted label.

If this label applies to all facilities, enter the establishment (headquarters) address.

Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Source Plasma

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label include an infectious disease test statement?	( ) Yes ( ) No
>	Please enter the infectious disease test statement.
	[Multi-Line Plain Text]
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?	( ) Yes ( ) No
>	Is biohazard labeling included?

		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does this label have a blank space to write in the antibody?	( ) Yes ( ) No

Select the specific antibody label(s) you are submitting.	
Item 1	
Item 2	
Item 3	

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor in a Disease State with an Antibody (IgG and/or IgM)

Item: 1 (could contain up to 100 items with 1 required)

Select the type of product for manufacturing.	( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

BLA Source Plasma

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the storage temperature (set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?		( ) Yes ( ) No
>	Is biohazard labeling included? Note: All IgM antibody products should be labeled as "Biohazard".	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does this label specifically state the disease condition?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor with a High-Risk Status

Item: 1 (could contain up to 100 items with 1 required)

Select the type of product for manufacturing.	( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).
[L]
> Please explain why the appropriate information is not included on this label.

	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name and address of the manufacturer on submitted label.

If this label applies to all facilities, enter the establishment (headquarters) address.

Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Is the expiration date less than or equal to ten years?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the storage temperature (set by consignee).	

Is there space for the total plasma volume or weight?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	

BLA Source Plasma

	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?		( ) Yes ( ) No
>	Does product and sample label include a "Biohazard" legend [610.40(h)(2)(ii)(B)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does this label contain the specific viral marker or risk factor (for example, positive for anti-HIV, reactive for HIV-1 RNA, positive for anti-HCV, reactive for HCV RNA, or reactive for HBsAg)?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Participating in an IND Study

Note:	Please contact your consumer safety officer to determine specific requirements for IND labeling.

Section: Standard Operating Procedures (SOP)

Standard Operating Procedures (SOPs)

Note:	The following sections are intended to ensure that all submissions include appropriate Standard Operating Procedures (SOPs) and supplementary information defined in other FDA documents and FDA regulations. The supporting documentation should demonstrate that the proposed manufacturing is in compliance with the law, the regulations and consistent with FDA guidance and recommendations. Information unchanged from previously approved supplements need not be submitted again. Instead, the information may be referenced by the BLA Supplement identification number. If it contributes to the clarity of the submission, previously submitted information should be included rather than referenced.

Donor Suitability

Are all of your donor suitability SOPs--including high-risk behavior, donor history, and informed consent--previously approved?	( ) Yes ( ) No

Note:	If all SOPs pertaining to donor suitability have not been previously approved, information for these SOPs that require FDA approval will be collected in subsequent sections of the submission process.

If all donor suitability SOPs have been previously approved, enter the FDA-assigned number(s) (STN).	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

High-Risk Behavior

Are all of your high-risk behavior SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved high-risk behavior SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Attach your procedure(s) and form(s) that that require FDA approval for the following:

Donor suitability criteria for Source Plasma donors which determine high-risk behavior.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach high-risk behavior questions / HIV/AIDS information.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

BLA Source Plasma

Donor History

Are all of your donor history SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved donor history SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Are you using an industry-developed Donor History Questionnaire (DHQ) that has been accepted by the FDA in a guidance document?			( ) Yes ( ) No
>	What version number?		
>	What organization?		

Note:	Attach your procedure(s) and form(s) that that require FDA approval for the following:

Procedure to perform donor history assessment of new and repeat donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor History Questionnaire.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Associated donor history forms, if applicable.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Informed Consent

Are all of your informed consent SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved informed consent SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the informed consent SOPs:

A description of the procedure.	( ) Yes

	( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

An explanation of the donation frequency.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Descriptions of the foreseeable risks, including side effects and hazards of solutions/drugs.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

An explanation that the procedure is voluntary.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

An explanation that consent may be withdrawn at any time.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

An explanation that the donor has the right to ask questions.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of the specific risks as described by the instrument manufacturer operator's manual.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of which tests will be performed, including NAT if applicable.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

BLA Source Plasma

If you use the National Donor Deferral Registry (NDDR), an explanation that states that the donor is added to a NDDR if viral test results are positive/reactive.	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of which regulatory or public health agencies will be notified of positive/reactive test results.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of education for "window period" in regard to AIDS testing.* *May be in AIDS information.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

No exculpatory language (e.g., "I relieve Blood Establishment of any and all liability for any injuries sustained as a result of my donation.").	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all informed consent SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Suitability (General)

Are all of your donor suitability SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved high-risk behavior SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Attach your procedure(s) and form(s) that that require FDA approval for the following:

Suitability of new donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Suitability of repeat donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Verification of the identity of the donor.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Determination of deferral status of donors, including but not limited to: national databases, previous deferral at your establishment(s), and deferral at local establishment(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Arm inspection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Acceptable vital signs, total protein, and hemoglobin of new and repeat donors (including acceptable results and method of documentation).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Acceptable weight of donor. Note: Weight must be more than 110 pounds.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Suitability of new donors by physician or physician substitute (if physician substitute program has been previously approved).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other applicable procedures.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Collection

Are all of your donor collection SOPs--including donor identification, arm preparation, venipuncture, product collection, sample collection, and quality control/maintenance--previously approved?	( ) Yes ( ) No
Note:	If all SOPs pertaining to donor collection have not been previously approved, information for these SOPs that require FDA approval will be collected in subsequent sections of the submission process.
If all donor collection SOPs have been previously approved, enter the FDA-assigned number(s) (STN).	

BLA Source Plasma

FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Donor Preparation

Are all of your donor preparation SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved donor preparation SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Attach your procedure(s) and form(s) that that require FDA approval for the following:

Verification of donor identity.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Determination of collection volume.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Preparation of instruments and disposals for collection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Arm Preparation

Are all of your arm preparation SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved arm preparation SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Select which arm preparation methods apply to your SOPs		
>	Two-Step Iodine	( ) Yes ( ) No

>	Soap and Acetone/Alcohol	( ) Yes ( ) No
>	One-Step Gel	( ) Yes ( ) No
>	Chloraprep	( ) Yes ( ) No

Two-Step Iodine	
Note:	Confirm that the following steps are included in your attached SOPs.

Using a sterile swab, scrub area for 30 seconds with 0.7% aqueous scrub solution of iodophor compound (e.g., PVP-iodine or poloxamer-iodine complex). Note: Excess foam may be removed with a sterile swab, but the arm need not be dry before the next step.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included. [Multi-Line Plain Text]

Apply iodophor complex solution (e.g., 10% PVP-iodine (or 2% iodine tincture)). Using a sterile swab, begin at the intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter. Let stand for 30 seconds. Note: This solution contains only 1% free iodine and need not be removed before completing venipuncture.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included. [Multi-Line Plain Text]

If not ready to do venipuncture immediately, cover the area with dry sterile gauze.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included. [Multi-Line Plain Text]

If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included. [Multi-Line Plain Text]

Soap and Acetone/Alcohol	
Note:	Confirm that the following steps are included in your attached SOPs.

Using a sterile swab, scrub vigorously with 15% aqueous (not alcoholic) soap or detergent solution for at least 30 seconds to clean away fat, oils, dirt, skin cells, and other debris.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.

	[Multi-Line Plain Text]

Remove soap and froth with 10% acetone in 70% isopropyl alcohol (one part acetone in nine parts isopropyl alcohol) using a new sterile swab and allow to dry.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apply tincture of iodine (2-3½% in 70% ethyl alcohol). Using a sterile swab, begin at intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter and allow to dry.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Using a sterile swab, remove iodine with 10% acetone in 70% isopropyl alcohol. Allow the solution to dry.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

If not ready to perform venipuncture immediately, cover site with dry sterile gauze.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

One-Step Gel	
Note:	Confirm that the following steps are included in your attached SOPs.

Apply a minimum of 1 mL of One Step Gel directly to the venipuncture site.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Using a sterile applicator and while holding at an approximate 30 degree angle, begin scrubbing in a circular motion over about a 1-inch area directly over the venipuncture site for a minimum of 30 seconds.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

After scrubbing for 30 seconds, use the same applicator to begin at intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Using a second sterile applicator and starting from the center of the 3 inch prepped area (venipuncture site) remove excess gel by moving gradually outward in concentric circles.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Allow site to air dry according to manufacturer's instructions.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Chloraprep	
Note:	Confirm that the following steps are included in your attached SOPs.

Scrub with repeated back-and-forth strokes for at least 30 seconds to completely wet area with antiseptic.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Scrub area should be approximately 2.5 inches square.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Allow to air dry for 30 seconds.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do not blot or wipe away.	( ) Yes

BLA Source Plasma

	( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach arm preparation SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Venipuncture

Are all of your venipuncture SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved venipuncture SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Attach your procedure(s) and form(s) that that require FDA approval for the following:

Venipuncture process.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Product Collection

Are all of your product collection SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved product collection SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Attach your procedure(s) and form(s) that that require FDA approval for the following:

BLA Source Plasma

Operation of apheresis instrument.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor collection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor reactions.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell loss.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sample Collection

Are all of your sample collection SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved sample collection SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following point is included in the sample collection SOPs:

Tubes are labeled before filling and verified against unit and donor.	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach sample collection SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Plasma Processing

Are all of your plasma processing SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved plasma processing SOPs, if applicable.

BLA Source Plasma

FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Attach your procedure(s) and form(s) that that require FDA approval for the following:

Processing of plasma after collection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Temperature and storage of product.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Blood and Blood Component Manufacturing

For licensed products only, attach SOP(s) for the manufacturing steps in product production and in-process control testing for blood and blood components.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Final Disposition

Are all of your final disposition SOPs--including procedures for shipment of plasma, quarantine and disposition of unsuitable products, shipment of inadvertently collected units, lookback donor/product, and donor notification--previously approved?	( ) Yes ( ) No

Note:	If all SOPs pertaining to final disposition have not been previously approved, information for these SOPs that require FDA approval will be collected in subsequent sections of the submission process.

If all final disposition SOPs have been previously approved, enter the FDA-assigned number(s) (STN).	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Shipment of Plasma

Are all of your shipment of plasma SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved shipment of plasma SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

BLA Source Plasma

Attach shipment of plasma SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quarantine and Disposition of Unsuitable Products

Are all of your quarantine and disposition of unsuitable products SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved quarantine and disposition of unsuitable products SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points for quarantine and disposition of unsuitable products are included in the attached SOPs:

Unsuitable products are quarantined in an area separated from components that are released or pending release.	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Units are labeled appropriately.	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Units are disposed of using biohazard precautions.	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach quarantine and disposition of unsuitable products SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Shipment of Inadvertently Collected Units

Are all of your shipment of inadvertently collected units SOPs previously approved? Select Not Applicable if you discard these units.	( ) Yes ( ) No ( ) Not Applicable

BLA Source Plasma

Enter the FDA-assigned number(s) (STN) for any previously approved shipment of inadvertently collected units SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points for shipment of inadvertently collected units are included in the attached SOPs:

Information on how to label inadventently collected units.	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach shipment of inadvertently collected units SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Lookback Donor/Product

Are all of your lookback donor/product SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved lookback donor/product SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Attach lookback donor/product SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Notification

Are all of your donor notification SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved donor notification SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	

BLA Source Plasma

FDA-Assigned Number (STN) 3	

Attach donor notification SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Type Specifics

Note:	The following section(s) are intended to verify that the SOPs contain the appropriate information for applicable donor types.

Vaccine Immunization Programs

Are all of your Vaccine Immunization Program SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved Vaccine Immunization Program SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the Vaccine Immunization Program SOPs:

Donor criteria.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Informed consent for each antigen.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Volume and route of administration.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Interval between injections.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.

	[Multi-Line Plain Text]

Criteria for discontinuation in the program.		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Acceptable titer levels.		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Booster intervals.		( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Attach current package insert of immunization.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach all Vaccine Immunization Program SOPs--including but not limited to donor suitability, donor history forms, and informed consent--that require FDA approval and are different from the Normal Source Plasma collections attached previously.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Immunization Program

Are all of your Red Blood Cell Immunization Program SOPs--including those for sterility testing and immunization of Source Plasma donors--previously approved?		( ) Yes ( ) No
Note:	If all SOPs pertaining to your Red Blood Cell Immunization Program have not been previously approved, information for these SOPs that require FDA approval will be collected in subsequent sections of the submission process.	
If all Red Blood Cell Immunization Program SOPs have been previously approved, enter the FDA-assigned number(s) (STN).		
FDA-Assigned Number (STN) 1		
FDA-Assigned Number (STN) 2		
FDA-Assigned Number (STN) 3		

Red Blood Cells Immunization Program

BLA Source Plasma

Are all of your Red Blood Cells Immunization Program SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved Red Blood Cells Immunization Program SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the Red Blood Cells Immunization Program SOPs:

Do the SOPs include donor suitability per requirements and recommendations applicable to donors of Red Blood Cells for transfusion [21 CFR 640.3]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include a protocol for collection for Whole Blood (including arm preparation)?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs define qualification of Red Blood Cells from a new donor to be considered a pedigreed donor (two-year qualification period), or qualification of Red Blood Cells from a pedigreed donor (one-year qualification period), as outlined in the FDA memorandum to licensed establishments performing Red Blood Cell immunizations, "Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma Donors" (March 14, 1995)?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Which method is used for glycerolizing and deglycerolizing the Red Blood Cells?	[ ] Meryman [ ] Valerie [ ] Other
Enter the method used for glycerolizing and deglycerolizing the Red Blood Cells.	

Are the deglycerolized Red Blood Cells tested for residual glycerol?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do SOPs include quality assurance procedures for all reagents (solutions) used for glycerolizing/deglyerolizing, including manufacturer's name, lot number, and expiration date?	( ) Yes ( ) No

BLA Source Plasma

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include ABO/Rh grouping, Red Blood Cell antibody testing, Red Blood Cells phenotyping for C, D, E, c, e, Kell, FY^a, and any additional antigens?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include a determination step for which a Red Blood Cell donor is selected for the Source Plasma Donor?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include the protocol for preparation of Red Blood Cells, including glycerolizing, thawing, deglycerolizing, aliquoting, and labeling as "For Further Manufacturing"? Details: The specific name of the final container should be provided. Deglycerolizing procedures should include removal of glycerol.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do SOPs include procedures for receipt of Red Blood Cells from contractor(s)?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include the protocol for labeling of immunogen Red Blood Cells?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Red Blood Cells Immunization Program SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sterility Testing

Are all of your sterility testing SOPs previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved sterility testing SOPs, if applicable.

BLA Source Plasma

FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the sterility testing SOPs:

Do the SOPs provide details for the sterility testing requirements? Details: Sterility testing must be performed on samples from one aliquot of deglycerolized RBCs from each lot (unit). One sample is cultured at day eight and the other sample is cultured after the maximun expiration date.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include a statement that sterility testing is needed to support an expiration date greater than 24 hours? Data: Results for sterility tests (as described above) should be submitted from at least 10 lots [All results must be negative].	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do SOPs explain ongoing check of sterility? Details: Must be performed on one aliquot of each lot (as described above); test at day eight must be negative before cells from that lot are injected.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do SOPs explain that the protocol for testing at day eight and at expiration is for 'manual' culturing methods? Note: If firm is using an automated system, they must follow the package insert for reading the results.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Submit sterility testing SOPs--including collecting samples and determining when to release the lot, and managing donors if a positive culture is identified--that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Immunization of Source Plasma Donors

Are all of your immunization of Source Plasma donors SOPs previously approved?	( ) Yes ( ) No

BLA Source Plasma

Enter the FDA-assigned number(s) (STN) for any previously approved immunization of Source Plasma donors SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the immunization of Source Plasma donors SOPs:

Do SOPs state that Source Plasma donors should meet all donor suitability criteria [21 CFR 640.63]? Note: Women should not be immunized unless physiologically or surgically incapable of childbearing.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs state that a physical examination of the donor will be performed by a qualified physician within one week prior to the first immunization?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do SOPs state that the medical director must review the informed consent with the donor and obtain his or her signature?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is the informed consent consistent with the CFR and applicable guidance documents?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs state that the medical director at the facility must approve the selection of the Red Blood Cells for the Source Plasma donor?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs state that the medical director must be on-site at the facility during injection?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs state that a qualified employee, trained by the physician, may administer the Red Blood Cell	( ) Yes

injection?	( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs state that Source Plasma donor selection, scheduling of the immunization, and the immune response including any donor reactions must be evaluated by a qualified physician?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include a list of the factors for which immunization will be attempted? Details: De novo for D only. Pre-existing for C, c, E, e, Kell, etc. Immunization for Lewis, P^1, and Sd^a not allowed.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include the volume of antigen, route of administration, schedule of injections, and intervals for boosters? Details: For De novo D immunization (the only De novo program permitted): maximum 50mL in a four-month period. For pre-existing RBC antibodies: maximum of 4mL up to five times/month, not to exceed 40mL in a six-month period.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs include criteria for evaluating the recipient's response and the titer levels for continuation in the program, as well as eligibility for participation in other plasmapheresis programs? Note: If not responding after 150mL of Red Blood Cells, discontinue in the program. Participation in a Red Blood Cell Immunization program does not necesarily exclude the donor from ever being a normal Source Plasma donor. Source Plasma donors who have been Red Blood Cell immunized are allowed to donate non-injectable products without waiting 12 months. Also, De novo donors that don't respond, pre-existing donors without a suitable titer, and excess plasma may be used.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is a record of the development of unexpected Red Blood Cell antibodies elicited by Red Blood Cell immunization on file at the facility?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach immunization records for five (5) donors who have been successfully immunized.

BLA Source Plasma

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach all immunization of Source Plasma donors SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor with a Pre-Existing Disease-Associated Antibody (IgG only)

Are all of the Donors with a Pre-Existing Disease-Associated Antibody (IgG only) SOPs previously submitted?	( ) Yes ( ) No

If yes, enter the date of submission for any previously approved Donor with a Pre-Existing Disease-Associated Antibody (IgG only) SOPs, if applicable.	
Item 1	
Item 2	
Item 3	

Attach all Donor with a Pre-Existing Disease-Associated Antibody (IgG only) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor in a Disease State with an Antibody (IgG and/or IgM)

Are all of your Donor in a Disease State with an Antibody (IgG and/or IgM) SOPs and informed consent forms previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved Donor in a Disease State with an Antibody (IgG and/or IgM) SOPs and informed consent forms, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the Donor in a Disease State with an Antibody (IgG and/or IgM) SOPs:

Donor suitability criteria for a normal Source Plasma donor, with applicable exceptions.		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

A statement that written approval from the donor's personal physician is necessary for participation in the program.	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the determination for the volume and frequency of collection (not to exceed those permitted for normal Source Plasma donors) must be made by the donor's personal physician.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the donor must be evaluated by the center physician before each donation.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that annual medical clearance by the donor's personal physician is necessary to continue in the program.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of any situations where additional evaluation and subsequent examination/approval by the donor's personal physician is necessary.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of laboratory tests used to monitor donor suitability and disease state condition.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of management of a donor reaction emergency, including recognition of reactions specific for each disease state.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Procedures to ensure donor safety during sample and plasma collection.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Criteria for discontinuing the donor in the program.	( ) Yes

	( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Handling, labeling, segregation, storage, and shipping of the products.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirmation of the zygosity of a donor, if applicable. Note: Hereditary Resistance to Activated Protein C has only been approved for heterozygous donors.	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Evaluation of the donor for deep vein thrombosis reactions, if applicable.	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach Donors in a Disease State with an Antibody (IgG and/or IgM) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Informed Consent Specific for Each Disease State	
Note:	Confirm that the following points are included in the Donor in a Disease State with an Antibody (IgG and/or IgM) informed consent form(s):

A description of the procedure and any reasonable risks and discomforts.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A description of additional reactions that may be possible because of the disease state.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the donor's plasma is being collected because it contains a specific property (antibody,	( ) Yes

trait, or protein) and that the level of this property will be monitored periodically in order to determine if the donor may continue in the program.	( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the plasmapheresis procedure may exacerbate the disease (or cause a rebound in the antibody level, if applicable) and long-term effects of repeated plasmapheresis are unknown.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the donor's personal physician has approved his or her participation in the program.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Donor in a Disease State with an Antibody (IgG and/or IgM) informed consent documentation that requires FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor with a High-Risk Status

Are all of your Donor with a High-Risk Status SOPs and informed consent forms previously approved?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved Donor with a High-Risk Status SOPs and informed consent forms, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the Donor with a High-Risk Status SOPs:

Donor suitability criteria for a normal Source Plasma donor, with applicable exceptions.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that written approval from the donor's personal physician for the volume of collection is necessary for participation in the program.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.

	[Multi-Line Plain Text]

A statement that plasmapheresis is limited to once per week. Note: Frequency may be increased to twice per week with written approval from a donor's personal physician.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the donor must have a monthly medical evaluation, including a physical examination, by a center physician. Note: This responsibility may not be delegated to any other person, e.g., physician substitute.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the donor must have serum protein electrophoresis initially and every two months. Note: Abnormal results requires the written approval for donation from a donor's personal physician.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that for HBsAg reactive, anti-HBc and HCV positive donors, ALT measurement is required initially and every month. Note: If ALT levels exceed two times the upper limits of normal values, the donor must be deferred until acceptable level occurs and a center physician reinstates the donor. Anti-HBc is only included in HR program if the donor does not meet normal suitability requirements and/or the donor does NOT also have anti-HBs.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that medical clearance is required annually from the donor's personal physician in order to continue in the program.	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that donor screening and processing should met Biosafety level 2 (BSL-2) requirements.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Donors with a High-Risk Status SOPs that require FDA approval.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Informed Consent for Donor with a High-Risk Status	
Note:	Confirm that the following points are included in the Donor with a High-Risk Status informed consent form(s):

A description of the procedure and any reasonable risks and discomforts.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the donor's plasma is being collected because it contains a specific property and the level of this property will be monitored periodically in order to determine if the donor may continue in the program.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the plasmapheresis procedure may exacerbate the disease (or cause a rebound in the antibody level, if applicable), and long-term effects of repeated plasmapheresis are unknown.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

A statement that the donor's personal physician has approved his or her participation in the program.	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach Donors with a High-Risk Status informed consent documentation that requires FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Participating in an IND Study

Attach all Donors Participating in an IND Study SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Physician Substitute

Are all of your Physician Substitute SOPs previously approved?	( ) Yes ( ) No

BLA Source Plasma

Enter the FDA-assigned number(s) (STN) for any previously approved Physician Substitute SOPs, if applicable.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Note:	Confirm that the following points are included in the Physician Substitute SOPs:

Do the SOPs state that physician substitutes must be graduates of recognized educational programs such as nursing, emergency technician, or physician assistant?	( ) Yes ( ) No
>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Do the SOPs state that the physician substitutes must be currently licensed and/or certified in the state?	( ) Yes ( ) No
>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Do the SOPs state that the physician substitutes must maintain current certification in CPR?	( ) Yes ( ) No
>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Do the SOPs describe the physician substitute training program?	( ) Yes ( ) No
>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Do the SOPs state that the physician responsible for training the physician substitute must evaluate the individual's performance after completion of training?	( ) Yes ( ) No
>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Submit a copy of the training program.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Submit a copy of the physician's evaluations, along with the physician substitutes' CVs, licenses and/or certificates, and a signed statement of understanding covering everything with which they will be involved.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Does the physician substitute's description of duties define limits of authority and provide specific instructions concerning handling of medical emergencies and consulting the medical director or plasma center physician?	( ) Yes ( ) No

>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Are the physician substitutes' responsibilities limited to prohibit involvement in TEP programs, HBsAg and/or HIV positive donor programs, and/or Red Blood Cell Immunization programs?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Attach all Physician Substitute program SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Submit a list of the physician substitute's involvement with any immunization programs, if applicable. Note: The physician substitute should have at least one additional week of training for each immunization program he/she is supervising. This training should include immunogen administration, hazards, and reactions.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Does the center physician perform weekly reviews of the donor immunization records and approve the schedule of injections?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate requirement is not followed.
	[Multi-Line Plain Text]

Section: Complete

Package Files for Submission

Stop:	Once you have ensured that all required questions are populated and all applicable documents have been attached within the submission, please begin the packaging process of your submission by selecting "Output" > "Package Files for Submission" or clicking the Package icon from the top toolbar. Specific directions for packaging your submission can be found in the eSubmitter User Manual.

