Public Webinar: FDA Review of Biologics License Applications (BLA) for Blood and Source Plasma

Anne Eder, M.D., Ph.D.

Director, Office of Blood Research and Review (OBRR)

Center for Biologics Evaluation and Research (CBER), FDA

May 12, 2026

The Workshop Will Address Blood Establishments…

That collect

- Blood and blood components
- Source Plasma

That are

- New License Applicants
  - Opening a Blood Center
- Established Firms
  - Acquiring a Facility

The Workshop Will NOT Address….

- Gene therapy, cell therapy

  OTP Town Hall: Best Practices for Preparing BLA Submissions for Cell and Gene Therapy Products - 06/04/2026 | FDA

- Human cells, tissues, or cellular or tissue-based products (HCT/P)
- Umbilical cord blood (UCB)
- Platelet rich plasma (PRP)
- Devices, In vitro diagnostics (IVDs)

U.S. Blood and Source Plasma Collections

2023

Blood and Blood Components for Transfusion

~ 12 million units collected

~ 13 million screened

~ 6.5 mil unique donors

Source Plasma for Further Manufacture

~ 50 million liters collected

~70% of **global** supply for plasma therapeutics

McDavid et al. *Transfusion* 2025; 63

U.S. Blood Establishments

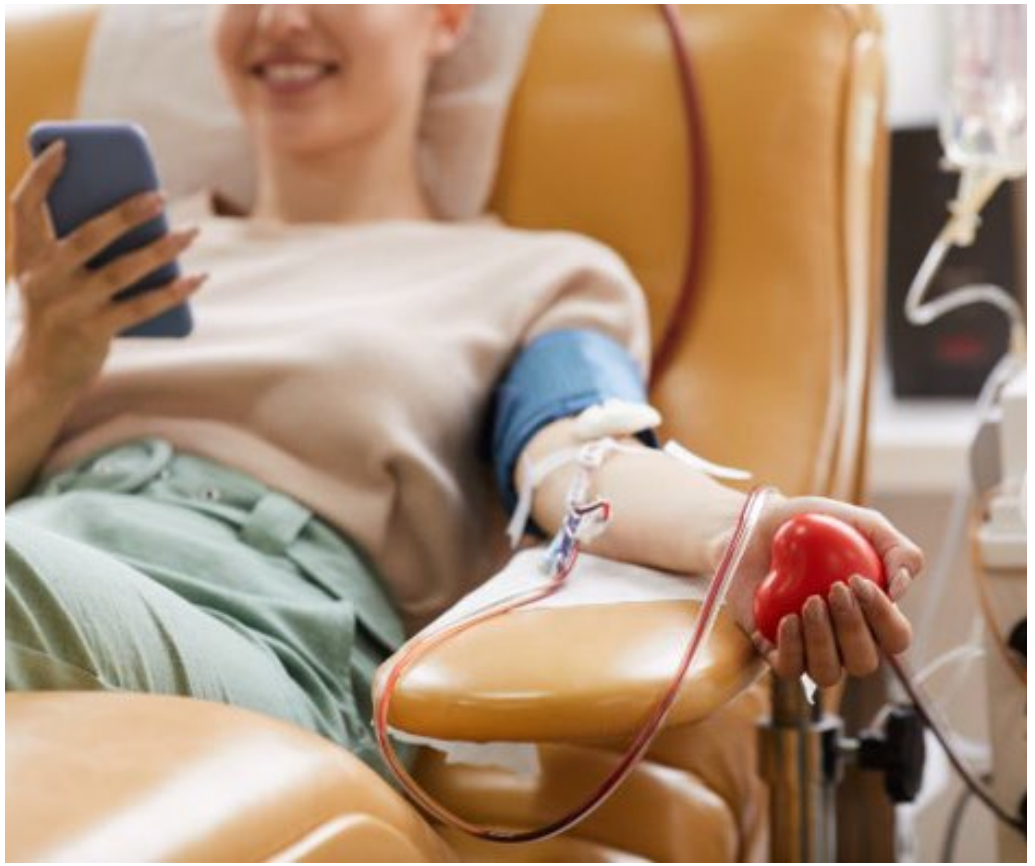
Products	License Holders (n)	Registered-only (n)	Establishments (n)
Source Plasma	**28**	--	**1204**
Blood and Components	**71***	--	**1000**
	--	**721**	**721**

*** Of these, 4 provide about 50-60% of US blood supply**

FDA, April 15, 2026

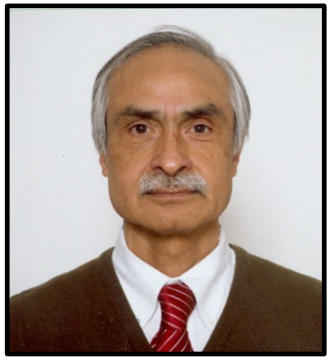
Office of Blood Research and Review

1. **Regulatory review**
   - Blood & blood components
   - Source Plasma
   - Devices for manufacturing
     - Donor screening, confirmatory tests
     - Collection sets, anticoagulants
     - Immunohematology reagents,
     - BECs
2. **Inspections and compliance**
3. **Policy development and preparedness**
4. **Mission-related research**



OBRR: Organization

Immediate Office of the Director (IOD)		
	Anne Eder, M.D., PhD	Director
	Orieji Illoh, M.D.	Deputy Director
	Jennifer Scharpf M.P.H.	Assoc. Dir., Policy
	Joseph Giglio	Assoc. Dir., Quality
	Cherry Geronimo	Chief, RHPM Staff
	Yeowon Kim, MD	Medical Officer



Div. Emerging Transfusion Transmitted Disease (DETTD)	
	Hira Nakhasi, PhD Director
	Peyton Hobson, PhD Deputy Director

Div. Blood Components & Devices (DBCD)	
	Wendy Paul MD Director
	Vacant, Deputy Director