Apheresis Main

Section: SOPs - General (Automated)

Standard Operating Procedures (SOPs)

Note:	The following sections are intended to ensure that all submissions include appropriate Standard Operating Procedures (SOPs) and supplementary information defined in other FDA documents and FDA regulations. The supporting documentation should demonstrate that the proposed manufacturing is in compliance with the law, the regulations and consistent with FDA guidance and recommendations. Unchanged information or unrevised SOPs from previously approved supplements need not be submitted again. Instead, the information may be referenced by the BLA Supplement identification number. If it contributes to the clarity of the submission, previously submitted information should be included rather than referenced.

Donor Suitability SOPs

Have all of your donor suitability SOPs--including high-risk behavior, donor history, informed consent, and Red Blood Cell loss--been previously approved by the FDA?	( ) Yes ( ) No

Select the Donor Suitability SOPs that are being submitted for approval by the FDA.
[ ] High-Risk Behavior SOPs & HIV/AIDS Information Sheets [ ] Donor History SOPs [ ] Informed Consent SOPs [ ] Donor Suitability (General) SOPs [ ] Red Blood Cell Loss (Donor Eligibility) SOPs [ ] Red Blood Cell Loss (Incomplete Procedures) SOPs

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Donor Suitability SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

High-Risk Behavior SOPs & HIV/AIDS Information Sheets

Attach High-Risk Behavior SOPs and HIV/AIDS information Sheets that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor History SOPs

Is the AABB Donor History Questionnaire (DHQ) being used at the facility?		( ) Yes ( ) No
>	Has the version of the DHQ being used been accepted by the FDA in a guidance document?	( ) Yes ( ) No

Apheresis Main

>	What version number is being used?	
>	What organization?	

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Procedure to perform donor history assessment of new and repeat donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor History Questionnaire.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Associated donor history forms, if applicable.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Informed Consent SOPs

Confirm that the following details are included in the Informed Consent SOPs:
[ ] A description of the procedure. [ ] An explanation of the donation frequency. [ ] Descriptions of the foreseeable risks, including side effects and hazards of solutions/drugs. [ ] An explanation that the procedure is voluntary. [ ] An explanation that consent may be withdrawn at any time. [ ] An explanation that the donor has the right to ask questions. [ ] A description of the specific risks as described by the instrument manufacturer [ ] A description of which tests will be performed. [ ] A description of which regulatory or public health agencies will be notified of positive/reactive test results. [ ] No exculpatory language (e.g., "I relieve Blood Establishment of any and all liability for any injuries sustained as a result of my donation.").

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Warning:	Do not attach the Apheresis Informed Consent form in this section. Specifics of this form will be addressed in the Informed Consent section of the submission.

Attach all informed consent SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Suitability (General) SOPs

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Apheresis Main

Suitability of new donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Suitability of repeat donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Verification of the identity of the donor.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Determination of deferral status of donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Arm inspection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Acceptable vital signs and hemoglobin of new and repeat donors (including acceptable results and method of documentation).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Acceptable weight of donor. (Weight must be more than 110 pounds).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other applicable procedures.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Loss (Donor Eligibility) SOPs

Confirm that the following details are included in the Red Blood Cell Loss (Donor Eligibility) SOPs.	
[ ] A deferral of eight weeks if a donor experiences a Red Blood Cell loss while donating a single unit of Red Blood Cells including platelets and/or plasma. [ ] A donor is allowed to donate platelets or plasma within eight weeks of a single unit of Red Blood Cell donation if the extracorporeal loss is less than 100 mL. [ ] A deferral of 16 weeks if a donor experiences a Red Blood Cell loss while donating a double unit of Red Blood Cells.	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apheresis Main

Attach all Red Blood Cell loss (donor eligibility) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Loss (Incomplete Procedures) SOPs

Are the donor deferral guidelines set forth in the table below included in the SOPs?	( ) Yes ( ) No

Red Blood Cell Loss, Incomplete Procedures

Donor's Initial Packed Red Blood Cell Loss	Donor's Second Packed Red Blood Cell Loss Within Eight Weeks	Eligibility
Less than 200 mL	No donation, or total from initial and second loss less than 200 mL	No deferral of donor for packed Red Blood Cell loss; frequency of donation of Platelets Pheresis as discussed in section III.B.2
More than 200 mL but less than 300 mL total	Donor is not eligible to donate for eight weeks from second loss	Total loss from initial and second loss of more than 300 mL
Donor is not eligible to donate for sixteen weeks from second loss	More than 200 mL but less than 300 mL	N/A
Donor is not eligible to donate for eight weeks from initial loss	Greater than or equal to 300 mL	N/A

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Red Blood Cell Loss (Incomplete Procedures) SOPs and forms that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Collection SOPs

Have all of your donor collection SOPs--including donor preparation, arm preparation, venipuncture, product collection, and sample collection--been previously approved by the FDA?	( ) Yes ( ) No

Select the Donor Collection SOPs that are being submitted for approval by the FDA.

Apheresis Main

[ ] Donor Preparation SOPs [ ] Arm Preparation SOPs [ ] Venipuncture SOPs [ ] Product Collection SOPs [ ] Sample Collection SOPs
Information: An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Donor Collection SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Donor Preparation SOPs

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Verification of donor identity.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Determination of product collection parameters.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Preparation of instruments and disposals for collection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Arm Preparation SOPs

Select which arm preparation methods apply to the SOPs
[ ] Two-Step Iodine [ ] Soap and Acetone/Alcohol [ ] One-Step Gel [ ] Chloraprep

Two-Step Iodine
Confirm that the following steps are included in the attached SOPs.
[ ] Step 1: Using a sterile swab, scrub area for 30 seconds with 0.7% aqueous scrub solution of iodophor compound (e.g., PVP-iodine or poloxamer-iodine complex). Note: Excess foam may be removed with a sterile swab, but the arm need not be dry before the next step.

[ ] Step 2: Apply iodophor complex solution (e.g., 10% PVP-iodine (or 2% iodine tincture)). Using a sterile swab, begin at the intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter. Let stand for 30 seconds. Note: This solution contains only 1% free iodine and need not be removed before completing venipuncture.

[ ] Step 3: If not ready to do venipuncture immediately, cover the area with dry sterile gauze.

[ ] Step 4: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Soap and Acetone/Alcohol

Confirm that the following steps are included in the attached SOPs.

[ ] Step 1: Using a sterile swab, scrub vigorously with 15% aqueous (not alcoholic) soap or detergent solution for at least 30 seconds to clean away fat, oils, dirt, skin cells, and other debris.

[ ] Step 2: Remove soap and froth with 10% acetone in 70% isopropyl alcohol (one part acetone in nine parts isopropyl alcohol) using a new sterile swab and allow to dry.

[ ] Step 3: Apply tincture of iodine (2-3½% in 70% ethyl alcohol). Using a sterile swab, begin at intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter and allow to dry.

[ ] Step 4: Using a sterile swab, remove iodine with 10% acetone in 70% isopropyl alcohol. Allow the solution to dry.

[ ] Step 5: If not ready to perform venipuncture immediately, cover site with dry sterile gauze.

[ ] Step 6: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

One-Step Gel

Confirm that the following steps are included in the attached SOPs.

[ ] Step 1: Apply a minimum of 1 mL of One Step Gel directly to the venipuncture site.

[ ] Step 2: Using a sterile applicator and while holding at an approximate 30 degree angle, begin scrubbing in a circular motion over about a 1-inch area directly over the venipuncture site for a minimum of 30 seconds.

[ ] Step 3: After scrubbing for 30 seconds, use the same applicator to begin at intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter.

[ ] Step 4: Using a second sterile applicator and starting from the center of the 3 inch prepped area (venipuncture site) remove excess gel by moving gradually outward in concentric circles.

[ ] Step 5: Allow site to air dry according to manufacturer's instructions.

[ ] Step 6: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Chloraprep

Confirm that the following steps are included in the attached SOPs.

[ ] Step 1: Scrub with repeated back-and-forth strokes for at least 30 seconds to completely wet area with antiseptic.

[ ] Step 2: Scrub area should be approximately 2.5 inches square.

[ ] Step 3: Allow to air dry for 30 seconds.

[ ] Step 4: Do not blot or wipe away. [ ] Step 5: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach arm preparation SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Venipuncture SOPs

Attach Venipuncture SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Product Collection SOPs

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Operation of apheresis instrument.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Product collection, including steps to remove products from instrument(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor reactions.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell loss documentation and deferrals.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sample Collection SOPs

Confirm that the following detail is included in the Sample Collection SOPs:	
[ ] Tubes are labeled before filling and verified against unit and donor.	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apheresis Main

Attach Sample Collection SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Final Disposition SOPs

Have all of your final disposition SOPs--including distribution and shipping of blood and blood components, and quarantine and disposition of unsuitable products--been previously approved by the FDA?	( ) Yes ( ) No

Select the Final Disposition SOPs that are being submitted for approval by the FDA.	
[ ] Disposition and Shipping of Blood and Blood Products SOPs [ ] Quarantine and Disposition of Unsuitable Products SOPs	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Final Disposition SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Distribution and Shipping of Blood and Blood Components SOPs

Attach distribution and shipping of blood and blood components SOPs that require FDA approval. (Note: Shipping procedures should include instructions for temperature monitoring).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quarantine and Disposition of Unsuitable Products SOPs

Confirm that the following details are included in the Quarantine and Disposition of Unsuitable Products SOPs.	
[ ] Unsuitable products are quarantined in an area separated from components that are released or pending release. [ ] Units are labeled appropriately (e.g., not for transfusion, biohazard, etc.). [ ] Units are disposed of using biohazard precautions.	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach Quarantine and Disposition of Unsuitable Products SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Misc SOPs

Apheresis Main

The unit has been centrifuged for five minutes if the product hematocrit is determined by centrifugation.	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Section: SOPs - Red Blood Cells (Automated)

Red Blood Cells (Automated)

Have all of your Red Blood Cell SOPs--including all apheresis SOPS, and quality control SOPs and data--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.
[ ] Apheresis SOPs [ ] Quality Control SOPs & Data

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously approved Red Blood Cell Apheresis SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Red Blood Cell Apheresis SOPs

Confirm that the following detail is included in your Red Blood Cell Apheresis SOPs.
[ ] A qualitative method of hematocrit or hemoglobin determination

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Red Blood Cell Apheresis SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Quality Control SOPs & Data

Do your Red Blood Cell Quality Control SOPs include an explanation that the monthly quality control data is to include testing of 50 units total per site?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apheresis Main

Do your Red Blood Cell Quality Control SOPs include an explanation that the monthly quality control data must meet 95% compliance?		( ) Yes ( ) No
>	Do your Quality Control SOPs include an indication that the process was investigated and repeated?	( ) Yes ( ) No

Do your Red Blood Cell Quality Control SOPs include an explanation that the products tested for quality control data meet a mean hemoglobin greater than or equal to 60 g or 180 mL per unit?	( ) Yes ( ) No ( ) Not Applicable

Do your Red Blood Cell Quality Control SOPs include an explanation that the products tested for quality control data meet the criteria that 95% hemoglobin is greater than 50 g or 150 mL per unit?	( ) Yes ( ) No ( ) Not Applicable

Do the actual Red Blood Cell Quality Control data results compare to the expected/absolute Red Blood Cell volume to the actual Red Blood Cell volume (or as described by the manufacturer)?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Attach all Red Blood Cell Quality Control SOPs and forms that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach two months of Red Blood Cell Quality Control data for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Platelet Pheresis (Automated)

Platelet Pheresis (Automated) SOPs

Have all of your Platelet Pheresis SOPs--including donatoin criteria, procedures, and quality control--been previously approved by the FDA?	( ) Yes ( ) No

Select the Platelet Pheresis SOPs that are being submitted for approval by the FDA.	
[ ] Donation Criteria SOPs [ ] Procedures SOPs [ ] Quality Control SOPs	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Platelet Pheresis SOPs.	
FDA-Assigned Number (STN) 1	

Apheresis Main

FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Donation Criteria SOPs

Confirm that the following details are included in the Platelet Pheresis Donation Criteria SOPs.
[ ] 48 hours are allowed between donations; two donations are allowed per seven days; and a maximum of 24 donations are allowed per year (singles) [ ] The total volume per donation is limited to 500 mL or 600 mL if the donor weighs 175 pounds or more [ ] Maximum Red Blood Cell loss per year should not exceed the Red Blood Cell loss allowed for Whole Blood collection

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your Platelet Pheresis Donation Criteria SOPs explain that a platelet count should be performed pre-donation (minimum 150,000)?		( ) Yes ( ) No
>	Do your Platelet Pheresis Donation Criteria SOPs explain that a pre-platelet count or a post count from the previous donation should be used?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Platelet Pheresis Donation Criteria SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Procedures SOPs

Confirm that the following details are included in the Platelet Pheresis Procedures SOPs.
[ ] Directions for managing cardiopulmonary adverse events [ ] An explanation that personnel should have specialized training and a periodic refresher [ ] An explanation that equipment should be standardized and calibrated on a regular basis [ ] An explanation of component processing [ ] An explanation that sterility testing should be performed during validation

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Platelet Pheresis Procedures SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control SOPs

Apheresis Main

Confirm that the following details are included in the DAILY Quality Control SOPs.
[ ] An explanation that platelet count and volume should be performed on all collections [ ] An explanation that separated plasma should be observed for hemolysis [ ] An explanation that if the products have visibly apparent Red Blood Cells (more than 2 mL), a sample is to be attached to the unit for comparability testing

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the MONTHLY Quality Control SOPs.
[ ] An explanation that platelet count/volume/pH quality control may be done at the time of issue or outdate. An explanation of a statistically significant quality control plan [ ] An explanation that a minimum of four collections per machine type, per product type, per site should be tested for quality control [ ] An explanation that 75%/95% of products tested should meet a platelet count of 3.0 x 10^11 [ ] An explanation that 100% or 95%/95% of products tested should meet a pH >= 6.2

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Platelets Quality Control SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Plasma (Automated)

Plasma (Automated)

Have all of your Plasma (Automated) SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved Plasma (Automated) SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Plasma (Automated) SOPs

Attach all the Plasma (Automated) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Plasma Frozen Within 24 Hours of Phlebotomy

Have all of your Plasma Frozen Within 24 Hours of Phlebotomy SOPs been previously approved by the FDA?	( ) Yes ( ) No

Apheresis Main

Enter the FDA-assigned number(s) (STN) for any previously approved Plasma Frozen Within 24 Hours of Phlebotomy SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Plasma Frozen Within 24 Hours of Phlebotomy SOPs

Confirm that the following details are included in the Plasma Frozen Within 24 Hours of Phlebotomy SOPs.	
[ ] Plasma is refrigerated within 8 hours of collection [ ] Plasma is frozen within 24 hours of collection	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all the Plasma Frozen Within 24 Hours of Phlebotomy SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Plasma Frozen Within 24 Hours After Phlebotomy & Held at RT up to 24 Hours

Have all of your Plasma Frozen Within 24 Hours After Phlebotomy & Held at Room Temperature up to 24 Hours SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved Plasma Frozen Within 24 Hours After Phlebotomy & Held at RT up to 24 Hours SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

PF24RT24 SOPs

Attach all the Plasma Frozen Within 24 Hours After Phlebotomy & Held at RT up to 24 Hours SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Fresh Frozen Plasma (Automated)

Fresh Frozen Plasma (Automated)

Have all of your Fresh Frozen Plasma (Automated) SOPs been previously approved by the FDA?	( ) Yes ( ) No

Apheresis Main

Enter the FDA-assigned number(s) (STN) for any previously approved Fresh Frozen Plasma (Automated) SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Fresh Frozen Plasma (Automated) SOPs

Attach all Fresh Frozen Plasma (Automated) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Add any additional comments and information pertaining to the Fresh Frozen Plasma (Automated) SOPs, if necessary.
[Multi-Line Plain Text]

Section: SOPs - Infrequent Source Plasma (Automated)

Infrequent Source Plasma

Have all of your Infrequent Source Plasma SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved Infrequent Source Plasma SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Infrequent Source Plasma SOPs

Confirm that the following details are included in the Infrequent Source Plasma SOPs.	
[ ] Donations occur every 28 days (or less frequently) need variance [ ] The donor has a minimum weight of 110 lbs [ ] The maximum allowable plasma volume per year excluding anticoagulant is 12.0 L if the donor is less than or equal to 175 lbs, or 14.4 L if the donor is more than 175 lbs [ ] The donor is not participating in other blood or plasma collection programs, or is not donating more often than every 4 weeks	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Maximum Allowable Plasma Volume Per Collection (Including Anticoagulant)

Apheresis Main

Donor Weight	Volume/Weight	Collection Volume/Weight
110-149 lbs	625 mL/640 g	690 mL/705 g
150-174 lbs	750 mL/770 g	825 mL/845 g
175 lbs	800 mL/820 g	880 mL/900 g

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Infrequent Source Plasma SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Add any additional comments and information pertaining to the Infrequent Source Plasma SOPs, if necessary.
[Multi-Line Plain Text]

Section: Informed Consent

Apheresis Informed Consent

Are you submitting an Informed Consent form for FDA approval as a part of this submission?	( ) Yes ( ) No

>	Select ALL the products that your facility collects by apheresis.
	[ ] Red Blood Cells [ ] Platelets [ ] Plasma [ ] Fresh Frozen Plasma [ ] Infrequent Source Plasma
>	Select ALL the devices that your facility operates for apheresis collection.
	[ ] Fenwal Alyx [ ] Fenwal Amicus [ ] Fenwal Auto-C [ ] Haemonetics Cymbal [ ] Haemonetics MCS Plus LN 8150 [ ] Haemonetics MCS Plus LN 9000 [ ] Haemonetics PCS2 [ ] Trima (version 4.0) [ ] Trima Accel (version 5.0 and above) [ ] Other

General

Confirm that the following details are included in the Informed Consent.

Apheresis Main

[ ] A description of the procedure [ ] A description of the donor frequency [ ] Descriptions of the foreseeable risks of the procedure, including potential side effects and hazard of the solutions/drugs [ ] An explanation that the procedure is voluntary [ ] An explanation that consent may be withdrawn at any time [ ] An explanation that the donor has the right to ask questions [ ] A review of AIDS information (if this information is located in another place, do not select this checkbox and explain below)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Red Blood Cells General

Confirm that the following foreseeable risks are described in the Informed Consent.
[ ] Anticoagulant side effects (tingling, tremors) [ ] Chills [ ] Complications at venipuncture site [ ] Convulsions due to changes in blood volume [ ] Dizziness [ ] Dyspnea [ ] Excessive tiredness [ ] Fainting [ ] Feeling of warmth [ ] Light headedness [ ] Nausea [ ] Pallor [ ] Vomiting

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Fenwal Alyx

Confirm that the following details are included in the Informed Consent.
[ ] An explanation of the potential risk of allergic reactions (skin redness, itching, hives) [ ] An explanation of the potential risk of chills [ ] An explanation of the potential risk of hypocalemia, including unusual taste or smell, tingling around the mouth or fingers, or muscle discomfort, twitching, or spasms [ ] An explanation of the potential risk of blood loss, hemolysis, air embolism, or blood clotting with improper device operation

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Fenwal Amicus

Apheresis Main

Confirm that the following details are included in the Informed Consent.
[ ] An explanation of the potential risk of hyperventilation [ ] An explanation of the potential risk of hematoma formation [ ] An explanation of the potential risk of syncopal reactions due to hypovolemia [ ] An explanation of the potential risk of hypocalemia (tingling), and in the case of severe hypocalemia, tetany, seizure, cardian arrhythmia, or death may occur [ ] An explanation of the potential risk of muscle discomfort, twitching, or spasms [ ] An explanation of the potential risk of unusual taste in the donor's mouth [ ] An explanation of the potential risk of blood loss, hemolysis, air embolism, and blood clotting with improper device operation

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Fenwal Auto-C

Confirm that the following foreseeable risks are described in the Informed Consent.
[ ] Air Embolism [ ] Anticoagulant side effects (tingling, tremors) [ ] Blood Clotting [ ] Bloodloss [ ] Complications at venipuncture site [ ] Fainting [ ] Hemolysis [ ] Hyperventilation [ ] Light headedness [ ] Syncopal Reactions/Hypovolemia [ ] Vomiting

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Haemonetics Cymbal

Confirm that the following details are included in the Informed Consent.
[ ] An explanation that donors of two units of Red Blood Cells may experience mild discomfort at a rate significantly higher than donors of one unit of Red Blood Cells and two units of Plasma. The increased rate of donor discomfort appears to result principally from the effects of citrate but may include those of Red Blood Cell loss

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Haemonetics PCS2

Confirm that the following details are included in the Informed Consent.
[ ] An explanation of the potential risk of air embolism [ ] An explanation of the potential risk of hypocalemia (tingling)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Trima (v. 4.0) & Trima Accel (v. 5.0 and above)

Confirm that the following details are included in the Informed Consent.
[ ] An explanation of the potential risk of fever [ ] An explanation of the potential risk of headache [ ] An explanation of the potential risk of unpleasant taste in the donor's mouth [ ] An explanation of the potential risk of digit and/or facial paresthesia [ ] An explanation of the potential risk of hypotension [ ] An explanation of the potential risk of urticaria/allergic reaction [ ] An explanation of the potential risk of anxiety

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Informed Consent Form

Attach Informed Consent form(s) that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Additional Information

Summary - General (Automated)

Enter any additional summary information that you wish to provide about the current request for your facility.
[Multi-Line Plain Text]

Apheresis Instruments

Section: Apheresis Instruments

Apheresis Instruments

Note:	If you have indicated that this submission includes information about particular collection instruments, please complete the following applicable sections.