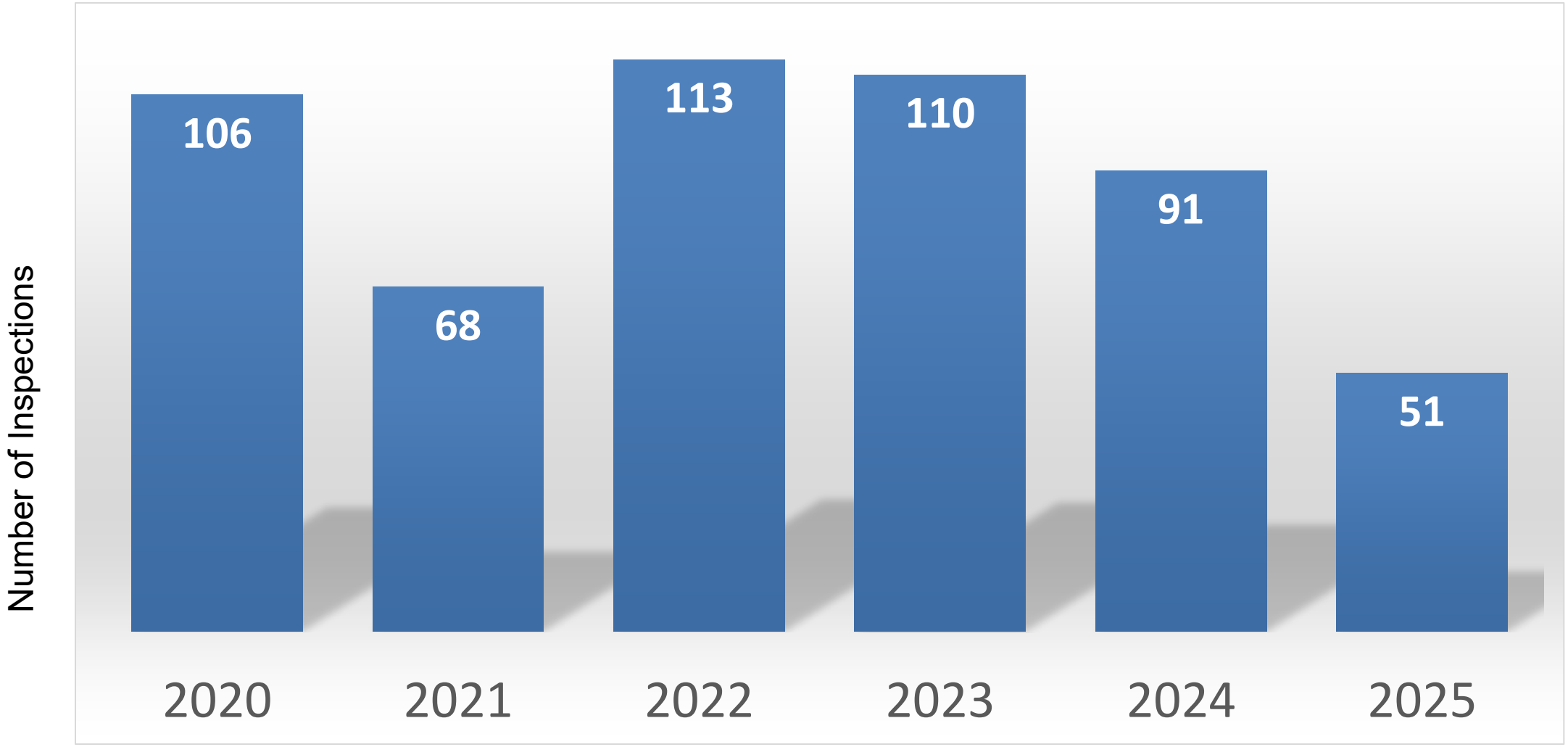
- Product Review Branch
- Laboratory of Emerging Pathogens
- Laboratory of Molecular Virology
- Device Review Branch
- Blood & Plasma Branch (BPB)
- Laboratory of Biochem. & Vasc. Biology
- Laboratory of Cellular Hematology

BPB Regulatory Review, 2025

Submission Type	Number Completed
Original Biologics License Application (BLA)	1
Prior Approval Supplement (PAS)	129
Changes Being Effected in 30 Days (CBE30) Supplement	97
Changes Being Effected (CBE) Supplement	52
Annual Reports	78
Product Correspondence	104
Total	461

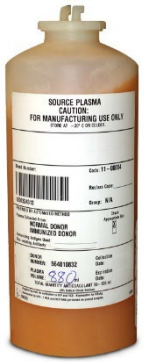
Jan 2025 to Dec 2025

BPB Preapproval Inspections



BPB Preapproval Inspections, 2025

36
Source Plasma Establishments



25
Blood Establishments

Blood and Plasma Branch, 2024

Back Row: Dr. Orieji Illoh, Mona Amin, Patricia Weddington, Brooke Spridgen, Camelita Bibby, Jaime Perry

Front Row: Christi Ann Samella, Camilla Smith, Barbara Peoples, Rick McBride (Retired), Thaddeus Nnabue, Miriam Montes, Michelle Gutierrez, Cathy McGraw, Dr. Wendy Paul

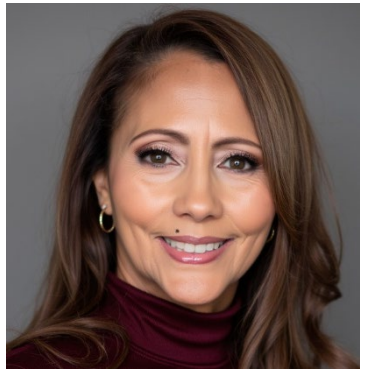
Not pictured: CSO/BPB: Racquel East, Dionne Cook, and Deborah Corpening; RPMS: Alpa Shah, Cherry Geronimo

OBRR Workshop Faculty

Wendy Paul, M.D.
Division Director,
DBCD
Moderator

Jennifer Scharpf M.P.H.
Assoc. Dir. Policy
IOD

Yeowon Kim MD, MHS
Medical Officer
IOD



Miriam Montes
MS, MT(ASCP)SBB
Branch Chief,
DBCD, BPB

Camilla Smith
BS, BB(ASCP)SBB, CQA(ASQ)
Team Lead
DBCD, BPB

Catherine McGraw MSN, RN
CSO
DBCD, BPB

Carmelita Bibby
MS, MLS(ASCP)BB
CSO
DBCD, BPB

Objectives

- Describe FDA regulatory requirements for the manufacture of blood and blood components, including Source Plasma
- Identify testing, donor deferral and notification requirements for relevant transfusion-transmitted infections (RTTIs) and donor reentry recommendations
- Explain the requirements and process for blood establishment registration
- Describe the steps in submitting a biologics license application (BLA) for blood and blood components
- Explain the BLA review process and common deficiencies in submissions
- Describe the pre-license and pre-approval inspection process and common citations

Objectives (Redux)

What you need to know about …

1. Regulatory requirements
2. RTTI testing, donor deferral, notification, reentry

What you need to do…

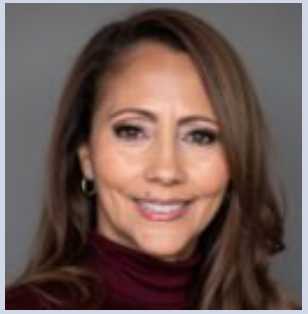
3. To register
4. To submit a BLA
5. During the BLA process
6. During an inspection

Q & A

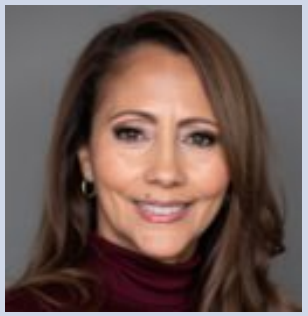
Faculty and Agenda, Part 1

9:15-9:45		**Jennifer Scharpf, M.P.H.** Associate Director for Policy, OBRR	**Regulatory Requirements for Blood and Blood Components, including Source Plasma**
9:45-10:15		**Yeowon Kim, MD, MHS** Medical Officer, OBRR	**Donation Testing, Donor Deferral, Requalification, and Notification**
10:15-10:45		**Carmelita Bibby, M.S., M.L.S.(ASCP)BB** Consumer Safety Officer, BPB	**Blood Establishment Registration and Facility Relocations**
10:45-11:00		**BREAK**	

Faculty and Agenda, Part 2

11:00-11:45		**Miriam Montes, MS, MT(ASCP)SBB** Branch Chief, BPB	**Submitting a BLA for Blood and Blood Components or Source Plasma**
11:45-12:15		**Camilla Smith, BS, BB(ASCP)SBB,CQA(ASQ),** Team Lead, BPB	**Biologics License Application (BLA) Review Process**
12:15-12:45		**Catherine McGraw, MSN, RN** Consumer Safety Officer, BPB	**FDA/OBRR Inspection Process, Expectations, and Common Citations**
12:45-1:00	**BREAK**		

Q&A, Closing Comments

1:00-1:45		**Miriam Montes, MS, MT(ASCP)SBB** Branch Chief, BPB	Questions submitted to FDA
		**Camilla Smith, BS, BB(ASCP)SBB,CQA(ASQ),** Team Lead, BPB	
1:45 - 2:00		**Anne Eder, MD PhD** Director, OBRR	Closing Comments
	Thank you for attending!		

Regulatory Requirements for Blood and Blood Components, Including Source Plasma

Jennifer Scharpf, M.P.H.
Associate Director for Policy
FDA/CBER/OBRR
May 12, 2026

Objectives

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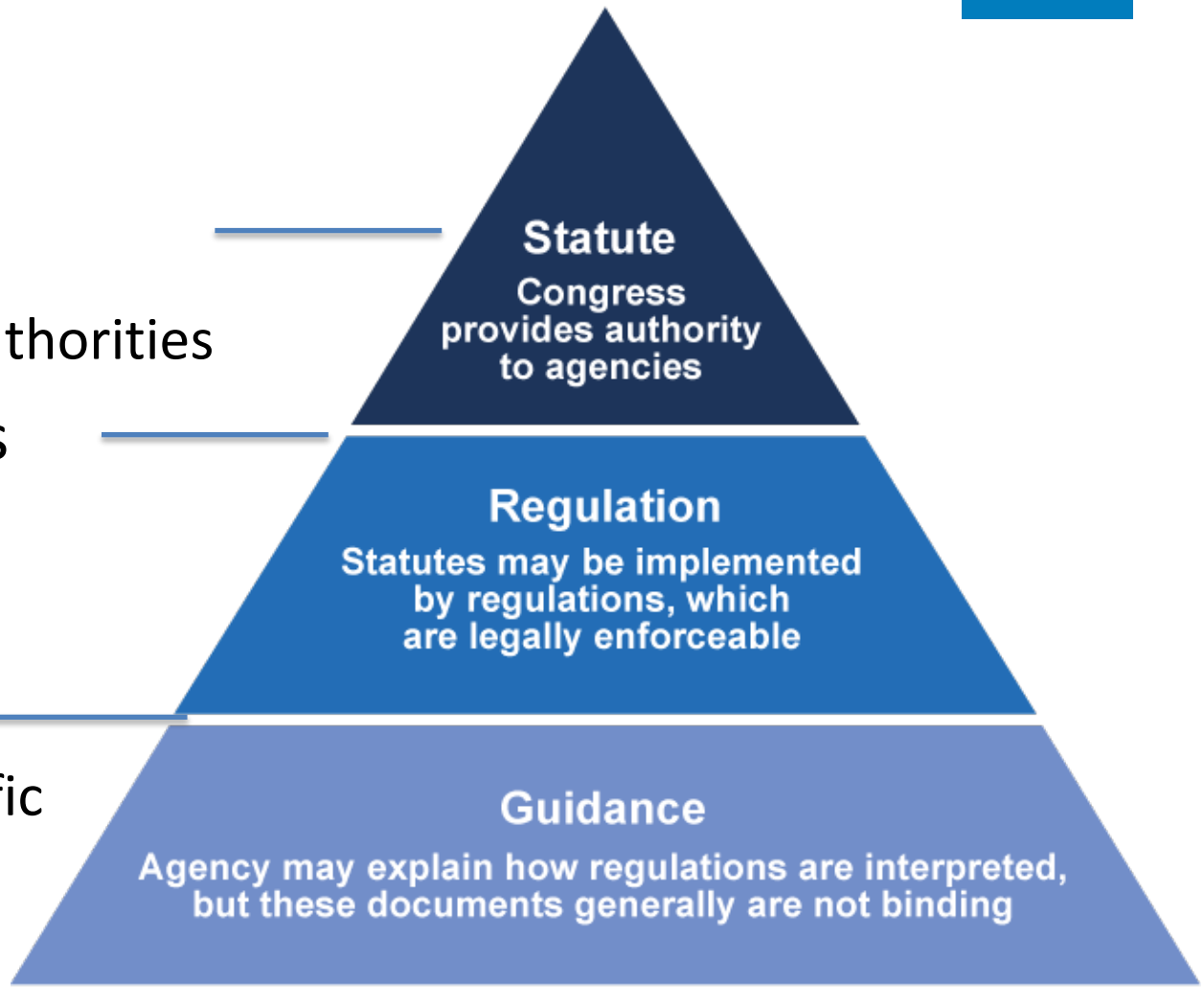
Outline

- Review statutory authorities
  - Historical perspective and current authorities
- Review code of federal regulations
  - General overview and blood specific regulations
- Review guidance documents
  - Policy development and blood specific guidance



Source: GAO analysis of regulatory authority | GAO-18-436T

Statutory Authorities

Biologics Control Act

- Biologics Control Act of 1902
  - "Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man" offered for sale, barter, or exchange in D.C. or interstate must be propagated and prepared at an establishment holding an unsuspended and unrevoked license."
  - "The purity of the substance is far more important than the purity of ordinary drugs…"
  - Authorized Hygienic Laboratory to issue regulations that govern all aspects of commercial production of biological products and conduct inspections.
  - 1934 – NIH issued regulations requiring proof of potency

Public Health Service (PHS) Act

1944 – Biologics Control Act was reenacted as section 351 PHS Act; section 361 PHS Act (control of communicable diseases) enacted

1947 – Regulations issued under which blood and plasma were defined as “analogous products” under statutory definition of biological product

1970 – Legislative fix added “blood, blood component and derivatives” to the definition of biological product

1972 – Biological products moved from NIH Division of Biologics Control to FDA Bureau of Biologics

2010 - Amended to add section 351 (k) for biosimilars

Public Health Service (PHS) Act

Blood is a biological product

- The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine**, blood, blood component or derivative**, allergenic product, protein, or analogous product….applicable to prevention, treatment, or cure of a disease or condition of human beings (42 USC 262 (i))

Section 351

- Requires a biologics license for distribution of any biological product in interstate commerce
- The biologics license application must demonstrate that the (1) product is safe, pure and potent **and** (2) facility meets standards to ensure product continues to be safe, pure and potent

Section 361

- Gives FDA the authority to issue regulations to prevent communicable diseases

Federal Food, Drug, and Cosmetic (FD&C) Act

- Section 351 (j) of PHS Act: FD&C Act applies to biological products
- Blood is a drug
  - Blood components are “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man” (21 USC 321 (g))
- Blood components are generally subject to the FD&C Act, including:
  - Current Good Manufacturing Practice (cGMP) requirements
  - Prohibitions on adulteration and misbranding of products
  - Inspection of manufacturing facilities

Regulations

Regulations (Rules)

- Regulations are requirements set by a government agency under statutory authority from Congress
  - FDA's authority to conduct rulemaking is in the FD&C Act and PHS Act
- Have the force and effect of law
- Provide more detailed legal standards, greater clarity than what is described in underlying statute
- Help ensure uniformity of enforcement

Regulations (Rules)

- **Administrative Procedures Act**
- **Notice and comment rulemaking**
  - Publish proposed rule in Federal Register
  - Ensures opportunity for public participation through written comments
  - Final rule includes codified text and preamble that responds to public comments and provides basis for regulations
- **Unified Agenda**
  - List of upcoming regulatory and deregulatory activities by federal agencies
  - Increases transparency and used to signal an Agency's regulatory priorities
  - https://www.reginfo.gov/public/do/eAgendaMain

Code of Federal Regulations (CFR)

- FDA's regulations are in Title 21 CFR (Food and Drugs)
- Selected provisions
  - Part 1-99 General provisions
    - Recalls, administrative procedures, advisory committees, good guidance practice
  - Part 200-300 Drugs
    - Labeling, cGMP, investigational new drugs
  - **Part 600-680 Biologics**
  - Part 800 Devices
  - Part 1271 Human cells and tissues

Title 21 CFR, Subchapter F Biologics

Part 600 – General; Establishment standards

Part 601 – Licensing

Part 606 – cGMP for blood and blood components

Part 607 – Blood registration and listing

Part 610 – General biological product standards

Part 630 – Requirements for blood and blood components for transfusion or further manufacturing

Part 640 – Additional standards for blood and blood products

Licensing

21 CFR Part 601

Examples include:

- Procedures for filing
- Complete response letter
- Issuance, denial, revocation of license
- Changes to an approved application (601.12)

  - Supplements and annual report
- Products in short supply (601.22)

Blood cGMP Regulations

21 CFR Part 606

Examples include:

- Personnel, facilities, equipment
- Standard operating procedures
- Container labeling requirements and circular of information
- Control of bacterial contamination
- Compatibility testing
- Records and reports
- Adverse event investigation and fatality reporting

Regulations to Protect Donor Health

21 CFR 630.10 and 630.15

Examples include:

- Donor acknowledgement and informed consent
- Donor questioning for medical conditions and medications
- Physical assessment and examination
- Hemoglobin and total protein measurement
- Donation frequency and deferral for red cell loss

Regulations to Assure Blood Safety

21 CFR Part 610.40 and 53; and 21 CFR 630.10 and 30 and 40

Examples include:

- Testing blood donations for relevant transfusion-transmitted infections (RTTI), i.e., HIV, HCV, HBV, HTLV, West Nile virus, Babesia, syphilis, Chagas disease
- Storage temperature and dating periods
- Donor questioning for risk factors for RTTI
- Donor deferral and notification
- Donation suitability

Additional Standards

21 CFR Part 640

Provides additional requirements, including proper name and source, collection, processing, testing, donor eligibility for:

- Whole Blood
- Red Cells
- Platelets
- Plasma
- Cryoprecipitate
- Source Plasma (syphilis testing, total protein determination and protein electrophoresis test, restrictions on distribution, quarantine hold)

Alternative Procedures

21 CFR 640.120

CBER Director may issue an exemption or alternative procedure to any requirement in subchapter F (Biologics), Chapter I (FDA) of Title 21 CFR

a) In response to a request from an individual establishment

b) To respond to a public health need (CBER issues notice, may be broadly applicable)

Investigational New Drug Application

21 CFR Part 312

Examples include:

- Requirement for an IND
- Labeling an investigational new drug (IND)
- Content of an IND application
- Phases of an investigation
- IND safety reporting
- Responsibilities of investigators and sponsors

Accessing the CFR

National Archives Electronic CFR (eCFR)

- Electronic access to current CFR
- Searchable
- Provides authority, source and history of each subpart
  - Including Federal Register notices with preambles

- Title 21 Food and Drugs
  eCFR :: Title 21 of the CFR -- Food and Drugs

- Title 42 Public Health (includes CMS/CLIA)
  eCFR :: Title 42 of the CFR -- Public Health

Guidance Documents

Guidance Documents

- Describe the agency's interpretation of a statutory or regulatory requirement
  - FDA's current thinking on a topic
  - Provide recommendations to industry *(must vs should)*
  - In some cases, describe FDA's intent to exercise enforcement discretion
- Industry may choose an alternative approach that complies with the relevant statutes and regulations
- Developed under Good Guidance Practices (21 CFR 10.115)
  - FDA must use guidance to communicate new policy to a broad audience
  - Most issued in draft, some "immediately in effect"
  - Federal register notice invites public comments

OBRR Policy Development

- Science-based, data driven

- Stakeholder and advisory input
  - Advisory Committees
  - Public workshops
  - Public comments

- CBER Guidance Agenda published annually, *available at*:
- Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2026 | FDA

Blood Guidance Documents

Provide recommendations on various topics, including:

- Donor eligibility (630.10)
- Relevant transfusion transmitted infections (630.3 (h)(2))
- Donation testing (610.40)
- Control of bacterial contamination (606.145)
- Recognition of circular of information (606.122), container labeling standards (606.121), donor history questionnaires (630.10)
- Development of novel products (Part 312, 601.12)
- Compliance policy (e.g., 630.10 (f); 630.30; 640.69 (f))

Blood guidance documents *available at*: https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances

Blood Guidance Documents

Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2026

(January 2026)

This is the list of guidance topics the Center for Biologics Evaluation and Research (CBER) is considering for development during Calendar Year 2026. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CBER has already issued Level 1 draft guidances that may be finalized following review of public comments. We currently intend to develop guidance documents on these topics; however, the Center is neither bound by this list of topics, nor required to issue every guidance document on this list. We are not precluded from developing guidance documents on topics not on this list.

In addition, we also submit lists of intended regulations to the Unified Regulatory Agenda available at https://www.reginfo.gov/public/do/eAgendaMain.

For further information regarding specific topics or guidances, please contact the Center for Biologics Evaluation and Research, Food and Drug Administration, industry.biologics@fda.hhs.gov.

Guidance Documents CBER is Considering in 2026:

CATEGORY – Blood and Blood Components:

- Considerations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Guidance for Industry
- Collection of Platelets by Automated Methods; Draft Guidance for Industry
- Recommendations for Testing Blood Donations for Hepatitis B Virus; Guidance for Industry
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry
- Recommendations for Testing Blood Donations for Human T- lymphotropic Viruses I and II; Draft Guidance for Industry