Section: Fenwal Alyx

Fenwal Alyx

Have all of the Fenwal Alyx SOPs--including general criteria, calculations for blood volume in containers, donor profiles, Red Blood Cell loss (Plasma loss), maintenance, and quality control--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] General Criteria [ ] Calculations for Blood Volume [ ] Donor Profiles [ ] Red Blood Cell Loss (Plasma Loss) [ ] Maintenance [ ] Quality Control	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Fenwal Alyx SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Select the products that are collected with this instrument.
[ ] ACD-A/AS-1 Red Blood Cells, Leukocyte Reduction (Double Unit Collection) [ ] ACD-A/AS-1 Red Blood Cell, Leukocyte Reduction, and Plasma

General Criteria

Confirm that the following details are included in the Fenwal Alyx General Criteria SOPs.
[ ] The pre-leukoreduced actual Red Blood Cell volume is +/-10% of the target Red Blood Cell volume [ ] The residual White Blood Cell count is less than 5.0 x 10e6 [ ] The percent recovery is recorded (greater than 85%) [ ] Instructions to correct volume differences greater than 10 mL between bags [ ] Instructions that early termination of leukocyte reduction may result in inadequate AS-1 delivery and product should be evaluated by the Medical Director [ ] Extended leukocyte reduction may result in display mesage that residual White Blood Cell and Red Blood Cell content should be checked

Apheresis Instruments

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for General Criteria that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Calculations for Blood Volume in Containers

Information:	It is not mandatory to use the following calculations for blood volume in containers as long as your firm has a method to calculate volumes. If the following calculations are not used by your firm to determine blood volume, please describe your firm's equations in the memo field at the bottom of the screen.

Is the equation below used by your firm and listed in the SOPs?	( ) Yes ( ) No ( ) Not Applicable
Total Plasma in Plasma Container (mL): [Total Container Weight (g) - Container Tare Weight (g)] / 1.03 g/mL	

Is the equation below used by your firm and listed in the SOPs?	( ) Yes ( ) No
Total Product Volume: Red Blood Cells and Plasma in Red Blood Cell Container (mL): [Total Container Weight (g) - Container Tare Weight (g)] / 1.08 g/mL	

Is the equation below used by your firm and listed in the SOPs?	( ) Yes ( ) No
Red Blood Cell Content of Red Blood Cell Container = Total Product Volume x 85%	

Is the equation below used by your firm and listed in the SOPs?	( ) Yes ( ) No
Whole Blood in In-Process Container (mL): [Total Container Weight (g) - Container Tare Weight (g)] / 1.05 g/mL	

Is the equation below used by your firm and listed in the SOPs?	( ) Yes ( ) No
Red Blood Cell Content of In-Process Container = Whole Blood in In-Process Container Value x Donor Hematocrit	

Is the equation below used by your firm and listed in the SOPs?	( ) Yes

Apheresis Instruments

	( ) No

Total Volume of Red Blood Cell Storage Container (mL): weigh each container separately and: [Total Container Weight (g) - Container Tare Weight (g)] / 1.06 g/mL

Is the equation below used by your firm and listed in the SOPs?	( ) Yes ( ) No

Product Hemoglobin = [Total Product Volume (mL) x Sample Hemoglobin (g/dL)] / 100mL

Describe the calculations used by your firm to determine blood volume.
[Multi-Line Plain Text]

Attach the SOP(s) for Calculations for Blood Volume that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profiles

Red Blood Cells, Leukocytes Reduced (Double Unit Collection)	
Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells, Leukocytes Reduced (Double Unit Collection): Allogeneic Male (Height 5'1")

Donor Weight	Pre-Donation Hematocrit	Pre-Donation Hemoglobin	Max Red Blood Cell Target Volume
130-149 lbs	40%	13.3 g/dL	360 mL
150-174 lbs	400 mL	175 lbs	420 mL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells, Leukocytes Reduced (Double Unit Collection): Allogeneic Female (Height 5'5")

Apheresis Instruments

Donor Weight	Pre-Donation Hematocrit	Pre-Donation Hemoglobin	Max Red Blood Cell Target Volume
150-174 lbs	40%	13.3 g/dL	360 mL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Red Blood Cells, Leukocytes Reduced and Plasma	
Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells, Leukocytes Reduced and Plasma; Allogeneic Male and Female

Donor Weight	Pre-Donation Hematocrit	Pre-Donation Hemoglobin	Max Red Blood Cell Target Volume	Max Plasma Target Volume
110-129 lbs	38-55%	12.5-18.3 g/dL	200 mL	450 mL
130-174 lbs	550 mL	175 lbs	38-50%	12.5-16.6 g/dL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Donor Profiles that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Loss (Plasma Loss)

Confirm that the following details are included in the Fenwal Alyx Red Blood Cell Loss (Plasma Loss) SOPs.
[ ] Red Blood Cell loss from the collection samples (including sample pouch) is included in the total volume (use of sample pouch) [ ] If the procedure is discontinued early: 110 mL (including 15 mL in tubing) [ ] Donor Red Blood Cell loss due to kit volume = Hematocrit x 110 mL [ ] If blood has not entered the separation chamber: less than or equal to 60 mL [ ] Donor Plasma loss due to kit volume = 110 mL - Donor Red Blood Cell loss. BR: Enable question if Plasma SOPs have not been previously approved (see "SOPs-Plasma & FFP" tab)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Red Blood Cell Loss (Plasma Loss) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,

	.zip)]

Maintenance

Confirm that the following details are included in the SOPs for maintenance procedures that are performed DAILY.	
[ ] Machine must be OFF at least once in a 24 hour period to perform self-checks [ ] Power cycle instrument [ ] Perform scale checks (500g and 1000g weights): +/- 3g [ ] Wipe centrifuge compartment	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed MONTHLY.	
[ ] Inspect/clean fan filters [ ] Clean pump block gasket [ ] Clean optical sensors [ ] Inspect centrifuge gasket	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed AS NEEDED.	
[ ] Clean touch screen [ ] Clean instrument housing	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control

Note:	Confirm that the following details are included in the SOPs for this instrument.

Red Blood Cells: Pre-leukocyte reduced actual Red Blood Cell volume is +/-10% of target (this is displayed by device).	( ) Yes ( ) No
Message:	Note: AABB standard or internally developed standard must be used to meet guidance recommendations.
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apheresis Instruments

Leukocyte Reduction: % recovery displayed by device (may be recorded on all units).	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Quality Control that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Fenwal Amicus

Fenwal Amicus

Have all of the Fenwal Amicus SOPs--including general criteria, product specifications, donor profile, sampling, and maintenance--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.

[ ] General Criteria
[ ] Product Specifications
[ ] Donor Profile
[ ] Sampling
[ ] Maintenance

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Fenwal Amicus SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Select the products that are collected with this instrument.

[ ] Single needle platelets with optional Red Blood Cells (ACD-A AS-1; require filtration for leukocyte reduction)
[ ] Plasma (Platelets drawn concurrently do not need to be re-licensed)
[ ] Double needle platelets with optional plasma

General Criteria

Confirm that the following procedures are included in the Fenwal Amicus General Criteria SOPs for plateletpheresis (White Blood Cells should be counted if the following procedures are followed).

[ ] Perform manual product transfer
[ ] Platelet storage container clamps are not closed before removing the kit from the instrument (Red Blood Cells will enter storage container)

Apheresis Instruments

[ ] Greater number of Red Blood Cells than expected is seen (1 inch in diameter near entrance to collection chamber is normal)

[ ] Centrifuge spins down during procedure

[ ] Procedure is paused for more than 135 seconds

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm the following guidelines are set as default values for the Fenwal Amicus instrument.

[ ] Recommended pre-platelet count 250,000

[ ] Single dose storage fluid (200-400 mL): recommend 285 mL

[ ] Double dose storage fluid (200-800 mL): recommend 570 mL

Message:	MPV 10.1 or greater (if actual value not entered); Hematocrit 42%; Weight 110 lbs; DN and SN yield adjuster: 1.00; Double dose limit: suggest 5.0

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the Fenwal Amicus General Criteria SOPs.

[ ] Estimator will calculate the expected post-donation platelet count, which should be greater than 100,000/uL

[ ] The specifications for the weight scales are as follows. Front Scales: 0 to 1200 gms or 0 to 2500 gms: +/-1% or 2 gms, whichever is greater. Rear Scales: 0 to 3600 gms: +/1% or 5 gms, whichever is greater

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the Fenwal Amicus Red Blood Cell Loss SOPs.

[ ] Specifications for kits (excluding plasma container, Whole Blood, and Red Blood Cell containers) are as follows: Single needle: 209 mL; Double needle: 205 mL

[ ] Blood sampling pack contains 50 mL of Whole Blood

[ ] Product sampling pack contains 3-5 mL

[ ] Specifications for Red Blood Cell kit volumes are as follows: Single needle: 64 mL (If reinfusion incomplete: Max Cycle Volume x Donor Hematocrit + 64 mL); Double needle: 60 mL

[ ] Plasma kit volumes (excluding plasma container, Whole Blood, and Red Blood Cell containers) is 145 mL for both Single and Double needle

[ ] Specifications for Red Blood Cell kit volumes after re-infusion are as follows: Single needle: 30 mL; Double needle: 20 mL (Note: For manual re-infusion, the operator must observe and monitor lines for presence of air, and Red Blood Cell loss must be calculated)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for General Criteria that require approval from the FDA.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Apheresis Instruments

Product Specifications

Do your Fenwal Amicus SOPs state that during platelet and/or plasma collection, the observance of more than ~6 inches of Red Blood Cells in the line from bottom right port of the right casette to the centrifuge pack OR in the plasma requires discontinuation of the procedure and re-infusion AND should have a residual White Blood Cell count performed on the product?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Platelets

Select the procedures that are followed for Whole Blood volume limit.

[ ] Single Does Whole Blood Volume Limit (for single Platelet) should be set at 5400 mL (maximum 5500 mL)
[ ] Double Dose Whole Blood Volume Limit (for double Platelets) should be set at 6900 mL (maximum 7000 mL)
[ ] Triple Platelets maximum processed volume is 8000 mL (maximum 8000 mL)
[ ] Total Plasma volume should be within 20 mL or +/- 10%, whichever is greater, of target total plasma volume
[ ] Maximum Platelet per container and minimum volumes (including ACD) to ensure a pH of at least 6.2
[ ] 4.7 x 10^11 maximum per bag

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]
Message:	Note: Software version 2.52 and above will alarm for conditions that may require that the product be counted for White Blood Cells.

Are your specifications for leukoreduced platelets <5 x 10e6 99% of the time with 99% confidence and <1 x 10e6 98% of the time with 97% confidence?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Concurrent Red Blood Cells

Select the procedures that are followed for Concurrent Red Blood Cells.

[ ] Absolute Red Blood Cell Volume: displayed or calculated volume = [Red Blood Cell product weight (gms) - tare weight of Red Blood Cell containter (gms) / density factor (1.077 g/mL)]
[ ] Absolute Red Blood Cell Volume = Volume x Hematocrit of product (~85%)
[ ] Expected is 190-210 mL

Message:	Note: Have ~85% hematocrit. Container weight : 32 gms, tubing 0.2 gms/inch

Attach the SOP(s) for Product Specifications that require approval from the FDA.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profile

Apheresis Instruments

Do your donor criteria meet the national standards?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the estimator is used for all of the following.
[ ] Recommended 100,000/uL post-donation estimated count [ ] Donor pre-donation platelet count. In absence of pre-count, use 250,000 [ ] Calculated Hematocrit: After 10-15 minutes of processing, observe "Calculated Hematocrit" parameter on screen; add 10% for the approximate unanticoagulated Whole Blood hematocrit; If different from current hematocrit value in Estimator by more than 4 percentage points, enter new value. Calculated Hematocrit should not be used to determine donor eligibility [ ] Weight [ ] Height (default is 60 inches) [ ] Gender (default is female) [ ] Yield or Whole Blood to process [ ] Red Blood Cell Volume (default is 0 mL) [ ] Volume out per kg (estimate of maximum donor ECV) may recommend less than or equal to 10.5 mL/kg (AABB std) [ ] MPV [ ] Hematocrit

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Donor Profile that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sampling

Note:	Pre-collection sampling may be done using the Return line (single needle) or Inlet line (double needle).

Confirm that the following details are explained in the Fenwal Amicus Sampling SOPs.
[ ] If the Interlink Injection site is used before two hermetic seals are made on the line leading to the kit, the system is considered "opened" and the expiration time is 24 hours [ ] Platelet samples placed in pediatric 2 mL EDTA tubes need a dilution correction factor of 1.02

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Sampling that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Apheresis Instruments

Maintenance

Note:	Confirm that the following details are included in the SOPs for this instrument.

Confirm that the following details are included in the SOPs for maintenance procedures that are performed ROUTINELY.
[ ] Clean touch screen [ ] Clean spills

Message:	Lubrication of pump head is to be performed by Fenwal service personnel only.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed WEEKLY +/- 2 DAYS.
[ ] Clean or check air inlet filter [ ] Clean interface detector system [ ] Clean window and ramp

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed BIANNUALLY +/- 30 DAYS.
[ ] Replace gaskets

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed ANNUALLY +/- 30 DAYS.
[ ] PM and calibration

Message:	PM and calibration is to be performed by Fenwal service personnel only.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Fenwal Auto-C

Fenwal Auto-C

Apheresis Instruments

Have all of the Fenwal Auto-C SOPs--including Product Specifications, Sampling, and Maintenance--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] Product Specifications [ ] Sampling [ ] Maintenance	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Fenwal Auto-C SOPs.	
Item 1	
Item 2	
Item 3	

Product Specifications

Attach the SOP(s) for Product Specifications that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sampling

Attach the SOP(s) for Sampling that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Maintenance

Confirm that the following details are included in the SOPs for maintenance procedures that are performed DAILY.	
[ ] Verify Weigh Scale Operation [ ] Clean fluid spills from the instrument if present	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed WEEKLY.	
[ ] Device Support turns freely when rotated [ ] When closed, the Hgb Detector Door snaps shut and remains closed [ ] When closed, the Pressure Transducer Door snaps shut and remains closed [ ] The Collection Container Hanger is straight and securely attached to the Weigh Scale Assembly	
>	Please explain why the appropriate information is not included.

Apheresis Instruments

	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed MONTHLY.	
[ ] Clean the Reservoir Channel, Hgb Detector guide and Air Detector channel [ ] Clean the Pump Roller and verify pump rollers turn freely. Replace any worn or loose components [ ] Inspect Transducer Luers for blockage or damage to the outside surface [ ] Remove and clean lower air filter per cleaning instructions	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) and forms for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Haemonetics Cymbal

Haemonetics Cymbal

Have all of the Haemonetics Cymbal SOPs--including general criteria, donor profile, maintenance, and quality control--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] General Criteria [ ] Donor Profile [ ] Maintenance [ ] Quality Control	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Haemonetics Cymbal SOPs.	
Item 1	
Item 2	
Item 3	

Select the products that are collected with this instrument.
[ ] Red Blood Cell, Leukocytes Reduced (Double Unit) - CP2D/AS-3

General Criteria

Confirm that the following details are included in the Haemonetics Cymbal SOPs.
[ ] Less than 5.0 x 10^6 residual White Blood Cells.

Apheresis Instruments

[ ] For the units tested for monthly quality control each site should confirm that the units contain at least a Red Blood Cell mass of 150 mL in 95% of the units sampled. A mean of 150 mL for the two unit collections is also acceptable.

[ ] If the "QC Products" message is displayed the site should perform a failure investigation and confirm the Red Blood Cell mass per the following procedure. Each unit should contain a minimum Red Blood Cell mass of 150 mL (minimum hemoglobin 42.5 g) in 95% of the units tested. Total product hemoglobin may be used in place of Red Blood Cell mass. Each unit should also contain less than 5.0 x 10^6 residual White Blood Cells.

[ ] Do not use the luer connector before the procedure terminates. Using the luer connector compromises the sterility of the disposable set.

[ ] Do not replace the pre-attached disposable needle under any circumstances.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for General Criteria that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profile

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

	Weight	Height	Hematocrit
Allogeneic Male	130 lbs	61 inches	40%
Allogeneic Female	150 lbs	65 inches	Autologous Male
130 lbs	N/A	Autologous Female	150 lbs

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Donor Profile that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Maintenance

Note:	The frequency of cleaning for each individual Cymbal device depends on the number of procedures performed.

Confirm that the following details are included in the SOPs for maintenance procedures that are performed DAILY.

[ ] Clean the exterior surfaces, including the pressure monitors

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apheresis Instruments

Confirm that the following details are included in the SOPs for maintenance procedures that are performed WEEKLY.
[ ] Clean the air detectors [ ] Clean the Red Blood Cell sensor [ ] Clean the inside of the centrifuge components and the retainer ring

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed BI-WEEKLY.
[ ] Clean and grease the D-ring

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed MONTHLY.
[ ] Clean the pump rotors [ ] Clean the pump wells [ ] Clean the fluid detector and the valve module

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed QUARTERLY.
[ ] Clean the air filter

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed BI-ANNUALLY.
[ ] If the device is unused, plug it into an AC power source for 6 hours to recharge the internal battery

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed EVERY TWO YEARS.
[ ] Contact a qualified service representative to replace the internal battery backup and perform a leakage current test

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed AS NEEDED.

Apheresis Instruments

[ ] Bar-code reader [ ] Scales (do not pout cleaning fluid over the scales) [ ] Pressure cuff

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control

Do the SOPs explain how to obtain a Red Blood Cell sample for Quality Control using the steps below?	( ) Yes ( ) No

Red Blood Cell Bag Air Evacuation and Quality Control Sample

- Mix the Red Blood Cell product thoroughly
- Hold one of the Red Blood Cell bags with ports facing up and open the yellow clamp
- Remove the white tape on the tubing coils
- Place the air pouches at a higher level than the Red Blood Cell bags
- Hermetically seal each Red Blood Cell product below the Y connector and separate the two final product bags
- Squeeze the bag until fluid starts to enter the air pouch
- Check the Red Blood Cell bag for any trapped air
- If air is trapped, continue to squeeze until the air enters the air/sample pouch, then gravity feed the excess fluid back into the product bag ensuring that there is a small amount of fluid left in the pouch to take a Quality Control sample
- Clamp the line off while holding the product bag
- Repeat for the second product bag
- Heat seal close to the air/sample pouch
- Do not seal the remaining segments at this time

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs explain the following methods to measure Total Product Volume if "QC Products" message appears?	( ) Yes ( ) No

Methods for Measuring Total Product Volume

Method 1:

- Take separate weights of the product and any empty Red Blood Cell bag
- Zero a calibrated scale
- Weight an appropriate empty Red Blood Cell bag
- Weigh the Red Blood Cell product
- Subtract the weight of the empty Red Blood Cell bag from the weight of the Red Blood Cell product *[Product Weight = Total Product Weight - Empty Red Blood Cell Bag]*
- Determine the total volume in the Red Blood Cell product bag *[Total Volume (mL) = Product Weight (G) / 1.058]*
- Document the total volume

Method 2:

- Tare the scale before weighing the Red Blood Cell product
- Zero a calibrated scale
- Place an appropriate empty Red Blood Cell bag on the scale and tare (re-zero) the scale
- Place the Red Blood Cell product on the scale to determine the product weight
- Determine the volume in the Red Blood Cell product bag *[Total Volume (mL) = Product Weight (G) / 1.058]*
- Document the total volume

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Quality Control that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Haemonetics MCS Plus LN 8150

Haemonetics MCS Plus LN 8150

Have all of the Haemonetics MCS Plus LN 8150 SOPs--including general criteria, sampling and calculations, donor profile, maintenance, and quality control--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.
[ ] General Criteria [ ] Sampling and Calculations

Apheresis Instruments

[ ] Donor Profile
[ ] Maintenance
[ ] Quality Control

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Haemonetics MCS Plus LN 8150 SOPs.	
Item 1	
Item 2	
Item 3	

Select the products that are collected with this instrument.

[ ] Red Blood Cells and Plasma
[ ] Red Blood Cells (Single Unit)
[ ] Red Blood Cells (Double Unit)
[ ] Red Blood Cells, Leukocytes Reduced (Single Unit)
[ ] Red Blood Cells, Leukocytes Reduced (Double Unit)

General Criteria

Confirm that the following details are included in the Haemonetics MCS Plus LN 8150 General Criteria SOPs.

[ ] Storage at room temperature: filter within 8 hours of venipuncture; 10-25 minutes
[ ] Storage at 1C-6C: filter within 72 hours of venipuncture; 20-35 minutes
[ ] Products that fail leukocyte reduction specifications should be evaluated for residual White Blood Cells and percent recovery
[ ] Greater than 85% recovery of Red Blood Cell mass

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for General Criteria that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sampling and Calculations

Confirm that the following details are included in the Haemonetics MCS Plus LN 8150 Sampling and Calculations SOPs.

[ ] Sample must be collected from (distal portion of) Red Blood Cell bag tubing
[ ] Stripping, mixing, sampling, and measurement should occur as soon as possible following each other

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apheresis Instruments

Red Blood Cells, Non-Leukocytes Reduced
Confirm that the following details are included in the Haemonetics MCS Plus LN 8150 Sampling and Calculations SOPs for Red Blood Cells, Non-Leukocytes Reduced.
[ ] Product Weight = Total Product Weight - Empty Bag [ ] Total Volume (mL) = Product Weight (g) / 1.058 (SG of 1.06 may be used) [ ] Absolute Red Blood Cell Volume = (Sample Hematocrit/100) x Product Volume

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Red Blood Cells, Leukocytes Reduced	
Message:	For prefiltration sampling procedure, use filtration harness which includes filter and Red Blood Cell bags; for postfiltration use empty Red Blood Cell bag.
Confirm that the following details are included in the Haemonetics MCS Plus LN 8150 Sampling and Calculations SOPs for Red Blood Cells, Leukocytes Reduced.	
[ ] Product Weight = Total Product Weight - Empty Bag [ ] Total Volume (mL) = Product Weight (g) / 1.058 (SG of 1.06 may be used) [ ] Absolute Red Blood Cell Volume = (Sample Hematocrit/100) x Product Volume [ ] Red Blood Cells remaining in disposable set = 5-10 mL absolute Red Blood Cells	

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Sampling and Calculations that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profile

Red Blood Cells

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells: Allogeneic Male

Donor Weight	Predonation Hematocrit	Predonation Hemoglobin	Max Red Blood Cell Target Volume
110-129 lbs	38-41%	12.5-13.9 g/dL	185 mL
42%	14.0 g/dL	190 mL	130-149 lbs
38-41%	12.5-13.9 g/dL	190 mL	42%

14.0 g/dL	195 mL	150-174 lbs	38-41%
12.5-13.9 g/dL	200 mL	42%	14.0 g/dL
210 mL	175 lbs	38-41%	12.5-13.9 g/dL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells: Allogeneic Female

Donor Weight	Predonation Hematocrit	Predonation Hemoglobin	Max Red Blood Cell Target Volume
110-129 lbs	38-41%	12.5-13.9 g/dL	180 mL
42%	14.0 g/dL	130-149 lbs	38-41%
12.5-13.9 g/dL	185 mL	42%	14.0 g/dL
190 mL	150-174 lbs	38-41%	12.5-13.9 g/dL
190 mL	42%	14.0 g/dL	195 mL
175 lbs	38-41%	12.5-13.9 g/dL	200 mL

>	Please explain why all of the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells: Autologous Male

Donor Weight	Predonation Hematocrit	Predonation Hemoglobin	Max Red Blood Cell Target Volume
110-129 lbs	34-37%	11.3-12.4 g/dL	170 mL
38-41%	12.5-13.9 g/dL	185 mL	42%
14.0 g/dL	190 mL	130-149 lbs	34-37%
11.3-12.4 g/dL	180 mL	38-41%	12.5-13.9 g/dL

190 mL	42%	14.0 g/dL	195 mL
150-174 lbs	34-37%	11.3-12.4 g/dL	190 mL
38-41%	12.5-13.9 g/dL	200 mL	42%
14.0 g/dL	210 mL	175 lbs	34-37%
11.3-12.4 g/dL	200 mL	38-41%	12.5-13.9 g/dL
210 mL	42%	14.0 g/dL	210 mL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells: Autologous Female

Donor Weight	Predonation Hematocrit	Predonation Hemoglobin	Max Red Blood Cell Target Volume
110-129 lbs	34-37%	11.3-12.4 g/dL	160 mL
38-41%	12.5-13.9 g/dL	180 mL	42%
14.0 g/dL	180 mL	130-149 lbs	34-37%
11.3-12.4 g/dL	170 mL	38-41%	12.5-13.9 g/dL
185 mL	42%	14.0 g/dL	190 mL
150-174 lbs	34-37%	11.3-12.4 g/dL	180 mL
38-41%	12.5-13.9 g/dL	190 mL	42%
14.0 g/dL	195 mL	175 lbs	34-37%
11.3-12.4 g/dL	190 mL	38-41%	12.5-13.9 g/dL
200 mL	42%	14.0 g/dL	210 mL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Plasma

Do your donor criteria meet the profiles outlined below?	( ) Yes

	( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Red Blood Cells, Leukocytes Reduced (Double Unit)

Do your donor criteria meet the profile outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells, Leukocytes Reduced (Double Unit): Allogeneic Male (Height 5'1")

Donor Weight	Predonation Hematocrit	Predonation Hemoglobin	Max Red Blood Cell Target Volume
130 lbs	40%	13.3 g/dL	350 mL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profile outlined below?	( ) Yes ( ) No ( ) Not Applicable

Red Blood Cells, Leukocytes Reduced (Double Unit): Allogeneic Female (Height 5'5")

Donor Weight	Predonation Hematocrit	Predonation Hemoglobin	Max Red Blood Cell Target Volume
150 lbs	40%	13.3 g/dL	360 mL

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No

Apheresis Instruments

	( ) Not Applicable

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Donor Profile that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Maintenance

Confirm that the following details are included in the SOPs for maintenance procedures that are performed DAILY.
[ ] Machine must be OFF at least once in a 24 hour period to perform self-checks [ ] Weigher to be checked daily using a certified weight [Acceptable range (displayed volume) = +/-1% or 495-505g (500g); 990-1010g (1000g); 1485-1515g (1500g)] [ ] Clean SPM/DPM [ ] Clean surfaces and control panel (also must be performed with spill)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed MONTHLY AND WITH A SPILL.
[ ] Clean centrifuge well and cover [ ] Clean pumps [ ] Clean bowl optics and line sensor [ ] Clean air detectors

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed MONTHLY.
[ ] Clean air filters/filter screen [ ] Inspect O-rings and apply grease [ ] Current leakage, per local regulations with spill and after major voltage surge.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following detail is included in the SOPs for maintenance procedures that are performed ANNUALLY +/- 45 DAYS.	
[ ] Preventative maintenance by manufacturer	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control

Confirm that the following details are included in the Haemonetics MCS Plus LN 8150 Quality Control SOPs.	
[ ] Single Red Blood Cells OR each of two Red Blood Cells from a double collection (non-leukocyte reduced): Total Red Blood Cell volume is +/- 15% of target in 95% [ ] Double Red Blood Cells with leukocyte reduction (LN832F) filter: Mean greater than or equal to 153 mL in 95%; 180 mL per bag is default [ ] Instructions for aborted procedures	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Quality Control that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Haemonetics MCS Plus LN 9000

Haemonetics MCS Plus LN 9000

Have all of the Haemonetics MCS Plus LN 9000 SOPs--including general criteria, sampling and calculations, donor profile, and maintenance--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] General Criteria [ ] Sampling and Calculations [ ] Donor Profile [ ] Maintenance	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Haemonetics MCS Plus LN 9000 SOPs.	
Item 1	

Apheresis Instruments

Item 2	
Item 3	

Select the products that are collected with this instrument.

[ ] Single Platelets
[ ] Double Platelets
[ ] Single Platelets with Plasma
[ ] Platelets, Leukocytes Reduced with in-line filters
[ ] CPP Filter (LN 994CF)
[ ] Single Only, CLX (LN994F)

General Criteria

Confirm that the following details are included in the Haemonetics MCS Plus LN 9000 General Criteria SOPs.

[ ] Singles stored in approximately 200-300 mL of plasma
[ ] Doubles stored in approximately 350-450 mL of plasma

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Leukocyte Reduction

Do the SOPs explain that the pre-storage CPP LN 994CF filter must meet the acceptance criteria listed below?	( ) Yes ( ) No

	95%	99%
Single	$<5.0 \times 10^6$	$<1.0 \times 10^6$
Double	$<8.3 \times 10^6$	N/A

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs explain that the CLX LN 994F filter must meet the acceptance criteria listed below (up to 1 hr post collection)?	( ) Yes ( ) No

95%
$<5.0 \times 10^6$

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs explain that during Leukocyte Reduction, if Red Blood Cell spillover occurs, manual intervention of the process or volume processed is less than 5000 mL, and residual White Blood Cell count	( ) Yes ( ) No

should be done?	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs explain that reverse flow of filtered platelet back through the filter should be discarded?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Platelets

Do the SOPs explain that the CPP bag must meet the collection criteria listed below?	( ) Yes ( ) No

Per Bag	Platelets per mL
5.0×10^{11}	2600×10^{6}

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs explain that the CLX bag must meet the collection criteria listed below?	( ) Yes ( ) No

Per Bag
3.5×10^{11}

Note: Double Platelets - If Platelet count exceeeds bag limitations, an additional bag should be attached with a SCD.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the SOPs explain that for LN 994F filtration up to one hour post collection?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for General Criteria that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Apheresis Instruments

Sampling and Calculations

Confirm that the following details are included in the Haemonetics MCS Plus LN 9000 Sampling and Calculations SOPs.
[ ] Pre-procedure: if from injection port, 3-5 mL must be discarded [ ] Use a scale to ensure equal volume split between platelet bags [ ] Product Volume (mL) for Platelets and Plasma = [Total Product Weight - Empty Bag] / 1.026 BR: Enable question if Plasma SOPs have not been previously approved (see "SOPs-Plasma & FFP" tab)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Sampling and Calculations that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profile

Confirm that the following details are included in the Haemonetics MCS Plus LN 9000 Donor Profile SOPs.
[ ] Whole Blood donors are screened for sex, height, weight, hematocrit (or hemoglobin x 3), and pre-donation platelet count [ ] Predonation count may be historical, an average, or default (250,000) [ ] Residual blood in set is ~55 mL, of which ~45 mL is plasma [ ] Maximum volume of Red Blood Cells in LN 994 is 190 mL [ ] Plasma: 500 mL donors under 175 lbs; 600 mL donors > 175 lbs. BR: Enable question if Plasma SOPs have not been previously approved (see "SOPs-Plasma & FFP" tab)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Donor Profile that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Maintenance

Confirm that the following details are included in the SOPs for maintenance procedures that are performed DAILY.
[ ] Clean SPM/DPM

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed MONTHLY.
[ ] Inspect L gasket and apply silicone grease (vacuum centrifuge only; not mechanical) [ ] Clean disposable ID window [ ] Clean air detectors [ ] Clean line sensor

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed MONTHLY AND WITH SPILL.
[ ] Clean optic bowl lens [ ] Clean pumps [ ] Clean exterior surface and user panel

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed QUARTERLY.
[ ] Clean air filters [ ] Current leakage, per local regulations with spill and after major voltage surge.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed ANNUALLY.
[ ] PM by manufacturer +/- 30 days

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Haemonetics PCS2

Haemonetics PCS2

Have all of the Haemonetics PCS2 SOPs--including product specifications, donor profile, sampling, and maintenance--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.
[ ] Product Specifications [ ] Donor Profile [ ] Sampling [ ] Maintenance

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Apheresis Instruments

Enter the FDA-assigned numbers (STN) for any previously-approved Haemonetics PCS2 SOPs.	
Item 1	
Item 2	
Item 3	

Product Specifications

Attach the SOP(s) for Product Specifications that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profile

Attach the SOP(s) for Donor Profile that include donor acceptability and plasma volumes that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sampling

Attach the SOP(s) for Sampling that include removing samples for testing that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Maintenance

Is this submission for a Commercial Plasma Center or a Blood Bank?	( ) Commercial Plasma Center ( ) Blood Bank

Select the instrument maintenance procedures that are performed DAILY.	
[ ] Weigher calibration test [ ] Clean all exterior surfaces [ ] Clean the donor pressure monitor (DPM)	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the instrument maintenance procedures that are performed WEEKLY at your Commerical Plasma Center(s).
[ ] Clean air detectors [ ] Clean line sensor [ ] Clean centrifuge well and chuck [ ] Clean fluid sensor [ ] Clean bowl optics lens

Apheresis Instruments

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the instrument maintenance procedures that are performed MONTHLY at your Commercial Plasma Center(s).
[ ] Clean pump rotors and wells [ ] Clean air filters [ ] Lubricate centrifuge O-ring

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the instrument maintenance procedures that are performed MONTHLY at your Blood Bank.
[ ] Clean air detectors [ ] Clean line sensor [ ] Clean centrifuge well and chuck [ ] Clean fluid sensor [ ] Clean bowl optics lens [ ] Clean pump rotors and wells [ ] Clean air filters [ ] Lubricate centrifuge O-ring

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) and forms for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Caridian BCT Trima (v4.0)

Caridian BCT Trima (v4.0)

Have all of the Trima (v4.0) SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.
[ ] General Criteria [ ] Product Specifications [ ] Donor Profile [ ] Maintenance [ ] Quality Control

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Apheresis Instruments

Enter the FDA-assigned numbers (STN) for any previously-approved Trima (v4.0) SOPs.	
Item 1	
Item 2	
Item 3	

Select the products that are collected with this instrument.
[ ] Platelets [ ] Red Blood Cells [ ] Red Blood Cells, Leukocytes Reduced [ ] Concurrent Plasma

General Criteria

Do your SOPs explain that retained plasma volume and Red Blood Cell loss must be monitored/tracked per procedure?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your SOPs include the Red Blood Cell loss criteria listed below?	( ) Yes ( ) No

Red Blood Cell Loss (Does Not Include Samples)

	Version 4
Extracorporeal Blood Volume	230 mL (~95 mL RBCs)
After Rinseback	30 mL RBC, 35 mL Plasma
No Rinseback	95 mL RBC, 112 mL Plasma

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for General Criteria that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Product Specifications

Platelets

Apheresis Instruments

Confirm that the following procedures are included in the SOPs for Trima product specifications for Platelets.
[ ] Concentration: 1000 x 10^3/ul to 2100 x 10^3/ul [ ] Maximum Yield: less than or equal to 5.1 x 10^11 per bag [ ] Volume: 100-400 mL/bag [ ] Daily qualification of platelets [ ] White Blood Cell and Platelet counts: within 48 hours of donation; within 6-24 hours of sample collection. If not tested within 6 hours, rotate/mix continuously at 20-24C. Immediately before counting, mix for 15 minutes

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Information:	Gambro 7-day platelet pheresis leukocyte reduced product requests should include the additional checklist for the variance.

Red Blood Cells

Confirm that the following procedures are included in the SOPs for Trima product specifications for Red Blood Cells.
[ ] Donor volume limits must be set (using height, weight, and gender) [ ] Red Blood Cells: Total Product Volume (TPV, which includes storage solution) = +/- 10% of Total Displayed Volume (TDV) + 100 mL storage solution. Calculate range or use formula: Lower Limit = (Displayed Volume + Additive Solution) x 0.9 and Upper Limit = (Displayed Volume + Additive Solution) x 1.1 OR [(TDV + 100) - TPV)] / (TDV + 100) x 100 [ ] dRBC: RBC: Total Product Volume (TPV, which includes storage solution) = +/- 10% of Total Displayed Volume (TDV) + 200 mL storage solution. Alternate: Product Volume of each unit (PV, which includes storage solution) = +/- 10% of Total Displaye Volume (TDV)/2 + 100 mL storage solution. Calculate range or use formyula: Lower Limit = (Displayed Volume + Additive Solution) x 0.9 and Upper Limit = (Displayed Volume + Additive Solution) x 1.1 [ ] Maximum 600 mL (including storage solution) [ ] The recommended Red Blood Cell dose range (Red Cell Mass) for optimal storage per Red Blood Cell bag (with 100 mL of AS-3) is 150 mL to 250 mL (not required)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Red Blood Cells, Leukocytes Reduced

Confirm that the following procedures are included in the SOPs for Trima product specifications for Red Blood Cells, Leukocytes Reduced.
[ ] Retain 85% of Red Blood Cells post filtration. Use hematocrit and volume to calculate Red Blood Cell content or mass [% recovery = (post-filtration volume x hematocrit) / (pre-filtration volume x hematocrit) x 100] OR measure hemoglobin [% recovery = (post hemoglobin x volume) / (pre hemoglobin x volume) x 100] OR use volume as a measure of filtration percent recovery [as submitted in 510k; % recovery = (post-filtration volume / pre-filtration volume) x 100] [ ] Less than 5.0 x 10^6 residual White Blood Cells

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Concurrent Plasma

Confirm that the following procedure is included in the SOPs for Trima product specifications for Concurrent Plasma.

Apheresis Instruments

[ ] Maximum plasma volume of 600 mL if to be frozen, 1000 mL if not to be frozen	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Product Specifications that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profile

Do your SOPs include the national standards for donor weight and hematocrit?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Red Blood Cells

Confirm that the following procedures are included in the SOPs for Trima donor profile for Red Blood Cells.		
[ ] Total Blood Volume is greater than 4500 mL [ ] Red Blood Cell loss not more than allowed for Whole Blood including residual volume from rinseback/lack of rinseback; Red Blood Cell product volume; donor samples		
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Plasma

Do your donor criteria meet the profiles outlined below?		( ) Yes ( ) No ( ) Not Applicable

Weight	% of Total Blood Volume/ procedure to be collected	Maximum Plasma to be collected per year
110-175 lbs	<15%	12.0 L

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Platelets

Do your SOPs include donor platelet count algorithm; pre-donation; average; pre-donation from previous donation; default (200,000)?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	

Apheresis Instruments

	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No

Weight	% of Total Blood Volume/ procedure to be collected	Maximum Plasma to be collected per year
110-175 lbs	15%	12.0 L

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Donor Profile that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Maintenance

Do the SOPs explain that the Safe Seal system (for sealing tubing) must be cleaned when contaminated?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following detail is included in the SOPs for maintenance procedures that are performed DAILY.
[ ] Clean Spills

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following detail is included in the SOPs for maintenance procedures that are performed WEEKLY AND AS NECESSARY.
[ ] Clean sensors and valves

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed PERIODICALLY.
[ ] Clean pump housing and pump rotors [ ] Clean fluid leak detector

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Apheresis Instruments

Confirm that the following details are included in the SOPs for maintenance procedures that are performed AFTER A BLOOD SPILL.
[ ] Clean the centrifuge chamber [ ] Remove and clean the filter

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control

Do the SOPs include the below criteria for Quality Control for Caridian BCT Trima (v4.0)?	( ) Yes ( ) No

Total Product Volume (TPV, including additive) is +/- 10% of [Total Display Volume or target (TDV) + 100 mL] in 95%.

This can be calculated two ways:

1. Range:
   Lower Limit: (TDV + 100 mL) x 0.9
   Upper Limit: (TDV + 100 mL) x 1.1
2. [(TPV - TDV + 100) / (TDV + 100)] x 100 = % Difference

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Quality Control that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Caridian BCT Trima Accel (v5.0 and above)

Caridian BCT Trima Accel (v5.0 and above)

Have all of the Caridian BCT Trima Accel (v5.0 and above) SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.
[ ] General Criteria [ ] Product Specifications [ ] Donor Profile [ ] Maintenance

Apheresis Instruments

[ ] Quality Control	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Trima Accel (v5.0 and above) SOPs.	
Item 1	
Item 2	
Item 3	

Select the products that are collected with this instrument.

[ ] Platelets
[ ] Red Blood Cells
[ ] Red Blood Cells, Leukocytes Reduced
[ ] Concurrent Plasma

General Criteria

Do your SOPs explain that retained plasma volume and Red Blood Cell loss must be monitored/tracked per procedure?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your SOPs include the Red Blood Cell loss criteria listed below?	( ) Yes ( ) No

Red Blood Cell Loss (Does Not Include Samples)

	Version 5		
Platelets Only	RBC/Plasma	LRS Platelets/ RBC/Plasma	Extracorporeal Blood Volume
95 mL	182 mL (~200 mL RBCs)	196 mL	After Rinseback
30 mL	25 mL RBC, 40 mL Plasma	30 mL RBC, 33 mL Plasma	No Rinseback

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for General Criteria that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,

	.zip)]

Product Specifications

Platelets

Confirm that the following procedures are included in the SOPs for Trima Accel product specifications for Platelets.
[ ] Concentration: 1000 x 10^3/ul to 2100 x 10^3/ul [ ] Maximum Yield: less than or equal to 5.1 x 10^11 per bag [ ] Volume: 100-400 mL/bag [ ] Daily qualification of platelets [ ] White Blood Cell and Platelet counts: within 48 hours of donation; within 6-24 hours of sample collection. If not tested within 6 hours, rotate/mix continuously at 20-24C. Immediately before counting, mix for 15 minutes

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Information:	Gambro 7-day platelet pheresis leukocyte reduced product requests should include the additional checklist for the variance.

Red Blood Cells

Confirm that the following procedures are included in the SOPs for Trima Accel product specifications for Red Blood Cells.
[ ] Donor volume limits must be set (using height, weight, and gender) [ ] Red Blood Cells: Total Product Volume (TPV, which includes storage solution) = +/- 10% of Total Displayed Volume (TDV) + 100 mL storage solution. Calculate range or use formula: Lower Limit = (Displayed Volume + Additive Solution) x 0.9 and Upper Limit = (Displayed Volume + Additive Solution) x 1.1 OR [(TDV + 100) - TPV)] / (TDV + 100) x 100 [ ] dRBC: RBC: Total Product Volume (TPV, which includes storage solution) = +/- 10% of Total Displayed Volume (TDV) + 200 mL storage solution. Alternate: Product Volume of each unit (PV, which includes storage solution) = +/- 10% of Total Displaye Volume (TDV)/2 + 100 mL storage solution. Calculate range or use formyula: Lower Limit = (Displayed Volume + Additive Solution) x 0.9 and Upper Limit = (Displayed Volume + Additive Solution) x 1.1 [ ] Maximum 600 mL (including storage solution) [ ] The recommended Red Blood Cell dose range (Red Cell Mass) for optimal storage per Red Blood Cell bag (with 100 mL of AS-3) is 150 mL to 250 mL (not required)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Red Blood Cells, Leukocytes Reduced

Confirm that the following procedures are included in the SOPs for Trima Accel product specifications for Red Blood Cells, Leukocytes Reduced.
[ ] Retain 85% of Red Blood Cells post filtration. Use hematocrit and volume to calculate Red Blood Cell content or mass [% recovery = (post-filtration volume x hematocrit) / (pre-filtration volume x hematocrit) x 100] OR measure hemoglobin [% recovery = (post hemoglobin x volume) / (pre hemoglobin x volume) x 100] OR use volume as a measure of filtration percent recovery [as submitted in 510k; % recovery = (post-filtration volume / pre-filtration volume) x 100] [ ] Less than 5.0 x 10^6 residual White Blood Cells

Apheresis Instruments

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Concurrent Plasma

Confirm that the following procedures are included in the SOPs for Trima Accel product specifications for Concurrent Plasma.

[ ] Maximum plasma volume of 600 mL if to be frozen, 1000 mL if not to be frozen

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Product Specifications that require approval from the FDA.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Profile

Do your SOPs include the national standards for donor weight and hematocrit?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Red Blood Cells

Confirm that the following procedures are included in the SOPs for Trima donor profile for Red Blood Cells.

[ ] Total Blood Volume is greater than 4500 mL

[ ] Red Blood Cell loss not more than allowed for Whole Blood including residual volume from rinseback/lack of rinseback; Red Blood Cell product volume; donor samples

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Plasma

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No ( ) Not Applicable

Weight	% of Total Blood Volume/ procedure to be collected	Maximum Plasma to be collected per year
110-175 lbs	<15%	12.0 L

>	Please explain why the appropriate information is not included.

Apheresis Instruments

	[Multi-Line Plain Text]

Platelets

Do your SOPs include donor platelet count algorithm; pre-donation; average; pre-donation from previous donation; default (200,000)?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your donor criteria meet the profiles outlined below?	( ) Yes ( ) No

Weight	% of Total Blood Volume/ procedure to be collected	Maximum Plasma to be collected per year
110-175 lbs	15%	12.0 L

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Donor Profile that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Maintenance

Do the SOPs explain that the Safe Seal system (for sealing tubing) must be cleaned when contaminated?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following detail is included in the SOPs for maintenance procedures that are performed DAILY.
[ ] Clean Spills
> Please explain why the appropriate information is not included.
[Multi-Line Plain Text]

Confirm that the following detail is included in the SOPs for maintenance procedures that are performed WEEKLY AND AS NECESSARY.
[ ] Clean sensors and valves
> Please explain why the appropriate information is not included.
[Multi-Line Plain Text]

Apheresis Instruments

Confirm that the following details are included in the SOPs for maintenance procedures that are performed PERIODICALLY.
[ ] Clean pump housing and pump rotors [ ] Clean fluid leak detector

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for maintenance procedures that are performed AFTER A BLOOD SPILL.
[ ] Clean the centrifuge chamber [ ] Remove and clean the filter

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Maintenance that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control

Do the SOPs include the below criteria for Quality Control for Caridian BCT Trima Accel (v5.0+)?	( ) Yes ( ) No

Total Product Volume (TPV, including additive) is +/- 10% of [Total Display Volume or target (TDV) + 100 mL] in 95%.