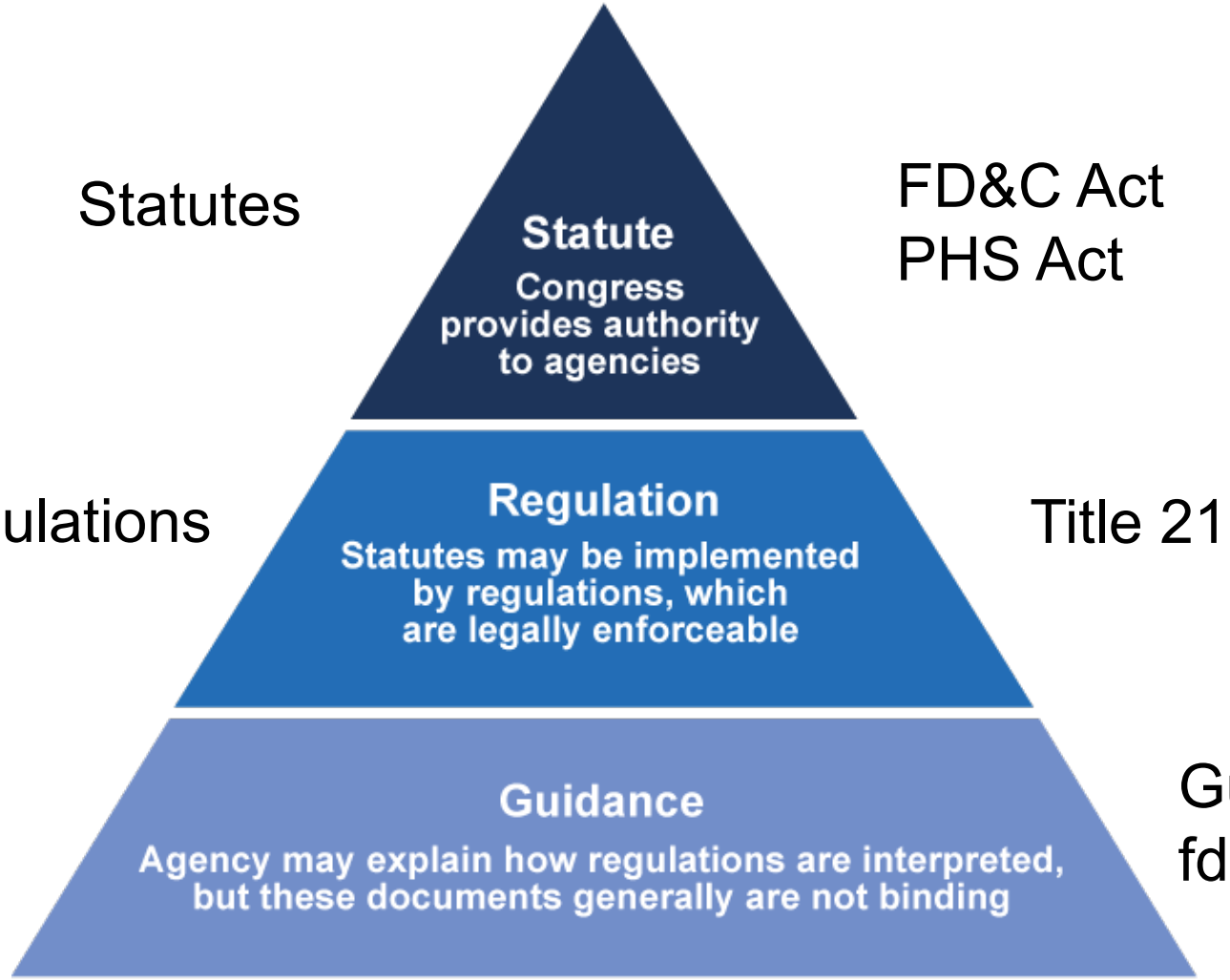
Safety Communications

- Developed to provide the public with important information about the safety and availability of biological products
- Audience may be regulated industry, health care providers, blood donors and consumers
- Provides our considerations on an emerging safety issue (not guidance)
- Cybersecurity in blood establishments; Reporting septic transfusion reactions and bacterial contamination of platelets
  - Safety & Availability (Biologics) | FDA

Conclusion

Statutes

FD&C Act
PHS Act



Regulations

Title 21 CFR

Guidance

Guidance for Industry
fda.gov

Source: GAO analysis of regulatory authority | GAO-18-436T


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Relevant Transfusion-Transmitted Infections (RTTI) Screening, Donor Deferral, Notification, Requalification (Reentry)

Yeowon Kim, MD, MHS

Medical Officer

FDA/CBER/OBRR

May 12, 2026

Objectives

1. Describe FDA regulatory requirements for the manufacture of blood and blood components, including Source Plasma
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TTI/RTTI Regulatory Framework (1)

- Transfusion-transmitted infection (TTI)
  - **Fatal or life-threatening**, cause permanent impairment, or necessitate medical or surgical intervention to prevent permanent impairment
  - **Potentially transmissible by blood transfusion**

- Relevant transfusion-transmitted infections (RTTIs) are a subset of TTIs that FDA considers to be the most important to the safety of the blood supply

10 Named RTTIs in the CFR
Human immunodeficiency virus, types 1 and 2 (HIV-1/2)
Hepatitis B virus (HBV)
Hepatitis C virus (HCV)
Human T-lymphotropic virus, types I and II (HTLV-I/II)
Treponema pallidum (syphilis)
West Nile virus (WNV)
Trypanosoma cruzi (Chagas disease)
Creutzfeldt-Jakob disease (CJD)
Variant Creutzfeldt-Jakob disease (vCJD)
Plasmodium species (malaria)

21 CFR 630.3(h)

TTI/RTTI Regulatory Framework (2)

- Additionally, **TTI becomes an RTTI** when:
  - **Sufficient incidence or prevalence** in the donor population or has been released and places donors at risk
  - **Appropriate screening measures** and/or an FDA licensed, cleared, or approved screening test is available
  - Examples: *Babesia* species (babesiosis), Zika virus (2016 - 2021)
- FDA makes this determination and will communicate when a TTI becomes an RTTI

21 CFR 630.3(h)

FDA Regulation of Blood Safety

- Providing educational materials to donors
  - Educational materials instruct donors with RTTI risk factors to not donate
- Questioning donors' health history
  - Donor history questionnaire (DHQ) and deferral for RTTI risk factors
- Screening and further testing for RTTIs
  - FDA List of Donor Screening Tests
- Maintaining cumulative donor deferral records to prevent ineligible individuals from donating
- Taking appropriate actions on postdonation information (e.g., component retrieval, lookback, recall)

1) 21 CFR 630.10(b); 2) 21 CFR 630.10(e), DHQ Guidance for Blood and Blood Components (May 2023), DHQ Guidance for Source Plasma (June 2023); 3) 21 CFR 610.40; 4) 21 CFR 606.160(b)(ii), 21 CFR 606.160(e); 5) 21 CFR 606.171, 21 CFR 610.46, 21 CFR 610.47

Screening for RTTIs

- Donor history questionnaire (DHQ) and accompanying materials
- Screening tests – test every donation, unless regulations and guidance provide an exception:
  - Every donation tested without exceptions: HIV-1/2, HBV, HCV
  - For blood donations for transfusions (not Source Plasma)
    - Every donation tested for: WNV, HTLV-I/II, syphilis;
    - One-time testing: Chagas
    - Geographic risk-based testing: Babesia
  - For Source Plasma, testing is not required for WNV, HTLV-I/II, Chagas, Babesia, malaria
  - Exceptions to testing for dedicated donations, blood/components used in medical devices that do not contain viable leukocytes, samples for clinical testing and research, and autologous donations

21 CFR 610.40, 630.10

RTTI Screening Tests: Blood vs. Source Plasma

	Blood Donation	Source Plasma
HBV	HBV DNA	HBV DNA
	HBsAg*	HBsAg
	Anti-HBc	not recommended
HCV	HCV RNA	HCV RNA
	Anti-HCV	Anti-HCV
HIV-1/2	HIV RNA	HIV RNA
	Anti-HIV-1,2	Anti-HIV-1,2
Syphilis	*T. pallidum* antibodies, RPR	*T. pallidum* antibodies, RPR
WNV	WNV RNA	not required
HTLV-I/II	Anti-HTLV-I, II	not required
Chagas	*T. cruzi* antibodies	not required
Babesia	*Babesia* species RNA, DNA (endemic states)	not required

*HBsAg Testing Draft Guidance (July 2025) recommends that testing for HBsAg is not necessary for donations other than Source Plasma when testing for HBV NAT and anti-HBc are done.

Why Ask Questions if Testing?

- Assures that donors are healthy at the time of donation and serves as a safeguard against collection donations from a donor with symptoms of an RTTI

- Lowers the burden of potential infectivity

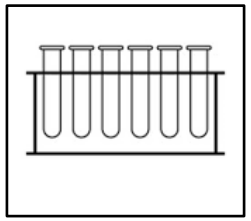
- Decreases the potential introduction of infectious unit

Approaches to RTTI Screening

Measure	RTTI
DHQ and Tests	HIV-1/2, HBV, HCV
	Treponema pallidum (syphilis)
	HTLV-I/II
	Plasmodium spp. (malaria) (selective)*
Test, only	West Nile virus (WNV) (Zika virus, 2016 - 2021)
	Trypanosoma cruzi (Chagas) (one-time)
DHQ, only (No Available Test)	Variant Creutzfeldt-Jakob disease, CJD
DHQ or Test	*Babesia spp. (geographic risk)*

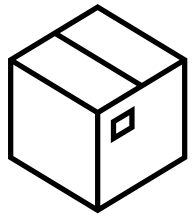
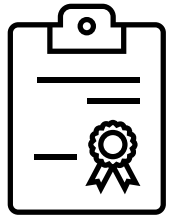
21 CFR 630.3(h); *Malaria Draft Guidance (January 2025); DHQ, donor history questionnaire

RTTI Testing: General Principles (1)

Topic	Excerpt	21 CFR Citation
Tests	Use one or more screening tests that FDA has licensed, approved, or cleared for such use, following the manufacturer's instructions.	606.65(e) 610.40(b)
CLIA	Perform testing in CLIA certified lab or equivalent	610.40(f) 640.71(a) [SP]
Samples 	Collect all samples for laboratory tests … at the time of filling the original container. **Label all containers** for all samples with donor's identification before collecting the samples all [BCs]	640.4 [WB] 640.23 [Platelets] 640.53 [Cryo AHF]
	Prior to filling, **identify all samples** so as to relate them directly to the donor of that unit of plasma…The same person prepares the samples and the final product at the same time [SP]	640.69(d) [SP]