This can be calculated two ways:

1Range:
Lower Limit: (TDV + 100 mL) x 0.9
Upper Limit: (TDV + 100 mL) x 1.1
2[(TPV - TDV + 100) / (TDV + 100)] x 100 = % Difference

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the SOP(s) for Quality Control that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Other Instrument

Other Instrument

BLA Manual Collection

Section: SOPs - General (Manual)

Standard Operating Procedures (SOPs)

Note:	The following sections are intended to ensure that all submissions include appropriate Standard Operating Procedures (SOPs) and supplementary information defined in other FDA documents and FDA regulations. The supporting documentation should demonstrate that the proposed manufacturing is in compliance with the law, the regulations and consistent with FDA guidance and recommendations. Unchanged information or unrevised SOPs from previously approved supplements need not be submitted again. Instead, the information may be referenced by the BLA Supplement identification number. If it contributes to the clarity of the submission, previously submitted information should be included rather than referenced.

Donor Suitability SOPs

Have all of your Donor Suitability SOPs--including high-risk behavior and HIV/AIDS information, donor history, informed consent, and Red Blood Cell loss--been previously approved by the FDA?	( ) Yes ( ) No

Select the Donor Suitability SOPs that are being submitted for approval by the FDA.
[ ] High-Risk Behavior & HIV/AIDS Information [ ] Donor History [ ] Informed Consent [ ] Donor Suitability (General) [ ] Red Blood Cell Loss (Donor Eligibility) [ ] Red Blood Cell Loss (Incomplete Apheresis Procedures)

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Donor Suitability SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

High-Risk Behavior SOPs & HIV/AIDS Information Sheets

Attach High-Risk Behavior SOPs and HIV/AIDS information Sheets that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor History SOPs

Is the AABB Donor History Questionnaire (DHQ) being used at the facility?		( ) Yes ( ) No
>	Has the version of the DHQ being used been accepted by the FDA in a guidance document?	( ) Yes ( ) No

>	What version number?	
>	What organization?	

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Procedure to perform donor history assessment of new and repeat donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor History Questionnaire.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Associated donor history forms, if applicable.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Informed Consent SOPs

Confirm that the following details are included in the Informed Consent SOPs.

[ ] A description of the procedure
[ ] An explanation of the donation frequency
[ ] Descriptions of the foreseeable risks, including side effects and hazards of solutions/drugs
[ ] An explanation that the procedure is voluntary
[ ] An explanation that consent may be withdrawn at any time
[ ] An explanation that the donor has the right to ask questions
[ ] A description of the specific risks as described by the instrument manufacturer
[ ] A description of which tests will be performed
[ ] A description of which regulatory or public health agencies will be notified of positive/reactive test results
[ ] No exculpatory language (e.g., "I relieve Blood Establishment of any and all liability for any injuries sustained as a result of my donation")

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Informed Consent SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Suitability (General) SOPs

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Suitability of new donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,

	.zip)]

Suitability of repeat donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Verification of the identity of the donor.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Determination of previous deferral status of donors.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Arm inspection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Acceptable vital signs and hemoglobin of new and repeat donors (including acceptable results and method of documentation).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Acceptable weight of donor. (Weight must be more than 110 pounds).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Referral.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other applicable procedures.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Loss (Donor Eligibility) SOPs

Confirm that the following details are included in the Red Blood Cell Loss (Donor Eligibility) SOPs.	
[ ] A deferral of eight weeks if donating a single unit of Red Blood Cells [ ] A deferral of 16 weeks if donating a double unit of Red Blood Cells	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

BLA Manual Collection

Attach all Red Blood Cell Loss (Donor Eligibility) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Loss (Incomplete Apheresis Procedures) SOPs

Are your Whole Blood donors allowed to donate apheresis?	( ) Yes ( ) No

Are the donor deferral guidelines set forth in the table below included in the SOPs?	( ) Yes ( ) No

Red Blood Cell Loss, Incomplete Apheresis Procedures

Donor's Initial Packed Red Blood Cell Loss	Donor's Second Packed Red Blood Cell Loss Within Eight Weeks	Eligibility
Less than 200 mL	No donation, or total from initial and second loss less than 200 mL	No deferral of donor for packed Red Blood Cell loss; frequency of donation of Platelets Pheresis as discussed in section III.B.2
More than 200 mL but less than 300 mL total	Donor is not eligible to donate for eight weeks from second loss	Total loss from initial and second loss of more than 300 mL
Donor is not eligible to donate for sixteen weeks from second loss	More than 200 mL but less than 300 mL	N/A
Donor is not eligible to donate for eight weeks from initial loss	Greater than or equal to 300 mL	N/A

>	Explain why the appropriate information is not included in your SOPs.
	[Multi-Line Plain Text]

Attach all Red Blood Cell Loss (Incomplete Apheresis Procedures) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Collection SOPs

Have all of your Donor Collection SOPs--including donor preparation, arm preparation, venipuncture, product collection, and sample collection--been previously approved by the FDA?	( ) Yes ( ) No

BLA Manual Collection

Select the Donor Collection SOPs that are being submitted for approval by the FDA.
[ ] Donor Preparation [ ] Arm Preparation [ ] Venipuncture [ ] Product Collection [ ] Sample Collection

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Donor Collection SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Donor Preparation SOPs

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Verification of donor identity.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Determination of product collection parameters.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Preparation of instruments and disposals for collection.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Arm Preparation SOPs

Select which Arm Preparation method(s) apply to the SOPs.
[ ] Two-Step Iodine [ ] Soap and Acetone/Alcohol [ ] One-Step Gel [ ] Chloraprep [ ] Other

Two-Step Iodine
Confirm that the following steps are included in the attached SOPs.

[ ] Step 1: Using a sterile swab, scrub area for 30 seconds with 0.7% aqueous scrub solution of iodophor compound (e.g., PVP-iodine or poloxamer-iodine complex). Note: Excess foam may be removed with a sterile swab, but the arm need not be dry before the next step.

[ ] Step 2: Apply iodophor complex solution (e.g., 10% PVP-iodine (or 2% iodine tincture)). Using a sterile swab, begin at the intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter. Let stand for 30 seconds. Note: This solution contains only 1% free iodine and need not be removed before completing venipuncture.

[ ] Step 3: If not ready to do venipuncture immediately, cover the area with dry sterile gauze.

[ ] Step 4: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Soap and Acetone/Alcohol

Confirm that the following steps are included in the attached SOPs.

[ ] Step 1: Using a sterile swab, scrub vigorously with 15% aqueous (not alcoholic) soap or detergent solution for at least 30 seconds to clean away fat, oils, dirt, skin cells, and other debris.

[ ] Step 2: Remove soap and froth with 10% acetone in 70% isopropyl alcohol (one part acetone in nine parts isopropyl alcohol) using a new sterile swab and allow to dry.

[ ] Step 3: Apply tincture of iodine (2-3½% in 70% ethyl alcohol). Using a sterile swab, begin at intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter and allow to dry.

[ ] Step 4: Using a sterile swab, remove iodine with 10% acetone in 70% isopropyl alcohol. Allow the solution to dry.

[ ] Step 5: If not ready to perform venipuncture immediately, cover site with dry sterile gauze.

[ ] Step 6: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

One-Step Gel

Confirm that the following steps are included in the attached SOPs.

[ ] Step 1: Apply a minimum of 1 mL of One Step Gel directly to the venipuncture site.

[ ] Step 2: Using a sterile applicator and while holding at an approximate 30 degree angle, begin scrubbing in a circular motion over about a 1-inch area directly over the venipuncture site for a minimum of 30 seconds.

[ ] Step 3: After scrubbing for 30 seconds, use the same applicator to begin at intended site of venipuncture and move gradually outward in concentric circles to form a total prepped area measuring at least 3 inches in diameter.

[ ] Step 4: Using a second sterile applicator and starting from the center of the 3 inch prepped area (venipuncture site) remove excess gel by moving gradually outward in concentric circles.

[ ] Step 5: Allow site to air dry according to manufacturer's instructions.

[ ] Step 6: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Chloraprep

Confirm that the following steps are included in the attached SOPs.

[ ] Step 1: Scrub with repeated back-and-forth strokes for at least 30 seconds to completely wet area with antiseptic.
[ ] Step 2: Scrub area should be approximately 2.5 inches square.
[ ] Step 3: Allow to air dry for 30 seconds.
[ ] Step 4: Do not blot or wipe away.
[ ] Step 5: If the site is touched, the complete arm preparation must be repeated. For example, the donor cannot bend the arm and the prepared site cannot be touched with the fingers or with any other non-sterile object.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Other
If Other, please describe Arm Preparation method and attach applicable package inserts with procedures below.
[Multi-Line Plain Text]

Attach Arm Preparation SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Venipuncture SOPs

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Venipuncture process.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Product Collection SOPs

Confirm that the following details are included in the Product Collection SOPs.
[ ] The statement, "Prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue" [ ] Documentation of start and stop times of phlebotomy

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Note:	Attach the procedure(s) and form(s) that that require FDA approval for the following:

Product collection, including steps to remove products from instrument(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor reactions.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell loss documentation and deferrals.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sample Collection SOPs

Confirm that the following detail is included in the Sample Collection SOPs.	
[ ] Tubes are labeled before filling and verified against unit and donor	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach Sample Collection SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Final Disposition SOPs

Have all of your Final Disposition SOPs--including distribution and shipping of blood and blood components, and quarantine and disposition of unsuitable products--been previously approved by the FDA?	( ) Yes ( ) No

Select the Final Disposition SOPs that are being submitted for approval by the FDA.	
[ ] Distribution and Shipping of Blood and Blood Components [ ] Quarantine and Disposition of Unsuitable Products	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Final Disposition SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Distribution and Shipping of Blood and Blood Components SOPs

Attach Distribution and Shipping of Blood and Blood Components SOPs that require FDA approval. (Note: Shipping procedures should include instructions for temperature monitoring).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quarantine and Disposition of Unsuitable Products SOPs

Confirm that the following details are included in the Quarantine and Disposition of Unsuitable Products SOPs.

[ ] Unsuitable products are quarantined in an area separated from components that are released or pending release [ ] Units are labeled appropriately (e.g., not for transfusion, biohazard, etc.) [ ] Units are disposed of using biohazard precautions

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach Quarantine and Disposition of Unsuitable Products SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Whole Blood (Manual)

Whole Blood SOPs

Have all of your Whole Blood SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Whole Blood SOPs that are being submitted for approval by the FDA.	
[ ] Manufacturing [ ] Quality Control	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Whole Blood SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Manufacturing SOPs

Confirm that the following details are included in the Whole Blood Manufacturing SOPs.
[ ] Details are consistent with bag manufacturer's instructions [ ] Storage: Immediately after processing, the Red Blood Cells shall be placed in storage and maintained at a temperature between 1 and 6C [21 CFR 640.11(a)] [ ] The product shall be inspected immediately after separation of the plasma, periodically during storage, and at the time of issue [21 CFR 640.11(b)] [ ] Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation [21 CFR 640.16 (a)] [ ] Instructions to include a supplement for the inadvertant collection of low volume units (less than 405 mL for 450 mL bag) of blood due to technical difficulties [ ] A statement that donors weighing less than 110 pounds will not be eligible for 500 mL collections

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Whole Blood Manufacturing SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control SOPs

Attach all Whole Blood Quality Control SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Red Blood Cells (Manual)

Red Blood Cells SOPs

Have all of your Red Blood Cells SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Red Blood Cells SOPs that are being submitted for approval by the FDA.	
[ ] Manufacturing [ ] Quality Control	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Red Blood Cell SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Manufacturing SOPs

Confirm that the following details are included in the Red Blood Cells Manufacturing SOPs.	
[ ] Details are consistent with bag manufacturer's instructions [ ] Storage: Immediately after processing, the Red Blood Cells shall be placed in storage and maintained at a temperature between 1 and 6C [21 CFR 640.11(a)] [ ] The product shall be inspected immediately after separation of the plasma, periodically during storage, and at the time of issue [21 CFR 640.11(b)] [ ] Red Blood Cells may be prepared either by centrifugation, done in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation [21 CFR 640.16 (a)] [ ] Instructions to include a supplement for the inadvertant collection of low volume units (less than 405 mL for 450 mL bag) of blood due to technical difficulties [ ] A statement that donors weighing less than 110 pounds will not be eligible for 500 mL collections	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Red Blood Cell Manufacturing SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control SOPs

Attach all Red Blood Cell Quality Control SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Platelets (Manual)

Platelets SOPs

Have all of your Platelets SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Platelets SOPs that are being submitted for approval by the FDA.	
[ ] Manufacturing [ ] Quality Control	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Platelets SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Manufacturing SOPs

Confirm that the following details are included in the Platelets Manufacturing SOPs.	
[ ] The phlebotomy shall be performed by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of, the donor's tissue [ ] Platelets must not be pooled during processing unless the platelets are pooled as specified in the directions for use for the blood collecting, processing, and storage system approved for such use by the Director, Center for Biologics Evaluation and Research [ ] During such transport, all reasonable methods shall be used to maintain the temperature as close as possible to a range between 20 and 24C until it arrives at the processing laboratory where it shall be held between 20 and 24C until the platelets are separated [ ] The time and speed of centrifugation must have been demonstrated to produce an unclumped product, without visible hemolysis, that yields a count of not less than 5.5x10^10 platelets per unit in at least 75 percent of the units tested [ ] Immediately after re-suspension, Platelets shall be placed in storage at the selected temperature range	
>	Please explain why the appropriate information is not included.

	[Multi-Line Plain Text]

Select the storage temperature range and agitation method of the Platelet concentration.
( ) Platelet concentrate is stored at 20 to 24C and a continuous gentle agitation is maintained throughout the storage period ( ) Platelet concentrate is stored at a temperature between 1 and 6C and agitation is optional ( ) Not Applicable

Attach all Platelets Manufacturing SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control SOPs

Confirm that the following details are included in the Platelets Quality Control SOPs.	
[ ] Each month four units prepared from different donors shall be tested at the end of the storage period [ ] 75% of the products tested should meet a platelet count of at least 5.5 x 10^10 [ ] 100% of products tested should meet a pH not less than 6.2 measured at the storage temperature of the unit [ ] Measurement should be taken of the actual plasma volume [ ] If the results of the quality control testing indicate that the product does not meet the prescribed requirements, immediate corrective action shall be taken and a record maintained of such action	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Platelets Quality Control SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Plasma (Manual)

Plasma (Manual)

Have all of your Plasma SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously-approved Plasma SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Plasma (Manual) SOPs

Confirm that the following details are included in the Plasma SOPs.
[ ] Plasma shall be obtained by separating plasma from blood collected from blood donors

BLA Manual Collection

[ ] The Whole Blood must be maintained at a temperature between 1 and 6C or as specified in the directions for use for the blood collecting, processing, and storage system approved for such use [ ] Plasma shall be separated from the Red Blood Cells and shall be stored at -18C or colder within 6 hours after transfer to the final container or within the timeframe specified in the directions for use for the blood collecting, processing, and storage system unless the product is to be stored as Liquid Plasma

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Plasma SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Plasma Cryoprecipitate Reduced

Are you licensed or are you requesting licensure in this submission for Cryoprecipitate AHF and Fresh Frozen Plasma?	( ) Yes ( ) No

Warning

Stop:	Licensure for Plasma Cryoprecipitated Reduced requires prior licensure for Cryprecipitated AHF and either Plasma or Fresh Frozen Plasma. In order to continue with this submission for Plasma Cryoprecipitated Reduced, please navigate back to the Core Questions screen and select the products for which you are not licensed in order to include them in this submission.

Plasma Frozen Within 24 Hours After Phlebotomy

Have all of your Plasma Frozen Within 24 Hours of Phlebotomy SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously-approved Plasma Frozen Within 24 Hours of Phlebotomy SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Plasma Frozen Within 24 Hours After Phlebotomy SOPs

Note:	The Critical Control Points listed below must be included in your SOPs for Plasma Frozen Within 24 Hours After Phlebotomy, but the SOPs do not have to be submitted to the FDA for approval if you are already approved for Fresh Frozen Plasma.

Have you already been approved for Fresh Frozen Plasma?	( ) Yes ( ) No

Confirm that the following details are included in the Plasma Frozen Within 24 Hours After Phlebotomy SOPs.	
[ ] Plasma is refrigerated within 8 hours of collection [ ] Plasma is frozen within 24 hours of collection	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Plasma Frozen Within 24 Hours After Phlebotomy SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Fresh Frozen Plasma (Manual)

Fresh Frozen Plasma SOPs

Have all of your Fresh Frozen Plasma SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Fresh Frozen Plasma SOPs that are being submitted for approval by the FDA.	
[ ] Manufacture [ ] Storage and Dating Period [ ] Thawing	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Fresh Frozen Plasma SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Manufacture SOPs

Confirm that the following details are included in the Fresh Frozen Plasma Manufacture SOPs for this product.	
[ ] Plasma may be separated within 8 hours of collection from Whole Blood that has been maintained at 20-24C or 1-6C [ ] Plasma from Whole Blood shall be placed at -18C or below within 8 hours of collection [ ] If plasma is frozen in a liquid freezing bath, the plasma container must be overwrapped for protection	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Note:	If many units of plasma are frozen at one time, rapid freezing can be accomplished by placing units in a dry ice-ethanol or dry ice-antifreez bath; in layers between blocks of dry ice; in a blast freezer; or in a mechanical freezer maintained at -65C or lower.

Are you using a rapid freezing method?	( ) Yes ( ) No

Attach all Fresh Frozen Plasma Manufacture SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Storage and Dating Period SOPs

Confirm that the following details are included in the Fresh Frozen Plasma Storage and Dating Period SOPs for this product.	
[ ] A method to demonstrate that freeze-thaw has not occurred [ ] The plasma is stored at -18C or colder [ ] Maximum dating period is one year from the date of collection	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Fresh Frozen Plasma Storage and Dating Period SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Thawing SOPs

Confirm that the following details are included in the Fresh Frozen Plasma Thawing SOPs for this product.	
[ ] When Fresh Frozen Plasma is thawed in a water bath, the ports should be protected from possible contamination either by overwrapping the unit in plastic or suspending the bag so the ports are not immersed [ ] If a microwave oven is used for thawing, it should be approved for this use [ ] Once thawed, Fresh Frozen Plasma should be transfused within 6 hours [606.122(m)(3)]. This expiration time is calculated from the time Fresh Frozen Plasma is placed in the thawing device. A 640-120 variance is needed to store thawed Fresh Frozen Plasma for 24 hours [ ] Thawed Fresh Frozen Plasma should be stored at 1-6C [ ] Thawed Fresh Frozen Plasma retains the Fresh Frozen Plasma label. Only the expiration date is changed [ ] Clarification that the disposition of thawed Fresh Frozen Plasma that is not transfused. Thawed Fresh Frozen Plasma should not be re-frozen	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Fresh Frozen Plasma Thawing SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: SOPs - Liquid Plasma (Manual)

Liquid Plasma

BLA Manual Collection

Have all of your Liquid Plasma SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously-approved Liquid Plasma SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Liquid Plasma SOPs

Confirm that the following details are included in your Liquid Plasma SOPs.	
[ ] Liquid Plasma shall be separated from the Red Blood Cells and shall be stored at temperature of 1 to 6C within 4 hours after filling the final container or within the timeframe specified inthe directions for use for the blood collecting, processing, and storage system	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Liquid Plasma SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Additional Information

Summary - General (Manual)

Enter any additional summary information that you wish to provide about the current request for your facility.
[Multi-Line Plain Text]

Apheresis Instruments

Have all of the SOPs for this instrument been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned number(s) (STN) for any previously approved SOPs for this instrument, if applicable.	
Item 1	
Item 2	
Item 3	

Enter any additional information that you wish to provide about this instrument.
[Multi-Line Plain Text]

Attach any applicable documents.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[HTML Text]

Source Leukocytes

Section: SOPs - Source Leukocytes

Overview

Warning:	Applications for the collection of Source Leukocytes by methodologies or frequencies other than those in the Guideline will be reviewed on a case-by-case basis. Approvals will be given only where donor safety can be clearly demonstrated and monitored.

Explain methodology for collection, which should assure maximum donor safety and sterility of blood components.
[Multi-Line Plain Text]

Is the storage temperature 10C or colder?		( ) Yes ( ) No
>	Enter the storage temperature.	

Are Source Leukocytes tested for all required/recommended infectious disease markers?	( ) Yes ( ) No

Source Leukocytes SOPs

Have all of your Source Leukocytes SOPs--including distribution prior to receiving test results, manufacture from whole blood, collection by manual apheresis (no additional monitoring), collection by manual apheresis (with additional monitoring), and informed consent--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.
[ ] Distribution Prior to Receiving Test Results SOPs [ ] Manufacture from Whole Blood SOPs [ ] Collection by Manual Apheresis (No Additional Monitoring) SOPs [ ] Collection by Manual Apheresis (With Additional Monitoring) SOPs [ ] Informed Consent SOPs and Forms
Information: An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Source Leukocytes SOPs.	
FDA-Assigned Number (STN) 1	
FDA-Assigned Number (STN) 2	
FDA-Assigned Number (STN) 3	

Distribution Prior to Receiving Test Results SOPs

Confirm that the following details are included in the Source Leukocytes Distribution Prior to Receiving Test Results SOPs.