BC = blood component, SP = Source Plasma, WB = Whole Blood, Cryo AHF = cryoprecipitated antihemophilic factor

RTTI Testing: General Principles (2)

Topic	Excerpt	21 CFR Citation
Shipping 	Do not ship or use donations with reactive screening tests (unless an exception is stated in CFR, e.g., for autologous use)	610.40(h)
	Blood components may be shipped before testing is completed only in documented emergency medical use (transfusion) [If for further manufacturing use, requires approval from FDA]	610.40(g)
Good Manu-facturing Practices 	Standard operating procedures (SOPs) must comply with regulations	606.100(a)
	Blood establishments must establish, maintain and follow SOPs for all steps in the collection, processing, compatibility testing, storage and distribution of blood and blood components, including… (1-22) • Method of accurately relating the product(s) to the donor • **Procedures for relating a unit of blood or blood component from the donor to its final disposition**	606.100(b) 606.100(b)(4) 606.100(b)(13)

What Must You Do When A Donation Tests Reactive? (1)

1. Do not ship or use the unit unless there is an exception. Label and quarantine the unit appropriately
2. Perform further testing with a licensed, approved, or cleared supplemental test
3. Defer and notify the donor. Add donor to deferral registry.
   - Exceptions to donor deferral:
     - A donor who tests reactive for anti-HBc or anti-HTLV-I/II, but is otherwise eligible to donate, may donate Source Plasma
     - Reactive anti-HBc or anti-HTLV-I/II on only one occasion [BC]
     - Prior reactive HBsAg for HBIg if currently negative [SP]
     - Autologous donor

1) 21 CFR 610.40(h), 21 CFR 630.30(b)(1), 21 CFR 606.121; 2) 21 CFR 610.40(e); 3) 21 CFR 610.41, 21 CFR 606.160(e), 21 CFR 630.40

Donor Notification

Topic	Excerpt	21 CFR Citation
Contact Info 	You must obtain…a **postal address** where the donor may be contacted for 8 weeks after donation	630.10(g)(1)
Notify any donor deferred for… 	• **A reactive RTTI screening test** • Eligibility criteria (i.e., **DHQ responses**, physical exam, too soon since last donation) • Endogenous bacterial infection (platelet donor)	630.40(a)
Content 	1. Notify of deferral, and the reason for the decision 2. If ineligible for a specific type of donation or blood component **3. The results of tests for RTTIs, including further testing** 4. Information concerning medical follow-up and counseling	630.40(b)
Time Period 	Reasonable attempts within 8 weeks Do not collect blood before determining that the donor is eligible	630.40(c) 630.10(a)
Document 	Document successful notification. • If unsuccessful, document reasonable attempts	630.40(c)

What Must You Do When A Donation Tests Reactive? (2)

4. Perform lookback for HIV and HCV
5. For other RTTIs, refer to guidances for product management recommendations, which may include:
   - Identify in-date blood and blood components previously donated by the donor
   - Quarantine such blood and blood components and notifying consignees to do the same
   - Take appropriate action based on results of further testing:
     - Release, destroy, or relabel quarantined in-date blood products consistent with test results
     - Possibly notify transfusion recipient's physician

4) 21 CFR 610.46, 21 CFR 610.47

Quarantine Hold Requirement for Source Plasma (NEW SLIDE ADDED AFTER WEBINAR)

- Source Plasma donated by paid donors determined to be suitable for further manufacturing into injectable products **must be held in quarantine for a minimum of 60 calendar days*** before it is released for further manufacturing.

- If a Source Plasma donor is deferred under 21 CFR 610.41 because of reactive test results, or if you determine the donor is ineligible under 21 CFR 630.10 because of RTTI risk factors, **you must not distribute any donations from that donor that are in the 60-day quarantine hold**.

- **The quarantine hold requirement in 21 CFR 640.69(f) does not allow release of donations that are in the 60-day quarantine hold based on results of further testing.**

*60 days defined in 21 CFR 640.69(f); FDA exercises enforcement discretion when SP donations are released from quarantine after 45 days, see Guidance on Compliance Policy For Source Plasma Quarantine Hold Requirements (October 2023)

Donor Requalification and Reentry (1)

- FDA licensed or cleared RTTI screening tests are highly sensitive and specific
- With millions of donations screened annually, there will be many reactive donations
  - Of the ~11.5 million units of whole blood and apheresis RBCs tested in 2023, 123,000 units were rejected for reactive screening tests (McDavid et al., 2025)
- In a healthy donor population, most reactive screening tests will be **false positive** due to low disease prevalence
- FDA recommends donor requalification and reentry

Donor Requalification and Reentry (2)

- A deferred donor subsequently may be found to be eligible...by a requalification method or process found acceptable for such purposes by FDA.

- Such a donor is considered no longer deferred.

- You may use…blood or blood components from a donor with a previous record of a reactive screening test(s) for evidence of...RTTI…if a) at the time of donation, the donor is shown…to be eligible by a requalification method or process found acceptable for such purposes by FDA…and b) all other screening tests are nonreactive.

21 CFR 610.41(b); 21 CFR 610.40(h)(2)(iv)

Donor Requalification and Reentry (3)

- General principles for requalification
  - Recommended time intervals between index reactive test results and testing performed for requalification depend on RTTI and the index reactive marker/screening test
  - Testing a follow-up (predonation) sample vs. a subsequent donation without predonation testing
- Refer to guidances for recommendations for requalification methods for each RTTI
- Blood establishments can also send to FDA individual reentry requests for deferred donors with test results not addressed by guidances or missing historical test results.

21 CFR 610.41(b)

Example: Donor Reentry Request

- Donor deferred for unconfirmed anti-HIV-1/2 test result
- Historical records from index donation in 1994 no longer available
- Donor states not getting retested for HIV
- Substitute index donation collected in 1995 was non-reactive for anti-HIV-1/2 screening test
- Follow-up sample collected in 2021 was non-reactive for HIV-1/2 Ag/Ab combo test and HIV-1/2 NAT
- Donor is currently healthy and denies associated risk factors, past exposure, or new medications
- FDA granted reentry, provided that at the time of future donations, all screening tests are non-reactive and all donor eligibility criteria are met

Example: HIV-1/2 Screening, Donor Deferral, Notification, Lookback, Requalification (Reentry)

Donor Education for HIV-1/2

- Blood establishments must provide "educational material concerning RTTIs to donors before donation when donor education about that RTTI, such as HIV, is necessary to assure the safety…of blood and blood components."

- Donor educational materials instruct potential donors to not donate if they have:
  - HIV or risk factors for HIV
  - Ever taken medications to treat HIV or are taking medications to prevent HIV
  - Symptoms of HIV infection (i.e., fever, enlarged lymph nodes, sore throat, and rash)

- Donor educational materials should indicate that individuals should not discontinue their prescribed medications, including medications to prevent HIV, in order to donate blood.