Source Leukocytes

[ ] System for communicating test results to the consignee [ ] Procedure for quarantine of untested units [ ] Procedure for identification and disposal of unacceptable units	
>	Please explain why all of the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Source Leukocyte Distribution Prior to Receiving Test Results SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Manufacture from Whole Blood SOPs

Confirm that the following detail is included in the Source Leukocytes Manufacture from Whole Blood SOPs.	
[ ] Donors should meet all donor suitability criteria for Whole Blood collection defined in 21 CFR 640.3	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Source Leukocytes Manufacture from Whole Blood SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Collection by Manual Apheresis (No Additional Monitoring) SOPs

Confirm that the following details are included in the Source Leukocytes Collection by Manual Aperesis (No Additional Monitoring) SOPs.	
[ ] Only one unit of Source Leukocytes should be collected [ ] Collection should not be performed more frequently than once every eight weeks [ ] The unit should be obtained from the first unit of Whole Blood collected during the plasmapheresis procedure [ ] Donors should meet all suitability criteria for Source Plasma donors defined in 21 CFR 640.63	
>	Please explain why all of the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Source Leukocytes Collection by Manual Apheresis (No Additional Monitoring) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Collection by Manual Apheresis (With Additional Monitoring) SOPs

Confirm that the following details are included in the Source Leukocytes Collection by Manual Aperesis (With Additional Monitoring) SOPs.
[ ] Only one or two units of Source Leukocytes may be collected [ ] Collection should not be performed more frequently than once in a 48 hour period or twice in a seven day period

Source Leukocytes

[ ] Total collections should not exceed 32 units during a period of one year

[ ] White Blood Cell counts shall be performed on the donor within seven days prior to each collection. Leukocytes shall not be collected from donors whose White Blood Cell count is less than 4000/mm^3

[ ] Donors should meet all suitability criteria for Source Plasma donors defined in 21 CFR 640.63

>	Please explain why all of the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Source Leukocytes Collection by Manual Apheresis (With Additional Monitoring) SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Informed Consent SOPs and Forms

Does your Informed Consent adequately explain the potential risks of Source Leukocyte collection in a plasmapheresis program?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Source Leukocytes Informed Consent SOPs	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach all Informed Consent forms	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Cryoprecipitated AHF

Section: SOPs - Cryoprecipitated AHF

Cryoprecipitated AHF SOPs

Have all of your Cryoprecipitated AHF and Pooled Cryoprecipitated AHF SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Cryoprecipitated AHF and Pooled Cryoprecipitated AHF SOPs that are being submitted for approval by the FDA.
[ ] Manufacture SOPs [ ] Pre-Storage Pooling SOPs [ ] Storage and Dating Period SOPs [ ] Quality Control SOPs and Records [ ] Thawing Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF for Transfusion SOPs

Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned number(s) (STN) for any previously-approved Cryoprecipitated AHF and Pooled Cryoprecipitated AHF SOPs.	
Item 1	
Item 2	
Item 3	

Manufacture SOPs

Select the temperature of the freezer you are using.	( ) Set at less than or equal to -35C ( ) Set at less than or equal to -18C

>	Clarify how rapid freezing will be achieved.
	[Multi-Line Plain Text]

Confirm that the following details are included in the Cryoprecipitated AHF Manufacture SOPs.
[ ] The statement, "Prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue" [ ] Instructions that start and stop times of phlebotomy should be documented [ ] Plasma may be separated within 8 hours of collection from Whole Blood that has been maintained at 20-24C [ ] Plasma from Whole Blood shall be placed at -18C or below within 8 hours of collection [ ] The frozen Plasma shall be stored and maintained at -18C or colder until thawed for further processing [ ] Frozen Plasma shall be thawed at 1-6C and the Cryoprecipitated AHF harvesting should begin as soon as possible after the Plasma is thawed to obtain maximum potency [ ] The Cryoprecipitated AHF should be frozen solid within one hour of the time the cryoprecipitate is removed from the refrigerated centrifuge unless it will be part of pool

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Cryoprecipitated AHF

Attach all Cryoprecipitated AHF Manufacture SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Pre-Storage Pooling SOPs

Confirm that the following details are included in the Pooled Cryoprecipitated AHF SOPs.		
[ ] Pooled Cryoprecipitated AHF should be placed in the freezer within one hour of the time that the pre-cryoprecipitated plasma is removed from the refrigerated centrifuge (Note: Include data to support an alternate procedure) [ ] Pooling must be done by sterile docking the individual Cryoprecipitated AHF units to the pooling bag [ ] Diluent, if used to rinse the Cryoprecipitated AHF bags, must be sterilely docked to maintain closed system [ ] The number of individual Cryoprecipitated AHF units used to make the Pooled Cryoprecipitated AHF units must be specified		
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Information:	Please request an alternative procedure to 21 CFR 640.54(b)(2) under the provisions of 21 CFR 640.120 if you will be using a diluent to rinse the individual Cryoprecipitated AHF bags as part of the pre-storage pooling procedure.
Select the diluent used.	( ) 0.9% saline ( ) Compatible Plasma

Attach all Pooled Cryoprecipitated AHF SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Storage and Dating Period SOPs

Confirm that the following details are included in the Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF Storage and Dating Period SOPs.		
[ ] The Cryoprecipitated AHF and Pooled Cryoprecipitated AHF shall be stored at -18 C or colder [ ] Individual Cryoprecipitated AHF units: the maximum dating period is one year from the collection date [ ] Pre-Storage Pooled Cryoprecipitated AHF units: the maximum dating period is one year from the collection date of the oldest unit in the pool [ ] Frozen product should be packed in dry ice during shipping		
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Attach all Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF Storage and Dating Period SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Cryoprecipitated AHF

Quality Control SOPs and Records

Confirm that the following details are included in the Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF Quality Control SOPs.
[ ] Individual Cryoprecipitated AHF units: test four units per month (units may be pooled prior to testing) [ ] Pre-Storage Pooled Cryoprecipitated AHF units: one pooled unit per month; pooled unit must contain at least four individual units [ ] Mean AHF content must be at least 80 IU per unit [21 CFR 640.56(d)] [ ] At least 150 mg fibrinogen per unit [21 CFR 606.122(n)] [ ] Quality Control testing only needs to be performed in months in which the product is prepared [ ] Product acceptance criteria limits should be indicated in both SOP and Quality Control sheets [ ] Supervisory review should be indicated on Quality Control sheets

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF Quality Control SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach two months of Quality Control data for Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Thawing for Transfusion SOPs

Does your establishment pool individual Cryoprecipitated AHF units before issuance?	( ) Yes ( ) No

Confirm that the following details are included in the Thawing Cryoprecipitated AHF and/or Pooled Cryoprecipitated AHF for Transfusion SOPs.
[ ] For transfusion, the product must be thawed at 30-37 C using a plastic overwrap to prevent bacterial contamination from the waterbath [ ] The number of individual Cryoprecipitated AHF units used to make the post-storage Pooled Cryoprecipitated AHF units must be specified [ ] The thawed product shall be stored at 20-24 C for the applicable time [ ] Expiry for individual Cryoprecipitated AHF unit: 6 hours [ ] Expiry for pre-storage Pooled Cryoprecipitated AHF unit: 6 hours [ ] Expiry for post-storage Pooled Cryoprecipitated AHF unit when a sterile docking device was used (product was spiked for pooling): 4 hours

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Cryoprecipitated AHF and Pooled Cryoprecipitated AHF for transfusion SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Manufacturing Modifications

Section: Irradiated Blood Products

Irradiated Blood Products

Warning:	Licensure of irradiated blood products requires a CBER inspection at the irradiating facility.

Have all of the required Irradiated Blood Products SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] General SOPs [ ] Labeling SOPs [ ] Quality Control SOPs & Form	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Irradiated Blood Products SOPs.	
FDA-assigned number (STN) 1	
FDA-assigned number (STN) 2	
FDA-assigned number (STN) 3	

Do you use a contractor to perform irradiation (this applies to primary contractors and "back-up" contractors)?	( ) Yes ( ) No

General SOPs

Confirm that the following details are included in the Irradiation SOPs.
[ ] Irradiator type is Ce-137. (Do not select this checkbox if another type of irradiator or x-ray is used. Enter the information for the type used in the field below)
[ ] Dose delivered to the center of the container (2500 cGy to central portion of container and 1500 cGy minimum dose at any other point)
[ ] Length of time required to deliver irradiation, calculated from decay of original source, set by irradiator manufacturer
[ ] Monitoring to determine actual delivery. Should perform initial validation, then annually for Ce-137, semi-annually for Co-60, and after mechanical repairs. Should use thermoluminescence dosimeter (TLD) chips or other direct method of measurement
[ ] Should perform mapping on a fully loaded canister (may use "dummy" units filled with water) to obtain the maximum and minimum dose of irradiation to which the blood components will be subjected
[ ] Maximum number of units that may be irradiated at one time (should validate this process, review records during inspection)
[ ] How and when frozen products are irradiated
[ ] The dating period for Red Blood Cell products should not be more than 28 days from the date of irradiation, but not to exceed the dating period of the original product. The dating period for platelets and thawed plasma is unchanged
[ ] Maintenance SOP
[ ] The two months of irradiation records should be representative of all product classes for which licensure is requested. (Two months of records for each product is not required for review, evaluate irradiation process)

Manufacturing Modifications

>	Please enter the irradiator type that is used or explain why any other appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Irradiation SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Labeling SOPs

Confirm that the following details are included in the Irradiated Blood Products Labeling SOPs.	
[ ] Final containers permanently labeled as "irradiated." Note: Tie-tags and Rad-Sure(R) indicators are not acceptable for proper name [ ] No extraneous labels (e.g., purple "irradiated" sticker)	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Irradiated Blood Products Labeling SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control SOPs & Form

Confirm that the following details are included in the Irradiated Blood Product Quality Control SOPs.	
[ ] Should use an indicator with each batch. [Rad-Sure(R), dosimeter sensor such as TN-ID-50 Irradiator Dosimetry System, validated piece of X-ray fild, or Rad-Tag(R) for X-ray systems.]. If applying for frozen products, verify that indicator is not being subjected to unacceptable temperatures [less than 50C for Rad-Sure(R)] [ ] If the irradiator in use has a backup timer, the two timers should be quality controlled monthly (checked against a certified stopwatch)	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following procedures are included in the quality control of the indicator system in use.	
[ ] Storage temperature indicator checks [ ] Shipping temperature [ ] Expected Results for each new lot (comparison with the old lot) [ ] Documentation of such quality control [ ] Investigation of failures and corrective actions	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the irradiation records or quality control.
[ ] Daily comparison of timer to back-up timer if available; otherwise check timer with certified stopwatch [ ] Daily check of turntable rotation

Manufacturing Modifications

[ ] Duration of irradiation
[ ] Time in and out of storage environment (not to exceed 30 mins)
[ ] Level or dose of irradiation
[ ] Documentation of indicator performance
[ ] Operator ID
[ ] Date and time
[ ] Site of irradiation

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Irradiation Quality Control SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach the Quality Control form that requires approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Irradiation Contractor

Item: 1 (could contain up to 1000 items with 1 required)

Is the irradiation contract facility registered with FDA?	( ) Yes ( ) No
Name of Contractor	
Registration Number	

Do you ("the applicant") have SOPs or a process to ensure that the contractor performs manufacturing steps according to the applicant's specifications?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the applicant have SOPs or a process to ensure that the contractor is in compliance with all applicable regulations?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the applicant have SOPs or a process to describe steps performed for the applicant and the contractor?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Manufacturing Modifications

Does an agreement exist between the applicant and the contractor that outlines the responsibilites of each?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Has the irradiation process been inspected by the FDA?	( ) Yes ( ) No
Select the items which the applicant has received from the contractor.	[ ] Terms of agreement [ ] Contractor's irradiation SOPs [ ] Dosimetry results

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Section: Leukocyte Reduction

Leukocyte Reduction

Have all of the required Leukocyte Reduction SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] General SOPs [ ] Quality Control SOPs	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Leukocyte Reduction SOPs.	
FDA-assigned number (STN) 1	
FDA-assigned number (STN) 2	
FDA-assigned number (STN) 3	

General SOPs

Select which validated or cleared device(s) is used.	[ ] Flow Cytometry [ ] Nageotte [ ] Imagn

Confirm that the following details are included in the Leukocyte Reduction SOPs.
[ ] Name and manufacturer of all equipment used for Leukocyte Reduction, including filter manufacturer and model number, and apheresis device manufacturer, model number, and software version number [ ] The time period in which leukofiltration is performed is consistent with the manufacturer's directions

Manufacturing Modifications

[ ] Instructions for handling and labeling of units that do not meet the criteria of leukoreduction [ ] Instructions for failure investigation of unacceptable units

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your Leukocyte Reduction SOPs include any additional quality control requirements per the manufacturer?	( ) Yes ( ) No

>	Explain the additional requirements.
	[Multi-Line Plain Text]

Attach the Leukocyte Reduction SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control SOPs

Confirm that the following details are included in the Leukocyte Reduction Quality Control SOPs.
[ ] Residual White Blood Cell limit of 5.0 x 10e6 is per collection for Platelet pheresis [ ] Residual White Blood Cell limit of 5.0 x 10e6 is per unit for Red Blood Cells (including double Red Blood Cells) [ ] Platelets pheresis (doubles and triples): When one piece of the collection has a residual White Blood Cell count > 5.0 x 10e6, the device has failed to leukocyte reduce and a failure investigation should be initiated [ ] Counting each of the "baby" bags and labeling as leukoreduced if the residual White Blood Cell count < 5.0 x 10e6 is appropriate providing a failure investigation of the collection is completed (optional: the firm may choose to discard) [ ] 1% of collections for each product type, or, if less than 400 per month, four of each product type are selected at random [ ] Any other manufacturer's post-filtration specifications: Haemonetics MCS Plus LN 8150 mean Red Blood Cells >= 153 mL; Trima may include a minimum Red Blood Cell volume of 160 mL [ ] The product meets 85% recovery [ ] Alyx Red Blood Cells and Haemonetics MCS+ 9000 plateletpheresis with LN994CF filter are auto-filtered. Residual White Blood Cell count is required and evidence of 85% component recovery is displayed by the device software [ ] Trima, Amicus, Spectra LRS Turbo 7.0 plateletpheresis: do not use filtration so residual White Blood Cell count quality control is required; evidence of 85% component recovery is not

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do your SOPs include non-Leukocyte Reduced labeling of failed units?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the products tested for quality control data meet a mean hemoglobin greater than or equal to 51 g or 153 mL per unit?	( ) Yes ( ) No ( ) Not Applicable

Manufacturing Modifications

Do the products tested for quality control data meet the criteria that 95% hemoglobin is greater than 42.5 g or 128 mL per unit?	( ) Yes ( ) No ( ) Not Applicable

Attach the Leukocyte Reduction Quality Control SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Divided Product

Divided Product

Have all of the required Divided Product SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned numbers (STN) for any previously-approved Divided Product SOPs.	
FDA-assigned number (STN) 1	
FDA-assigned number (STN) 2	
FDA-assigned number (STN) 3	

Divided Product SOPs

Attach the Divided Product SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Washed Product

Red Blood Cells, Washed

Have all of the required Red Blood Cells, Washed SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] Manufacture of Red Blood Cells, Washed SOPs [ ] Sterility Testing of Red Blood Cells, Washed SOPs [ ] Quality Control SOPs	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Red Blood Cells, Washed SOPs.	
FDA-assigned number (STN) 1	
FDA-assigned number (STN) 2	

Manufacturing Modifications

FDA-assigned number (STN) 3	

Manufacture of Red Blood Cells, Washed SOPs

Confirm that the following details are included in the Manufacture of Red Blood Cells, Washed SOPs.	
[ ] Washing procedure should be consistent with automated cell washer manufacturer's directions [ ] 24 hour dating period from start of washing [ ] Supervisory review of all quality control records	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Manufacture of Red Blood Cells, Washed SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Sterility Testing of Red Blood Cells, Washed SOPs

Confirm that the following details are included in the Sterility Testing of Red Blood Cells, Washed SOPs.	
[ ] Sterility data for 10 units, if not approved for other washing procedures (i.e., deglycerolization) [ ] Explanation of on-going sterility checks after approval. Manufacturer determines the number of units tesed and frequency of testing [ ] If sterility testing is not performed in-house, provide the name, address, registration, and license number (if applicable) of laboratory performing sterility testing. Note: Laboratory must be CLIA-approved [ ] Statement from applicant that the sterility testing protocol is equivalent to or better than the method stated in 21 CFR 610.12	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Sterility Testing of Red Blood Cells, Washed SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control SOPs

Total Protein Determination	
Confirm that the following details are included in the Washed Product Quality Control SOPs for Total Protein Determination.	
[ ] Total Protein performed on supernatant for 100% of the units prepared [ ] Maximum acceptable level of 98 mg/dL residual protein remaining in the unit (typical range is 5-98 mg/dL) for transfusion to IgA deficient recipients [ ] Methodology for Total Protein should be capable of low level deteminations. Submission must include data such as: how much? for at least the 10 units tested for sterility, or the 8 units tested for recovery, if the sterility data is not needed, or some other number? [wording?]	
>	Please explain why the appropriate information is not included.

Manufacturing Modifications

	[Multi-Line Plain Text]

Red Blood Cell Recovery
Confirm that the following details are included in the Washed Product Quality Control SOPs for Red Blood Cell Recovery.
[ ] Quality control for 2 months, 4 units/month, or all units if manufacturer prepares less than 4/month. If sterility data is submitted, submit percent recovery for all 10 units. Acceptable Results: at least 80% recovery of Red Blood Cells in 75% of the units tested [ ] Quality control parameters [ ] Product disposition for products not meeting the criteria of Red Blood Cells, Washed [ ] Percent Red Blood Cell Recovery = [(Post-wash volume or weight Red Blood Cells x Post-wash hematocrit) / (Pre-wash volume or weight Red Blood Cells x Pre-wash hematocrit)] x 100

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Quality Control SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Frozen/Rejuvenated/Deglycerolized

RBCs, Frozen/Rejuvenated/Deglycerolized

Have all of the Red Blood Cells, Frozen, Rejuvenated, and Deglycerolized SOPs been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] Manufacture of RBCs Frozen/Rejuvenated/Deglycerolized SOPs [ ] Rejuvenation Procedure SOPs [ ] Quality Control SOPs & Form	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Red Blood Cells, Frozen, Rejuvenated, and Deglycerolized SOPs.	
Item 1	
Item 2	
Item 3	

Manufacture of RBCs, Frozen/Rejuvenated/Deglycerolized SOPs

Confirm that the following details are included in the Manufacture of Red Blood Cells, Frozen/Rejuvenated/Deglycerolized SOPs.

Manufacturing Modifications

[ ] Consistency with the manufacturer's instructions

[ ] Storage temperature for rejuvenated and non-rejuvenated frozen blood should be -65C or colder [21 CFR 640.17]

[ ] Storage of thawed Red Blood Cells should be set at 1C-6C

[ ] Expiration date for frozen blood should be 10 years

[ ] The lot number of solutions and containers for glycerolization and deglycerolization must be documented

[ ] Records show evidence of review from a second person

[ ] Frozen aliquot of plasma or serum reserved in the event other tests may be requried by the FDA in the future

[ ] The number of units being deglycerolized using one harness should be consistent with the manufacturer's directions

[ ] Expiration date for a deglycerolized unit of blood is 24 hours from the time thawed or 14 days if process in the Haemonetics Model 215 and stored in AS-3

[ ] Approved anticoagulant (units collected in any approved anticoagulant or anticoagulant/preservative solution can be frozen and deglycerolized)

[ ] Units should be sickle trait negative unless firm has special procedure for freezing sickle units

[ ] Unrejuvenated Red Blood Cells should be frozen within 6 days after collection

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Manufacture of Red Blood Cells, Frozen/Rejuvenated/Deglycerolized SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Rejuvenation Procedure SOPs

Confirm that the following details are included in the Rejuvenation Procedure SOPs.

[ ] Rejuvesol is currently the only approved rejuvenating solution and must be used aseptically and according to the manufacturer's directions

[ ] Only units collected in CPD, CPDA-1, and AS-1 can be rejuvenated. CP2D, AS-3, and AS-5 units cannot be rejuvenated

[ ] Units collected in CPD and CPDA-1 can be rejuvenated after 14 days of storage and up to 3 days after expiration

[ ] Expiration date of CPD and CPDA-1 rejuvenated frozen units is 10 years

[ ] Units collected isn AS-1 can be rejuvenated after 14 days storage but no more than 42 days of storage. Expired AS-1 units may not be rejuvenated

[ ] Expiration date of AS-1 rejuvenated frozen units is 3 years

[ ] Only Red Blood Cells from 450 mL Whole Blood units may be rejuvenated

[ ] Rejuvenated CPD and CPDA-1 cells must be washed to remove rejuvenating solution and transfused within 24 hours or frozen. Rejuvenated AS-1 cells may only be frozen (AS-3 and AS-5 Rejuvenated Red Blood Cells cannot be currently frozen)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Rejuvenation Procedure SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Manufacturing Modifications

Quality Control SOPs & Form

Are the sterility tests performed by an outside laboratory? Note: Laboratory must be CLIA-approved.	( ) Yes ( ) No

>	Provide the name and address of the outside laboratory.	
	Outside Laboratory Name	
	Address	
	Telephone Number	
	Fax Number	

Confirm that the following details are included in the Quality Control SOPs.
[ ] Sterility checks using methods approved to test Red Blood Cells. Sterility should be done periodically and continue post-approval. Blood intended for transfusion must not be tested for sterility by a method that entails entering the final container before the blood is issued for transfusion [21 CFR 640.5(d)]
[ ] Quality Control parameters including product acceptance criteria limits
[ ] Monitoring removal of glycerol on each unit (can be performed on either a sample from the last wash or from the unit). Acceptable limits based on methodology used. Acceptable methodologies include determining the amount of free hemoglobin in the final product and determining osmolality
[ ] Determining percent Red Blood Cell recovery, calculated from original volume
[ ] Frequency of quality control tests (periodic and routine) and what tests are performed
[ ] Sterility data (100% no growth)
[ ] Percent Red Blood Cell recovery greater than 80% for 100% of units
[ ] Examination of last wash supernatant (100% clear or less than 3% based on method used)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Quality Control SOP(s) that require approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach the Quality Control form that requires approval from the FDA.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Processes

Section: Alternative Procedures

Alternative Procedures

Note:	The Director, Center for Biologics Evaluation and Research, may approve an exception or alternative to any requirement in subchapter F of chapter I of title 21 of the Code of Federal Regulations regarding blood, blood components, or blood products. Requests for such exceptions or alternative shall ordinarily be in writing. Licensed establishments shall submit such requests in accordance with section 601.12 of this chapter. However, in limited circumstances, such request may be made orally and permission may be given orally by the Director. Oral requests and approvals must be promptly followed by written requests and writted approvals.

Select the alternative procedure(s) applicable for this submission.	[ ] HIV/HCV/HBV Supplemental Testing [ ] Hemochromatosis [ ] Individual Donor Re-entry Request(s) [ ] Other

HIV/HCV/HBV Supplemental Testing

Have all of the HIV/HCV/HBV Supplemental Testing SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned numbers (STN) for any previously-approved HIV/HCV/HBV Supplemental Testing SOPs.	
Item 1	
Item 2	
Item 3	

HIV/HCV/HBV Supplemental Testing SOPs

Select the supplemental tests.	[ ] HCV [ ] HIV [ ] HBV

Confirm that the following details are included in the SOPs for regulation 21 CFR 610.40(e).	
[ ] To not perform supplemental testing for HCV for each donation with a repeatedly reactive anti-HCV EIA screening test only if the individual donation HCV NAT result is either reactive or discriminatory reactive using HCV-specific primers [ ] To not perform supplemental testing for HIV-1 for each donation with a repeatedly reactive anti-HIV EIA screening test only if the individual donation HIV-1 NAT result is either reactive or discriminatory reactive using HIV-specific primers [ ] To not perform supplemental testing for HBV for each donation with a repeatedly reactive HBsAg screening test only if the individual donation HBV NAT result is reactive using an approved HBV NAT	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for regulation 21 CFR 610.46(a)(2&3).