21 CFR 630.10(b), HIV Guidance (May 2023)

HIV Risk Factors for Questioning

Deferral	Questions
3 months	• Sexual contact with new partner or more than 1 partner • Taken oral medication prevent HIV • Received payment (money, drugs, other) for sex • Used needles to take drugs not prescribed (NP IDU) • Blood transfusion • Contact with someone else's blood / needlestick • Sexual contact with individual with HIV / received payment for sex / engaged in NP IDU • Syphilis, gonorrhea, or treatment for syphilis or gonorrhea
None or **3** months	• Tattoo/piercing (no deferral if state regulated, sterile, single use)
2 years	• Taken medication by injection to prevent HIV
Indefinite	• Ever had a positive test for HIV • Ever taken any medication to treat HIV

HIV Guidance (May 2023)

Testing for HIV-1/2

- Licensed donor screening tests:
  - Nucleic acid tests (NAT) for HIV-1 (minipool, multiplex HIV-1/HBV/HCV)
  - Antibody tests for antibodies to both HIV-1/2

- Further (confirmatory) testing:
  - Licensed HIV-1 NAT intended for donor screening with limited supplemental claim if donation is reactive on both HIV-1 NAT and anti-HIV-1/2 antibody screening tests
  - Licensed confirmatory tests for anti-HIV-1/2

FDA Safety Communication, 12/20/2019

Important Information for Potential Donors of Blood and Blood Products

Individuals who have ever tested positive for HIV should not donate blood

- FDA-approved antiretroviral drugs…can reduce the HIV viral load of individuals to undetectable levels as determined by conventional testing.
- However, these antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient.
- Although undetectable still equals untransmissible for sexual transmission ($U = U_{sex}$), this does not apply to transfusion transmission.

Link to FDA Safety Communication (12/20/2019)

Testing for HIV-1/2

Excerpt	21 CFR Citation
Test <u>each donation</u> for evidence of **HIV**, HCV, HBV*	610.40(a)(1)
Perform <u>one or more licensed</u>, approved or cleared tests, in accordance with the manufacturer's instructions	610.40(b)
<u>Further test each donation</u>, including autologous donations, **<u>found to be reactive by a donor screening test</u>** using a licensed, approved, or cleared supplemental test, when available. If no such supplemental test is available, perform one or more licensed, approved or cleared tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status.*	610.40(e)
<u>Donor requalification/reentry after falsely reactive</u> screening tests by a method found acceptable by FDA	610.41

*See 21 CFR 610.40(c)-(e) for exceptions

Commonly Asked Question
(AMENDED AFTER WEBINAR)

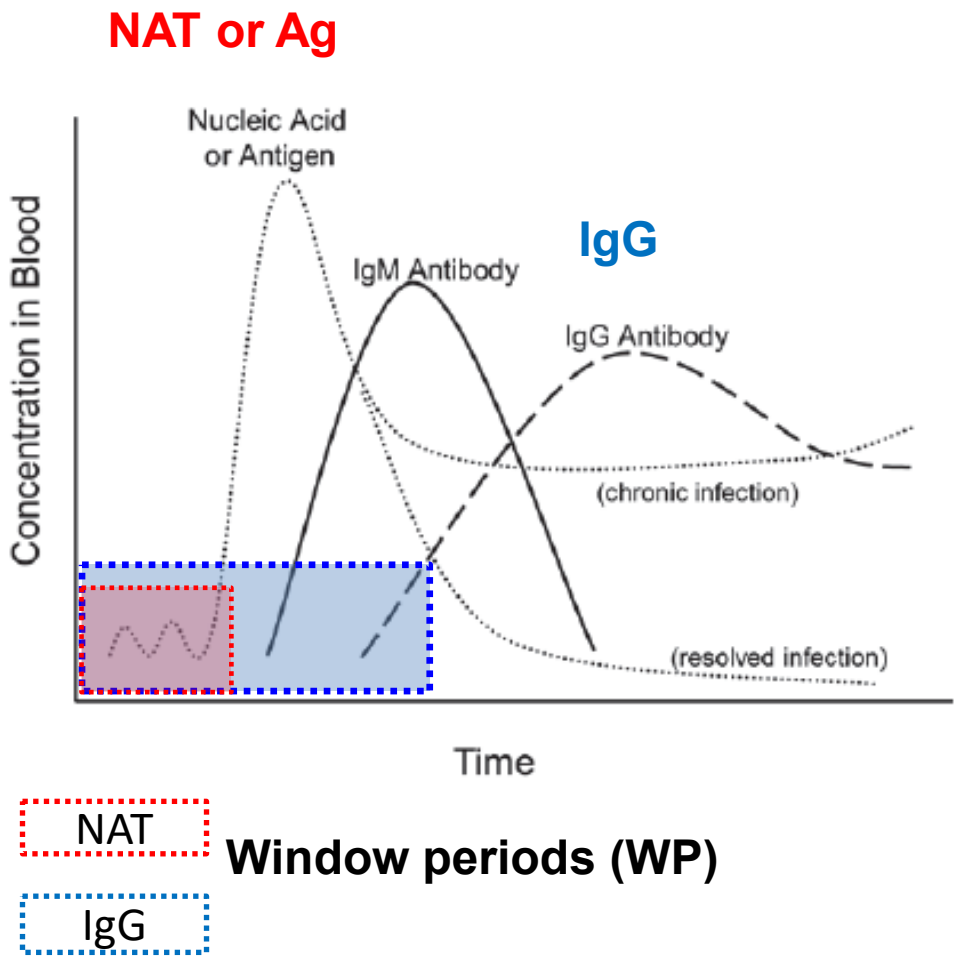
Q: Can I release a donation that was initially reactive on screening for HIV if further testing is negative?

A: No, you must not ship or use the reactive donation unless there is an exception (e.g., autologous use).

In general, ~~I~~if further testing is negative on the reactive donation, you may release prior donations involved in lookback under 21 CFR 610.46 and 21 CFR 610.47. However, Source Plasma donations from that donor that are in the 60-day quarantine hold under 21 CFR 640.69(f) must not be distributed to make an injectable product, regardless of the results of further testing.

Note: Slide was amended to provide clarification about the separate quarantine hold requirements for Source Plasma in 21 CFR 640.69. Additions are in red text and deletions are in strikethrough.

HIV Window Period & Transfusion Risk



NAT	NAT WP (d)	Residual Risk; 2020-23
HIV	9.1	1 : 4.4 million
HCV	7.4	1 : 6.3 million
HBV	18.5	1 : 2.3 million

Huseynova E et al. Transfusion 2025;65:1876-1887.

HIV Lookback – Timeframe

- **Within 3 calendar days** after a donor tests reactive for evidence of HIV infection…or when you are made aware of other reliable test results or information indicating evidence of HIV infection, you must review all records required…to identify blood and blood components previously donated by such a donor.

- Blood components involved in lookback:
  - **Twelve months and less** before the donor's most recent **nonreactive screening tests**, or
  - **Twelve months and less** before the donor's **reactive direct viral detection test** (e.g., nucleic acid test) and **nonreactive antibody screening test**, whichever is the lesser period…

21 CFR 610.46 (HIV)

HIV Lookback – Blood Center Actions

For blood components involved in lookback, blood centers must:

- **Quarantine** all previously collected in-date blood and blood components…if intended for use in another person or for further manufacture into injectable products except pooled blood components intended solely for manufacturing into products that are manufactured using validated viral clearance procedures…

- **Perform further testing** for HIV as required…on the reactive donation. If further testing is:
  - Negative: release **prior** donations
  - Positive: destroy or relabel quarantined in-date blood and blood components

- **Notify consignee** so they can take appropriate actions, which includes notification of transfusion recipients or the recipient's physician

21 CFR 610.46 (HIV)

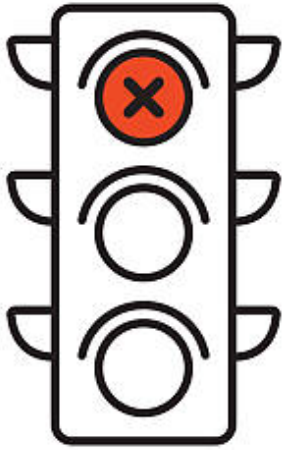
Commonly Asked Question

Q: Can I requalify a donor with a falsely reactive screening test result (serological or NAT) for HIV?