Processes

[ ] For donations that are exempted from supplemental testing as described above, to be exempt from performing HIV-1 supplemental testing and from notifying consignees of distributed products of the results of the HIV-1 supplemental testing

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for regulations 21 CFR 610.47(a)(2&3) and 610.48(a)(2&4).
[ ] For donations that are exempted from supplemental testing as described above, to be exempt from performing HCV supplemental testing and from notifying consignees of distributed products of the results of the HCV supplemental testing

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the SOPs for regulation 21 CFR 630.6(a).
[ ] To be exempt from obtaining HCV supplemental test results for donations with a repeatedly reactive anti-HCV EIA screening test and an individual donation HCV NAT result that is either reactive or discriminatory reactive before notifying donors of their deferral [ ] To be exempt from obtaining HIV-1 supplemental test results for donations with a repeatedly reactive anti-HIV EIA screening test and an individual donation HIV-1 NAT result that is either reactive or discriminatory reactive before notifying donors of their deferral [ ] To be exempt from obtaining HBV supplemental test results for donations with a repeatedly reactive HBsAg screening test and an individual donation HBV NAT result that is reactive using an approved HBV NAT before notifying donors of their deferral

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all HIV/HCV/HBV Supplemental Testing SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Hemochromatosis

Have all of the Hemochromatosis SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned numbers (STN) for any previously-approved Hemochromatosis SOPs.	
Item 1	
Item 2	
Item 3	

Hemochromatosis SOPs

Confirm that the following details are included in the labeling variance for this product.
[ ] A request for alternative procedure from 21 CFR 640.3(d) to collect blood and blood components from donors with

Processes

hereditary hemochromatosis, without special labeling [ ] Informed consent, or other written acknowledgement signed by the donor stating that the donor will not be charged a fee for the phlebotomy even if he or she is found to be ineligible as an allogeneic blood donor

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Are you requesting to omit the physician examination if the donor returns within eight weeks of donation?	( ) Yes ( ) No

Confirm that the following detail is included in the physician examination variance.
[ ] A request for alternative procedure from 21 CFR 640.3(f) under the provisions of 21 CFR 640.120 to collect blood products from donors with hereditary hemochromatosis more frequently than every 8 weeks, without examination by a physician at the time of donation, provided donor has a physician's prescription (bearing instructions regarding frequency of phlebotomy and hematocrit/hemoglobin limits) for therapeutic phlebotomy for hemochromatosis

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Hemochromatosis SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Individual Donor Re-entry Request(s)

Attach applicable documentation for your request.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other

Attach applicable documentation for your request.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Computer-Assisted Interactive Donor History

Computer-Assisted Interactive Donor History (CASI)

Have all of the Computer-Assisted Interactive Donor History SOPs been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned numbers (STN) for any previously-approved Computer-Assisted Interactive Donor History SOPs.	
Item 1	
Item 2	

Processes

Item 3	

Select the type of CASI used by your firm.	( ) Web-Based (Can Be Accessed Remotely) ( ) Non Web-Based (Only Used In-House)

Software Overview

Enter the name of the software manufacturer.
Enter the name of the software program.
Enter the version or release number of the software program.

Confirm that the following items are included in the description of the CASI program's capabilities and functions.
[ ] Whether donor suitability decisions are made exclusively by the computer program or by blood center personnel [ ] If the system is interfaced (i.e., connected) with regulated devices (e.g., blood establishment computer software (BECS) or other instruments) [ ] Whether program is accessible outside of the facility [ ] If the system is interfaced at other locations where program is installed or it is a stand-alone system [ ] If the CASI is accessable from a remote location over the internet (web-based CASI) [ ] Whether the computer software is 510(k) cleared

Enter the BK number of the 510(k) submission.	

>	Explain why the appropriate information is not included in your SOPs.
	[Multi-Line Plain Text]

Select the questionnaire that is being administered by the computer.	( ) Firm's own questionnaire ( ) DHQ (accepted by FDA in a guidance document)

Are the medical history questions and/or AIDS high risk questions administered by the computer?	( ) Yes ( ) No

Provide the descriptive titles of the individuals who can modify the software (e.g., software manufacturer, user, etc.).	
Individual 1	
Individual 2	
Individual 3	

Attach a copy of any instructions given to donors on how to use the computer program. If applicable, include any additional instructions needed for the web-based CASI.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Processes

Attach a copy of the printed questionnaire.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach screenshots of all screens. (Note: If you have been already approved for an on-site CASI and are now applying for a web-based CASI, include only those new screens applicable to the web-based CASI.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Is the questionnaire administered on the computer in multiple languages?	( ) Yes ( ) No

>	Provide a description of the proficiency of the translator(s) of the appropriate languague(s).
	[Multi-Line Plain Text]

Attach the on-site validation protocol to describe the process used to validate the software. This should address testing of interfaces and upgrade and revalidation protocols. (Note: Do not submit the actual validation data. If you are already approved for an on-site CASI and are now applying for a web-based CASI, include the validation protocol for the web-based CASI.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

System Location(s)

List the facilities, donor centers, and/or mobiles where the system will be installed and used.	
Location 1	
Location 2	
Location 3	

Provide a description of the interfaces between locations, if applicable.
[Multi-Line Plain Text]

Data Collection and Security

Provide a description of who is authorized to access the system and enter or change data.
[Multi-Line Plain Text]

Provide a description of how access to the system is managed (e.g., authorization/deauthorization procedures).
[Multi-Line Plain Text]

Donor Interviews and Personnel Responsibilities SOPs

Confirm that the following details are included in the CASI Donor Interviews and Responsibilites of Center Personnel SOPs.

Processes

[ ] Who may use the program, i.e., new donors and/or repeat donors

[ ] The definition of new versus repeat donors

[ ] Description of alternatives for donor screening, if the donor does not wish to use or is unable to use the computer-assisted screening program (e.g., visually impaired individuals)

[ ] How the privacy of donors during screening is assured (e.g., private screening booths)

[ ] Availability of staff if donor has a question

[ ] How changes to donor responses or interviewer's comments are documented

[ ] Methods used to assess the donor's comprehension of questions and documentation of this assessment

[ ] How the donor's signature is obtained

[ ] Review of the donor history questionnaire by staff before blood collection, if applicable, and documentation of review

[ ] Alternative procedures if the computer system is unavailable

[ ] How revisions to the questionnaire are handled (e.g., donors are administered new questions by direct oral questioning, etc.) [Note: Revised and new questions should be highlighted in some manner for at least one year so that donors will be aware of the change]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all CASI Donor Interviews and Personnel Responsibilities SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Web-Based CASI SOPs

Confirm that the following details are included in the Web-Based CASI SOPs.

[ ] How donors would gain access to the system (i.e., is the program password protected?)

[ ] How donors would contact the center if they have questions while completing the questionnaire

[ ] Confirming the donor's identity when he/she arrives at the donor center

[ ] Determining if the donor completed the questionnaire in a private setting

[ ] Determining if the questionnaire was completed on the day of donation and actions to take if the donor appears the day after he/she completed the questionnaire [Note: The ability to obtain clarifying information within 24 hours after donation does not allow the donor to come in to donate the day after completing the questionnaire]

[ ] When the informed consent will be administered (e.g., on-site or while completing the web-based questionnaire)

[ ] Documenting (electronic or hard copy) responses to all questions including questions the donor center may ask the donor about how he/she completed the questionnaire

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Web-Based CASI SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Sterile Connecting Devices

Sterile Connecting Devices

Processes

Have all of the Sterile Connecting Devices SOPs been previously submitted to the FDA?	( ) Yes ( ) No

Enter the FDA-assigned numbers (STN) for any previously-approved Sterile Connecting Device SOPs.	
Item 1	
Item 2	
Item 3	

Sterile Connecting Devices SOPs

Select the uses of your Sterile Connecting Device (STCD).

[ ] Add a new or smaller needle to a blood collection set
[ ] Prepare components
[ ] Pool blood components
[ ] Make aliquots for pediatric use or divided units of Whole Blood, Red Blood Cells, or Fresh Frozen Plasma
[ ] Attach processing solutions (glycerol, saline)
[ ] Attach an FDA-cleared Leukocyte Reduction filter
[ ] Remove samples from blood products for testing

Confirm that the following details are included in the STCD SOPs.

[ ] An explanation of changes in the assembly of collection and storage containers and in processing steps that involve the STCD for every product made
[ ] Techniques for the detection of leakage or air bubbles (including specific instructions for handling products with faulty welds)
[ ] Procedures for labeling aliquots or split products. Record keeping should be adequate to permit tracking and recall of all components
[ ] A desctiption of the minimum volume of split products. (Final container labeling may need to be revised to reflect different product volumes)

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that your records reflect the following details.

[ ] Date of the sterile connection
[ ] Lot numbers of the original containers and needles, and of those being added
[ ] Lot number of the STCD wafer
[ ] Initials of the individual preparing the containers
[ ] Record of each STCD weld inspection
[ ] Any corrective action taken

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Note:	The preparation of non-standard blood components using an STCD is limited to research settings only, and should be conducted only under an investigational new drug exemption.

Processes

Note:	Split or divided products are not considered new products, and do not require a BLA supplement as long as the manufacturer is licensed for the original product, including approval for each anticoagulant used, and final product containers approved for storage of the component being prepared are used. New labels should be submitted for review.

Attach all Sterile Connecting Device SOPs.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Autologous Donations

Autologous Donations

Have all of the Autologous Donations SOPs--including manufacturing and labeling--been previously approved by the FDA?	( ) Yes ( ) No

Select the Standard Operating Procedures (SOPs) that are being submitted for approval by the FDA in this submission.	
[ ] Manufacturing [ ] Labeling	
Information:	An unselected checkbox implies that the SOPs have been previously approved by the FDA. Please ensure that the FDA-assigned number(s) (STN) for all previously-approved SOPs have been included in the table below.

Enter the FDA-assigned numbers (STN) for any previously-approved Autologous Donations SOPs.	
Item 1	
Item 2	
Item 3	

Manufacturing SOPs

Confirm that the following details are included in the Autologous Donations Manufacturing SOPs.	
[ ] Written orders from the physician for autologous donations [ ] Criteria checklists for donor suitability and donor AIDS questions. (If not crossing over, do not need to ask AIDS questions.) [ ] Minimum Hct of 33% of Hgb of 11 gm/dL^2 [ ] Interval of donation up to physicians. Last donation should not be drawn within 72 hours of anticipated surgery [ ] Written consent to the procedure that should include all of the information required for allogeneic donation (physician and state Department of Health notification, window period testing, permanent deferral list if positive results) [ ] Disposition of unused products [ ] The policy for the use of autologous blood that meets normal donor suitability criteria for allogeneic use	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the Autologous Donations SOPs regarding low volume.

Processes

[ ] Do not need to adjust the anticoagulant unless drawing less than 300 mL of blood

[ ] All units containing less than 405 mL are to be labeled as Low Volume units

[ ] All components may be made from autologous low volume units provided that the anticoagulant is adjusted if plasma components are prepared

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the Autologous Donations SOPs regarding testing.

[ ] All FDA required tests (HBsAg, HIV, syphilis) should be performed. Donors who are repeatedly reactive for HIV or HBsAg must be permanently deferred for allogeneic donations.

[ ] Exception to testing requirement may be made if the blood products are only for the autologous donor, are used at the site of collection, and all products not used by the donor are destroyed. This does not apply to licensed autologous blood.

[ ] Required tests may be performed on the first unit of blood collected from a donor in a 30-day period; subsequent units should be labeled appropriately.

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following details are included in the Autologous Donations SOPs regarding reactive units.

[ ] Units that are confirmed positive for HIV, HCV, or HBsAg may be distributed only for autologous use provided that a written, signed, and dated request is received fromt he patient's physician

[ ] Syphilis-confirmed positive, anti-HTLV-I/II, or anti-HBc repeatedly reactive units require notification of the patient's physician

[ ] Autologous units that are repeatedly reactive for any of the infectious disease markers, without a negative confirmatory test, should be permanently labeled with a biohazard label prior to release for transfusion

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Autologous Donations Manufacturing SOPs that require FDA approval.

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Labeling SOPs

Confirm that the following details are included in the Autologous Donations Labeling SOPs.

[ ] Information adequately identifying patient (e.g., name, blood group, hospital, identification number)

[ ] Date of donation

[ ] The statement, "FOR AUTOLOGOUS USE ONLY"

[ ] If donor fails to meet any of the Whole Blood donor suitability requirements, "FOR AUTOLOGOUS USE ONLY" label in place of blood group label

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Confirm that the following variances have been granted under 21 CFR 640.120.

Processes

[ ] 21 CFR 606.121(c)(5) for "Autologous Donations" [ ] 21 CFR 606.121(d) for green full-face label [ ] 21 CFR 606.121(d)(2) for black ink

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Do the Autologous Donations Labeling SOPs use standard product codes?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach all Autologous Donations Labeling SOPs that require FDA approval.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Other Process

Other

Have all of the SOPs for this process been previously approved by the FDA?	( ) Yes ( ) No

Enter the FDA-assigned numbers (STN) for any previously-approved SOPs.	
Item 1	
Item 2	
Item 3	

Enter any additional information that you wish to provide about this process.
[Multi-Line Plain Text]

Attach any applicable documents.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Details	[Multi-Line Plain Text]

BLA Labeling

Section: Labeling - General

Labeling

Are you submitting new or revised labels as part of the submission? Note: A Circular of Information is considered a label.	( ) Yes ( ) No

A previously approved label(s) or Instruction Circular (e.g. "Circular of Information") is being used without change. Provide the FDA-assigned number(s) (STN) to reference the previously approved label(s).

STN 1	
STN 2	
STN 3	

Part I. Transmittal of Labels and Circulars

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

TRANSMITTAL OF LABELS AND CIRCULARS

Form Approved: OMB Number 0910-0338

Expiration Date: September 30, 2008

CHECK ONE:	( ) Draft ( ) Final (in distribution)

Note:	NOTE: No license may be granted unless this completed submittal form has been received (U.S. Public Health Service Act, Section 351; the Federal Food, Drug, and Cosmetic Act, Section 502; and Title 21 U.S. Code of Federal Regulations, Part 600).

MANUFACTURER NAME AND RETURN ADDRESS	
Establishment Name	
Address	
Registration	

LICENSE NO.	
PRODUCT NAME	
[Multi-Line Plain Text]	

BLA Labeling

Part II. Labeling Details and Comments

LABELING DETAILS

LABEL TYPE CODE
[ ] CIRC (Circular) [ ] CONT (Container) [ ] PACK (Package) [ ] DILT (Diluent) [ ] BLST (Bilster) [ ] CRTN (Carton) [ ] PCKR (Packer) [ ] SHIP (Shipping) [ ] BULK (Bulk) [ ] OTHR (Other)

REPLACES PREVIOUS LABEL

REVIEW AND REVISION NO.	
DATE	[Date]

SUBMISSION REASONS (Check all that apply)	
[ ] Anticoagulant/Additive Change [ ] Contraindications, Adverse Reactions, Precautions [ ] Dosage Change [ ] Editorial, Format [ ] Manufacturing Method Change [ ] New Formulation [ ] New Indication [ ] New Product [ ] New Scientific Information [ ] Other (specify)	
>	If Other, please specify. Additional notes can be provided in the COMMENTS section below.

SELECT IF THIS LABELING IS IN SUPPORT OF:		( ) Application ( ) Supplement ( ) Part of an Annual Report
>	Associated BLA/PLA No.	

COMMENTS (Include any Manuf. ID number, description or revision no. of label being replaced.)
[Multi-Line Plain Text]

BLA Labeling

Circular of Information

Are you submitting a new or revised Circular of Information as part of this submission?	( ) Yes ( ) No ( ) Not Applicable

Are you using the AABB/ARC/ABC Circular of Information?		( ) Yes ( ) No
>	What version of the Circular of Information are you using?	

Attach the Circular of Information.	
File Attachment	[Single File Attachment (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Source Plasma

Source Plasma Donor Type Specifics

Note:	The following section(s) are intended to verify that labeling contains the appropriate information for applicable donor types.

Normal

Item: 1 (could contain up to 1000 items with none required)

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

BLA Labeling

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Does this label include an infectious disease test statement?	( ) Yes

BLA Labeling

	( ) No
>	Please enter the infectious disease test statement.
	[Multi-Line Plain Text]
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?	( ) Yes ( ) No
>	Is biohazard labeling included? ( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Vaccine Immunization Program

Item: 1 (could contain up to 1000 items with none required)

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21

CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?	( ) Yes ( ) No
> Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

BLA Labeling

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label include an infectious disease test statement?	( ) Yes ( ) No

>	Please enter the infectious disease test statement.
	[Multi-Line Plain Text]
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?	( ) Yes ( ) No

>	Is biohazard labeling included?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the name of the licensed vaccine listed on this label?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.

BLA Labeling

	[Multi-Line Plain Text]

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Red Blood Cell Immunization Program

Select the products that you are requesting in this submission:		
>	Whole Blood and/or Red Blood Cells for Further Manufacturing	( ) Yes ( ) No
>	Glycerolized Immunogen Red Blood Cells	( ) Yes ( ) No
>	Aliquots of Deglycerolized Immunogen Red Blood Cells	( ) Yes ( ) No
>	Syringe(s) with Deglycerolized Immunogen Red Blood Cells	( ) Yes ( ) No

Source Plasma Labels

Item: 1 (could contain up to 1000 items with none required)

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	

BLA Labeling

	[Multi-Line Plain Text]

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Does this label include an infectious disease test statement?	( ) Yes ( ) No
>	Please enter the infectious disease test statement.
	[Multi-Line Plain Text]
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?	( ) Yes ( ) No
>	Is biohazard labeling included? ( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is Source Plasma label for immunized plasma included?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on the label.
	[Multi-Line Plain Text]

Is the immunogen Red Blood Cell antigen listed on this label?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the immunogen Red Blood Cell antibody listed on this label?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Other Applicable Labels

Whole Blood and/or Red Blood Cells for Further Manufacturing

Do you have a previously-approved label for Whole Blood and/or Red Blood Cells for further manufacturing into immunogen Red Blood Cells?	( ) Yes ( ) No
> Enter the previously-approved FDA-assigned number (STN).	

Is the label for Whole Blood and/or Red Blood Cells for further manufacturing into immunogen Red Blood Cells included?	( ) Yes ( ) No
> Please explain why the appropriate information is not included.	
[Multi-Line Plain Text]	

Attach label(s) for Whole Blood and/or Red Blood Cells for further manufacturing into immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Glycerolized Red Blood Cells

Do you have a previously-approved label for glycerolized immunogen Red Blood Cells?	( ) Yes ( ) No
> Enter the previously-approved FDA-assigned number (STN).	

Is the label for glycerolized immunogen Red Blood Cells included?	( ) Yes ( ) No
> Please explain why the appropriate information is not included.	
[Multi-Line Plain Text]	

Attach label(s) for glycerolized immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Aliquots of Deglycerolized Immunogen Red Blood Cells

Do you have a previously-approved label for aliquots of deglycerolized immunogen Red Blood Cells?	( ) Yes

BLA Labeling

		( ) No
>	Enter the previously-approved FDA-assigned number (STN).	

Is the label for aliquots of deglycerolized immunogen Red Blood Cells included?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach label(s) for aliquots of deglycerolized immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Syringes with Deglycerolized Immunogen Red Blood Cells

Do you have a previously-approved label for syringes of deglycerolized immunogen Red Blood Cells?		( ) Yes ( ) No
>	Enter the previously-approved FDA-assigned number (STN).	

Will immunogen Red Blood Cells be temporarily stored in syringe (at 1-6C) for a period of time prior to injection? Answering "No" implies Red Blood Cells will be immediately injected.		( ) Yes ( ) No
>	Is the label for the syringe with deglycerolized immunogen Red Blood Cells to be stored at 1-6 C included?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach label(s) for syringes of deglycerolized immunogen Red Blood Cells.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor with a Pre-Existing Disease-Associated Antibody (IgG only)

Item: 1 (could contain up to 100 items with none required)

Select the type of product for manufacturing.	( ) Injectable Product ( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21

CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?	( ) Yes ( ) No
> Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Enter the storage temperature. (Injectable Products: -20C or colder; Noninjectable Products: set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

BLA Labeling

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label include an infectious disease test statement?	( ) Yes ( ) No

>	Please enter the infectious disease test statement.
	[Multi-Line Plain Text]
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?	( ) Yes ( ) No

>	Is biohazard labeling included?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label have a blank space to write in the antibody?	( ) Yes ( ) No
Select the specific antibody label(s) you are submitting.	

BLA Labeling

Item 1	
Item 2	
Item 3	

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor in a Disease State with an Antibody (IgG and/or IgM)

Item: 1 (could contain up to 1000 items with none required)

Select the type of product for manufacturing.	( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

BLA Labeling

Is the donor or bleed number included on this label?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the storage temperature (set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Does the product test positive for communicable disease agents?		( ) Yes ( ) No
>	Is biohazard labeling included? Note: All IgM antibody products should be labeled as "Biohazard".	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does this label specifically state the disease condition?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor with a High-Risk Status

Item: 1 (could contain up to 1000 items with none required)

Select the type of product for manufacturing.	( ) Noninjectable Product

Enter proper product name (must be in a prominent position and size [21 CFR 610.62]).

Select which of the following statements is contained on this label (must be in same size and type as proper name [21 CFR 640.70]).	
[L]	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is this product syphilis reactive?		( ) Yes ( ) No
>	Does this label include the statement, "Use Only for the Manufacture of Positive Control Reagents for the Serologic Test for Syphilis" [21 CFR 640.70(a)(9)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

BLA Labeling

Enter the name and address of the manufacturer on submitted label. If this label applies to all facilities, enter the establishment (headquarters) address.	
Establishment Name	
Address	

Enter the license number.	

Enter the registration number, if applicable.	

Is the donor or bleed number included on this label?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date less than or equal to ten years?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the storage temperature (set by consignee).	

Is there space for the total plasma volume or weight?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the name of anticoagulant.	

Is there space for the total volume of anticoagulant?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label indicate that the product was collected by automated method?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include HIV, HBV, and HCV viral marker test results?	( ) Yes

BLA Labeling

	( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the infectious disease test statement include an anti-HBc test statement?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the product test positive for communicable disease agents?		( ) Yes ( ) No
>	Does product and sample label include a "Biohazard" legend [610.40(h)(2)(ii)(B)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does this label contain the specific viral marker or risk factor (for example, positive for anti-HIV, reactive for HIV-1 RNA, positive for anti-HCV, reactive for HCV RNA, or reactive for HBsAg)?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Please add any additional comments about this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Donor Participating in an IND Study

Note:	Please contact your Consumer Safety Officer (CSO) to determine specific requirements for IND labeling.

Section: Labeling - Whole Blood

Whole Blood

Select the labeling standard being followed for your new or revised Whole Blood labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved
Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	

BLA Labeling

STN 1	
STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].		[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the product volume [21 CFR 606.121(c)(6)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	

BLA Labeling

	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the unit number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the expiration date [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select how the ABO group is displayed on the label [21 CFR 606.121(c)(12)].	( ) Black & White ( ) Color

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

BLA Labeling

ISBT

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].		[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the product volume [21 CFR 606.121(c)(6)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

BLA Labeling

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the ABO and Rh groups with the correct ISBT code [21 CFR 606.121(c)(12)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

BLA Labeling

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Red Blood Cells (Manual)

Red Blood Cells (Manual)

Select the labeling standard being followed for your new or revised Red Blood Cells (Manual) labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved

Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	
STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

BLA Labeling

Does this label display the correct eye-readable product code?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the unit number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No

BLA Labeling

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the expiration date [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select how the ABO group is displayed on the label [21 CFR 606.121(c)(12)].	( ) Black & White ( ) Color

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Caution: For Manufacturing Use Only" [ ] "Caution: For Research Use Only"

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

BLA Labeling

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No

BLA Labeling

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the ABO and Rh groups with the correct ISBT code [21 CFR 606.121(c)(12)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Caution: For Manufacturing Use Only" [ ] "Caution: For Laboratory Research Use Only" [ ] "Caution: For Use in Manufacturing Non-Injectable Products Only"
> Please explain why the appropriate information is not included.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Platelets (Manual)

Platelets (Manual)

Select the labeling standard being followed for your new or revised Platelets (Manual) labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved

Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	
STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

Does this label display the correct eye-readable product code?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

BLA Labeling

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the unit number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the expiration date [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select how the ABO group is displayed on the label [21 CFR 606.121(c)(12)].	( ) Black & White ( ) Color

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Caution: For Manufacturing Use Only"

BLA Labeling

[ ] "Caution: For Research Use Only"	
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

Does this label display the correct eye-readable product code?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i);	[L]

606.121(e)(1)(ii); 606.121(e)(2)(i)].	

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].		[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the product volume [21 CFR 606.121(c)(6)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

BLA Labeling

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the ABO and Rh groups with the correct ISBT code [21 CFR 606.121(c)(12)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Caution: For Manufacturing Use Only" [ ] "Caution: For Laboratory Research Use Only" [ ] "Caution: For Use in Manufacturing Non-Injectable Products Only"
> Please explain why the appropriate information is not included.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Plasma (Manual)

Plasma (Manual)

Select the labeling standard being followed for your new or revised Plasma (Manual) labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved
Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	
STN 2	

BLA Labeling

STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]

>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

BLA Labeling

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the unit number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the expiration date [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select how the ABO group is displayed on the label [21 CFR 606.121(c)(12)].	( ) Black & White ( ) Color

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]

BLA Labeling

If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

Does this label display the correct eye-readable product code?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Select the volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]
If Other, enter the volume.	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the volume of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

BLA Labeling

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Is the expiration date of this product less than 72 hours?		( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the ABO and Rh groups with the correct ISBT code [21 CFR 606.121(c)(12)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Attach label(s).

BLA Labeling

File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Red Blood Cells (Automated)

Red Blood Cells (Automated)

Select the labeling standard being followed for your new or revised Red Blood Cells (Automated) labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved

Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	
STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the name and volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

BLA Labeling

Select the amount of sodium in additive solution.	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].		[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the product volume [21 CFR 606.121(c)(6)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does the label display the unit number [21 CFR 606.121(c)(3)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does the label display the expiration date [21 CFR 606.121(c)(4)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Select how the ABO and Rh groups are displayed on the label [21 CFR 606.121(c)(12)].	( ) Black & White ( ) Color

BLA Labeling

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Is this an Autologous label?	( ) Yes ( ) No

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the name and volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]

BLA Labeling

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer [21 CFR 606.121(c)(2)].	

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.

BLA Labeling

	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the ABO and Rh group with the correct ISBT code [21 CFR 606.121(c)(12)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Platelets (Automated)

Platelets (Automated)

Select the labeling standard being followed for your new or revised Platelets (Automated) labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved
Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	

BLA Labeling

STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(ii)].	[L]

Does this label display the quantity of anticoagulant [21 CFR 606.121(e)(1)(i)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the platelet volume expressed within +/-10% or the volume range [21 CFR 606.121(c)(6)]?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes

BLA Labeling

	( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the unit number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the expiration date [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select how the ABO and Rh groups are displayed on the label [21 CFR 606.121(c)(12)].	( ) Black & White ( ) Color

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

BLA Labeling

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does the label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(ii)].	[L]

Does this label display the quantity of anticoagulant [21 CFR 606.121(e)(1)(i)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]

>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the platelet volume expressed within +/-10% or the volume range [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes

BLA Labeling

	( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer [21 CFR 606.121(c)(2)].	

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the ABO and Rh group with the correct ISBT code [21 CFR 606.121(c)(12)]?	

BLA Labeling

	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Fresh Frozen Plasma (Automated)

Fresh Frozen Plasma (Automated)

Select the labeling standard being followed for your new or revised Fresh Frozen Plasma (Automated) labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved
Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	
STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

BLA Labeling

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the name and volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the unit number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Does the label display the expiration date [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select how the ABO and Rh groups are displayed on the label [21 CFR 606.121(c)(12)].	( ) Black & White ( ) Color

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label contain the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable

BLA Labeling

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name of the source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the name of the anticoagulant/preservative [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]

Does the label display the product volume [21 CFR 606.121(c)(6)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer [21 CFR 606.121(c)(2)].	

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.

BLA Labeling

	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the ABO and Rh group with the correct ISBT code [21 CFR 606.121(c)(12)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Source Leukocytes

Source Leukocytes

Select the labeling standard being followed for your new or revised Source Leukocytes labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved
Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	

BLA Labeling

STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with 1 required)

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Caution: For Manufacturing Use Only" [ ] "Caution: For Research Use Only"

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number included on the label.	

Does the label display the donor, lot, or pool number(s) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does this label display the collection date?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	( ) Less than 10C ( ) Other
Enter the storage temperature.	

Does the label display the quantity of the product?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Does the label display the name and quantity of the anticoagulant?	( ) Yes ( ) No
Enter the name of the anticoagulant.	
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Select the test statement(s) included on the label.
[ ] "Negative by tests for HIV-1 antigen, antibodies to HIV, HBc, HCV, HTLV I/II, and nonreactive for HBsAg and syphilis" or equivalent [ ] "Negative by tests for antibodies to HIV, Hbc, HCV, and HTLV I/II and nonreactive for HBsAg, HCV RNA and HIV-1 RNA and syphilis" or equivalent [ ] "Caution: Do not use until results for _____ have been received from collection facility" or equivalent [ ] Other
If Other, enter the test statement.
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

Does the label indicate that the method of collection was automated?	( ) Yes ( ) No
> Please explain why the appropriate information is not included on this label.	
[Multi-Line Plain Text]	

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with 1 required)

BLA Labeling

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Caution: For Manufacturing Use Only" [ ] "Caution: For Laboratory Research Use Only" [ ] "Caution: For Use in Manufacturing Non-Injectable Products Only"

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number included on the label.	

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the collection date?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Select the storage temperature for the product displayed on the label.	( ) Less than 10C ( ) 20C to 24C ( ) Other
Enter the storage temperature.	

Does the label display the quantity of the product?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name and volume of the source blood?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the name of the anticoagulant?	( ) Yes ( ) No
Enter the name of the anticoagulant.	
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the test statements included on the label.
[ ] "Negative by tests for HIV-1 antigen, antibodies to HIV, HBc, HCV, HTLV I/II, and nonreactive for HBsAg and syphilis" or equivalent [ ] "Negative by tests for antibodies to HIV, Hbc, HCV, and HTLV I/II and nonreactive for HBsAg, HCV RNA and HIV-1 RNA and syphilis" or equivalent [ ] "Caution: Do not use until results for _____ have been received from collection facility" or equivalent [ ] Other
If Other, enter the test statement.
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Cryoprecipitated AHF

Cryoprecipitated AHF

BLA Labeling

Select the labeling standard being followed for your new or revised Cryoprecipitated AHF labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved

Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	
STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with 1 required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?		( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.	
	[Multi-Line Plain Text]	

Select the name and volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]

Select the name of the source blood anticoagulant [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].		[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.	
	[Multi-Line Plain Text]	

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No

BLA Labeling

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the donor or lot number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select how the ABO group is displayed on the label [21 CFR 606.121(c)(12)].	( ) Color ( ) Black & White

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

BLA Labeling

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with 1 required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]

>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer [21 CFR 606.121(c)(2)].	

BLA Labeling

Does the label display the correct facility code [first four numerical digits of the Donation Identification Number (DIN)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the ABO group with the correct ISBT code [21 CFR 606.121(c)(12)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)]

BLA Labeling

[ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)]
[ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)]
[ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Section: Labeling - Pooled Cryoprecipitated AHF

Pooled Cryoprecipitated AHF

Select the labeling standard being followed for your new or revised Pooled Cryoprecipitated AHF labels included in this submission, or indicate that your labels have been previously approved.	( ) Codabar ( ) ISBT ( ) Labels Have Been Previously Approved

Provide the FDA-assigned number(s) (STN) to reference previously approved label(s).	
STN 1	
STN 2	
STN 3	

Codabar

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Select the name and volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]

Select the name of the source blood anticoagulant [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Does the label display the product volume?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label indicate the number of units in the pool?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]
>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the donor or lot number [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

BLA Labeling

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select how the ABO group is displayed on the label [21 CFR 606.121(c)(12)].	( ) Color ( ) Black & White

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

Attach label(s). (NOTE: The machine-readable bar coding is not reviewed for accuracy.)	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

ISBT

Item: 1 (could contain up to 1000 items with none required)

Is this a Product Overlay Label?	( ) Yes ( ) No

Enter proper product name (must be in a prominent position and size) [21 CFR 606.121(c)(1)].

Select the product modification.	[L]
If Other, enter the modification.	

Does this label display the correct eye-readable product code?	( ) Yes ( ) No

BLA Labeling

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the modifier and attribute in the correct format?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the name and volume of source blood [CFR 21 606.121(c)(10); 606.121(e)(2)(i)].	[L]

Select the name of the source blood anticoagulant [21 CFR 606.121(e)(1)(i); 606.121(e)(1)(ii); 606.121(e)(2)(i)].	[L]

Does the label display the product volume?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label indicate the number of units in the pool?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the displayed recommended storage temperature (in degrees Celsius) [21 CFR 606.121(c)(7)].	[L]

>	If Other, enter the displayed storage temperature. If Not Displayed, please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the label display the name and address of the manufacturer [21 CFR 606.121(c)(2)]?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Enter the US license number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Enter the registration number of the manufacturer included on the label [21 CFR 606.121(c)(2)].	

Does the label display the donor classification in the same prominence as the proper product name [21 CFR 606.121(c)(5)]?	( ) Yes ( ) No

BLA Labeling

>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the Donation Identification Number (DIN) [21 CFR 606.121(c)(3)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display all of the letters and numbers in the DIN in a uniform font size and prominence?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Is the expiration date of this product less than 72 hours?	( ) Yes ( ) No
Does the label display the expiration date with a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]
Does the label display the expiration date without a printed expiration time [21 CFR 606.121(c)(4)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Does the label display the ABO group with the correct ISBT code [21 CFR 606.121(c)(12)]?	( ) Yes ( ) No
>	Please explain why the appropriate information is not included on this label.
	[Multi-Line Plain Text]

Select the Caution Statements included or enter N/A in the field below if Caution Statements do not apply to this label.
[ ] "Rx Only" [21 CFR 606.121(c)(8)(i)] [ ] "See Circular of Information for indications, contraindications, cautions, and methods of infusion" [21 CFR 606.121(c)(8)(ii)] [ ] "Properly identify intended recipient" [21 CFR 606.121(c)(8)(iii)] [ ] "This product may transmit infectious agents" [21 CFR 606.121(c)(9)]
> Please explain why the appropriate information is not included on this label.
[Multi-Line Plain Text]

Attach label(s).	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv,

	.zip)]

Validation & Quality Control Data

Section: Validation & Quality Control Data

Validation

Are you submitting validation as a part of this submission?	( ) Yes ( ) No ( ) Not Applicable

>	Select the products for which you are submitting validation data.
	[ ] Red Blood Cells [ ] Plasma (Automated) [ ] Platelet Pheresis [ ] Cryoprecipitated AHF [ ] Pooled Cryoprecipitated AHF

Red Blood Cells Validation

Confirm that the following details are included in the validation criteria for this product.
[ ] The inclusion of testing of 100 consecutive units - including singles and doubles - from all devices [ ] The actual validation results are compared to the actual/target value or a minimum hemoglobin/absolute Red Blood Cell per the manufacturer's directions

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach a summary of the Red Blood Cell validation for each facilitiy.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Plasma (Automated) Validation

Attach the Plasma validation plan.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Was the Plasma validation acceptable?	( ) Yes ( ) No

Attach the Plasma validation summary.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Platelet Pheresis Validation

Note:	Confirm that the following details are included in the validation criteria for this product.

Validation & Quality Control Data

Was an Equipment Installation Qualification performed and documented?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Does the Validation Protocol include all of the following items?	( ) Yes ( ) No

- A description of the equipment to be used
- Minimum/maximum acceptable values for the Platelets, Pheresis collection and/or component as specified by the automated blood cell separator device manufacturer
  - Total volume (after removal of samples for hematological testing and bacterial contamination testing), including per component (container) from double and triple collections
  - Actual Platelet yield
  - Residual White Blood Cell count (if Leukocytes Reduced) for the collection and components (if multiple components are colelcted), and percent Platelet retention when applicable
  - Concurrent component volume
  - pH measurement
- Manufacturer's specifications or recommendations for procesing parameters (i.e., actual Platelet yield and concentration, weight or volume collected)
- Description of supplies used in the collection (e.g., collection/storage containers, anticoagulants, etc.)
- Failure investigation criteria
- Personnel training criteria
- Standard operating procedures for performing each element of the collection process
- Documentation of the validation protocol criteria

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach the Validation Protocol.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Was each person engaged in the collection of Platelets, Pheresis, or training qualified to use the automated blood cell separator device?	( ) Yes ( ) No

Validation & Quality Control Data

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Did the product performance qualification for component collection process include all the following items?	( ) Yes ( ) No

- Actual Platelet yield (Platelet count x volume)
- pH as a measurement of quality after storage
- Percent Platelet retention
- Residual White Blood Cell count
- Volume

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is the following recommended Statistical Sampling Plan being used per device, per facility?	( ) Yes ( ) No

Test	Recommended Results	Target	Allowable Process Failures		
Actual Platelet yield of transfusable component	3.0×10^{11}	95%/75%	N=11	N=18	N=23

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is the following recommended Statistical Sampling Plan being used per device, per Blood Center?	( ) Yes ( ) No

Test	Recommended Results	Target	Allowable Process Failures		
pH	6.2	95%/95%	N=60	N=93	N=124

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is the following recommended Statistical Sampling Plan being used per device, per facility?	( ) Yes ( ) No

Test	Recommended Results	Target	Allowable Process Failures

Validation & Quality Control Data

Percent component retention	85% component retention if performed	95%/95%	N=60	N=93	N=124

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Is the following recommended Statistical Sampling Plan being used per device, per Blood Center?	( ) Yes ( ) No

Test	Recommended Results	Target	Allowable Process Failures		
Residual White Blood Cell count	Single Collection: < 5.0×10^6	95%/95%	N=60	N=93	N=124
0	1	2	Double Collection: Collection: < 8.0×10^6 or Components: < 5.0×10^6	95%/95%	N=60
N=93	N=124	0	1	2	Triple Collection: Collection: < 1.2 x 107 or Components: < 5.0 x 106
95%/95%	N=60	N=93	N=124	0	1

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Are any re-qualification/re-validation procedures for exceeding the allowable process failures included?	( ) Yes ( ) No

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Validation & Quality Control Data

Are any performance failure investigations included?	( ) Yes ( ) No ( ) Not Applicable

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Cryoprecipitated AHF Validation

Attach applicable documentation for Cryoprecipitated AHF validation.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Pooled Cryoprecipitated AHF Validation

Attach applicable documentation for Pooled Cryoprecipitated AHF validation.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Quality Control Data

Are you submitting quality control data as a part of this submission?	( ) Yes ( ) No ( ) Not Applicable

>	Select the products for which you are submitting quality control data.
	[ ] Red Blood Cells [ ] Platelet Pheresis [ ] Leukocyte Reduction [ ] Red Blood Cells, Washed [ ] Red Blood Cells, Frozen/Rejuvenated/Deglycerolized [ ] Cryoprecipitated AHF [ ] Pooled Cryoprecipitated AHF

Red Blood Cells Quality Control Data

Confirm that the following details are included in the Red Blood Cells quality control sheets.
[ ] Facility [21 CFR 211.194(a)(1)] [ ] Device manufacturer and type [21 CFR 211.194(a)(2)] [ ] Blood Unit Number [21 CFR 606.140(c)] [ ] Date of collection [21 CFR 211.194(a)(1)] [ ] Date of testing [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Interpretation of results [21 CFR 211.194(a)(6); 606.160(a)(1); 606.160(a)(2)(i)] [ ] Interpretation of month [ ] Yield [21 CFR 211.103; 211.186(b)(7)] [ ] Acceptable criteria [21 CFR 211.165(d)] [ ] Initials [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)]

Validation & Quality Control Data

[ ] Evidence of review [21 CFR 211.194(a)(8); 211.103] [ ] Records of calculations [21 CFR 211.194(a)(5)]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach two months of Red Blood Cells quality control data for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Comments	[Multi-Line Plain Text]

Platelet Pheresis Quality Control Data

Confirm that the following details are included in the Platelets quality control sheets.
[ ] Facility [21 CFR 211.194(a)(1)] [ ] Device manufacturer and type [21 CFR 211.194(a)(2)] [ ] Blood Unit Number [21 CFR 606.140(c)] [ ] Date of collection [21 CFR 211.194(a)(1)] [ ] Date of testing [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Interpretation of results [21 CFR 211.194(a)(6); 606.160(a)(1); 606.160(a)(2)(i)] [ ] Interpretation of month [ ] Yield [21 CFR 211.103; 211.186(b)(7)] [ ] Acceptable criteria [21 CFR 211.165(d)] [ ] Initials [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Evidence of review [21 CFR 211.194(a)(8); 211.103] [ ] Records of calculations [21 CFR 211.194(a)(5)]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach two months of Platelet Pheresis quality control data for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Comments	[Multi-Line Plain Text]

Leukocyte Reduction Quality Control Data

Confirm that the following details are included in the Leukocyte Reduction quality control sheets.
[ ] Facility [21 CFR 211.194(a)(1)] [ ] Device manufacturer and type [21 CFR 211.194(a)(2)] [ ] Blood Unit Number [21 CFR 606.140(c)] [ ] Date of collection [21 CFR 211.194(a)(1)] [ ] Date of testing [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Interpretation of results [21 CFR 211.194(a)(6); 606.160(a)(1); 606.160(a)(2)(i)] [ ] Interpretation of month

Validation & Quality Control Data

[ ] Yield [21 CFR 211.103; 211.186(b)(7)] [ ] Acceptable criteria [21 CFR 211.165(d)] [ ] Initials [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Evidence of review [21 CFR 211.194(a)(8); 211.103] [ ] Records of calculations [21 CFR 211.194(a)(5)]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach two months of Leukocyte Reduction quality control data for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Comments	[Multi-Line Plain Text]

Red Blood Cells, Washed Quality Control Data

Confirm that the following details are included in the Red Blood Cells, Washed quality control sheets.
[ ] Facility [21 CFR 211.194(a)(1)] [ ] Device manufacturer and type [21 CFR 211.194(a)(2)] [ ] Blood Unit Number [21 CFR 606.140(c)] [ ] Date of collection [21 CFR 211.194(a)(1)] [ ] Date of testing [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Interpretation of results [21 CFR 211.194(a)(6); 606.160(a)(1); 606.160(a)(2)(i)] [ ] Interpretation of month [ ] Yield [21 CFR 211.103; 211.186(b)(7)] [ ] Acceptable criteria [21 CFR 211.165(d)] [ ] Initials [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Evidence of review [21 CFR 211.194(a)(8); 211.103] [ ] Records of calculations [21 CFR 211.194(a)(5)]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach two months of Red Blood Cells, Washed quality control data for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach sterility testing for 10 units of Red Blood Cells, Washed for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Comments	[Multi-Line Plain Text]

Red Blood Cells, Frozen/Rejuvenated/Deglycerolized Quality Control Data

Confirm that the following details are included in the Red Blood Cells, Frozen/Rejuvenated/Deglycerolized quality control sheets.

Validation & Quality Control Data

[ ] Facility [21 CFR 211.194(a)(1)] [ ] Device manufacturer and type [21 CFR 211.194(a)(2)] [ ] Blood Unit Number [21 CFR 606.140(c)] [ ] Date of collection [21 CFR 211.194(a)(1)] [ ] Date of testing [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Interpretation of results [21 CFR 211.194(a)(6); 606.160(a)(1); 606.160(a)(2)(i)] [ ] Interpretation of month [ ] Yield [21 CFR 211.103; 211.186(b)(7)] [ ] Acceptable criteria [21 CFR 211.165(d)] [ ] Initials [21 CFR 211.194(a)(7); 600.12(a); 606.160(a)(1)] [ ] Evidence of review [21 CFR 211.194(a)(8); 211.103] [ ] Records of calculations [21 CFR 211.194(a)(5)]

>	Please explain why the appropriate information is not included.
	[Multi-Line Plain Text]

Attach sterility testing for 10 units of frozen blood units for Red Blood Cells, Frozen/Rejuvenated/Deglycerolized for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Attach sterility testing for 10 units of deglycerolized blood units for Red Blood Cells, Frozen/Rejuvenated/Deglycerolized for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]
Comments	[Multi-Line Plain Text]

Cryoprecipitated AHF Quality Control Data

Attach two months of Cryoprecipitated AHF quality control data for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]

Pooled Cryoprecipitated AHF Quality Control Data

Attach two months of Pooled Cryoprecipitated AHF quality control data for each facility included in this submission.	
File Attachment	[Multiple File Attachments (.pdf, .jpg, .gif, .tif, .avi, .wmv, .xpt, .xml, .dtd, .sgml, .mol, .xls, .csv, .zip)]