A: Yes, provided that the donor is eligible for requalification and results of follow-up testing support that the donor was never infected with HIV.

Donors Deferred for Reactive HIV-1/2 Screening Test: NOT Eligible for Requalification

	HIV-1 NAT	Anti-HIV-1/2	HIV-1 WB or IFA	HIV-1 p24
1.	**Reactive**	**Reactive**	Any	Any
2.	**Reactive**	Any	N/A	**Reactive**
3.	NR (or not done)	**Reactive**	**Positive**	Any
4.	NR (or not done)	**Reactive**	Any	**Reactive**

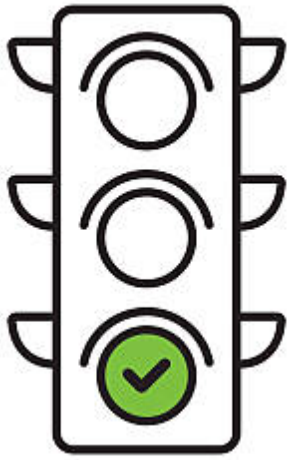


NR, nonreactive; N/A, not applicable

NOT eligible for requalification: 1) Reactive NAT confirmed by serology OR 2) reactive on different serological tests (NAT is NR or not done)

Donors Deferred for Reactive HIV-1/2 Screening Test: Eligible for Requalification

	HIV-1 NAT	Anti-HIV-1/2	HIV-1 WB or IFA	HIV-1 p24	Comment
1.	**Reactive**	NR	N/A	NR (if done)	—
2.	NR (or not done)	**Reactive**	If done: • Negative • Indeterminate • Unreadable	NR (if done)	May be eligible for requalification only if: • HIV-1 p24 (if done) is NR, AND • Second different HIV-2 test is NR
3.	NR (or not done)	NR	N/A	**Reactive**	HIV-1 p24 neutralization test can be positive or indeterminate



NR, nonreactive; N/A, not applicable

May be eligible for requalification: 1) Reactive NAT not confirmed by serology OR 2) reactive serological test not confirmed by NAT and/or a different serological test

Reentry After Likely False Positive HIV-1/2 Screening Test

- Testing scenarios on previous slide present likely falsely reactive screening test results (e.g., NAT-reactive but seronegative, reactive serological test not confirmed by NAT or another serological test)

- Waiting period: 8 weeks

- If follow-up individual (ID) NAT and anti-HIV-1/2 are negative, donor is eligible for future donation provided they meet all eligibility criteria

HIV-1 and HCV NAT Guidance (December 2017)

Closing Comments

- Multilayered approach to blood safety has resulted in safe blood supply
- FDA recommends donor reentry to maintain donor pool
- FDA continues to monitor for emerging TTIs and adjust RTTI screening requirements and recommendations based on current science
- Please check regularly FDA blood guidances and FDA biologics safety and availability communications to stay informed on current recommendations and emerging safety concerns


FDA
U.S. FOOD & DRUG
ADMINISTRATION

U.S. FOOD & DRUG ADMINISTRATION

Blood Establishment Registration and Facility Relocations

Carmelita Bibby, MS, MLS(ASCP)^{CM}BB^{CM}

Consumer Safety Officer, Blood and Plasma Branch

OBRR/CBER/FDA

May 12, 2026

Objectives

1. Describe FDA regulatory requirements for the manufacture of blood and blood components, including Source Plasma
2. Identify testing, donor deferral and notification requirements for relevant transfusion-transmitted infections (RTTIs) and donor reentry recommendations
3. **Explain the requirements and process for blood establishment registration**
4. Describe the steps in submitting a biologics license application (BLA) for blood and blood components
5. Explain the BLA review process and common deficiencies in submissions
6. Describe the pre-license and pre-approval inspection process and common citations

Why Does FDA Require Registration?

- Maintain information and track manufacturing facilities and products manufactured
- Identify and locate facilities for inspections
- Improves ability to respond to public health emergencies

Definitions and Applicable Regulations

- Blood Establishment Registration and product listing requirements : 21 CFR Part 607
- Definitions (21 CFR 607.3)
  - Blood and blood product (21 CFR 607.3(b))
  - Establishment (21 CFR 607.3(c))
  - Manufacture (21 CFR 607.3(d))

Who Must Register?

- All owners or operators of establishments that engage in the manufacturing of blood products
  - List all products that are for commercial distribution
- Must register before a biologics license application is submitted
- No registration fee is required for registration and listing for blood products

When Must a Blood Establishment Register?

- Within 5 days after beginning operations

  or

- 5 days after submission of BLA

  and

- Annually between October 1 and December 31
- Must update their blood product listing every June and December

21 CFR 607.21

Registration vs. Biologics License

- Registration alone, does not permit any blood establishment to ship blood products across state lines (i.e., interstate commerce)
- A biologics license must be in effect for blood products to be distributed and introduced into interstate commerce
- A blood establishment can be registered-only and not have a biologics license
  - Can operate and distribute blood and blood components within the state only

Who Is Exempt From Registration?

- Pharmacies that are not manufacturing blood products for sale
- Manufacturers of blood products which are not for sale, rather, are solely for use in research, teaching or analysis
- Persons who engage solely in the manufacturing of in vitro diagnostic (IVD) blood products and reagents not subject to licensing under Section 351 of the Public Health Service Act

21 CFR 607.65

Who Is Exempt From Registration? (2)

- Transfusion Services that do not collect or process blood and blood components and are certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988
- Examples of activities exempt from registration:
  - Compatibility testing
  - Preparing Red Blood Cells for transfusion
  - Pooling certain blood components before transfusion

Do I Need To Register My Transfusion Service?

Yes	No
• Irradiation, washing, pre-storage pooling, freezing, deglycerolization, and rejuvenation • Extending platelet expiration after bacterial testing • Acting as depot that routinely store and ship products to other hospitals	• Compatibility testing, preparing blood components for transfusion, pooling certain blood components before transfusion • Collecting and processing blood and blood components only in emergencies

How Do Blood Establishments Register?

- Registrations are submitted in the Electronic Blood Establishment Registration Product and Listing application (eBER): https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm

21 CFR 607.22

What Information Is Required?

- Legal Name, address and phone number
- Unique Facility Identifier
- Establishment Type
- Reporting Official
  - Person assigned or designated by the entity to engage in correspondences with the FDA
- List of blood products and processing or manufacturing activities

21 CFR 607.25

Unique Facility Identifier

- If registering for the first time, apply for a Data Universal Numbering System (DUNS) number, which is a Unique Facility Identifier.
- The DUNS Number is issued by Dun & Bradstreet (website): https://support.dnb.com/?cust=ImportSafetyRegistration

FDA Process After Submitting a New Registration

- The FDA Official Establishment Inventory Coordinator will contact the Reporting Official listed
- FDA Establishment Identifier (FEI) number (registration number) is assigned and made “Active”
- FDA provides the FEI number and registration summary report to the Reporting Official

Changes To Registration

Changes may include:

- Legal Name change (change in ownership, corporate, or partnership structure)
- Relocation (address change)
- Reporting Official
- Blood product handling activity including implementing or ceasing processing or manufacturing activities

Submit amendments to registration within **5 calendar days** of the change.

21 CFR 607.26

Changes To Registration (cont.)

- Update listing when introducing or discontinuing the manufacture of specific blood products (21 CFR 607.21)
  - Between June to December

Inactive Registrations

- If the current registration status is “INACTIVE”, it could mean the following:
  - INACTIVE – CLOSED: Out of business, or acquired by another company
  - INACTIVE – Temporary: Temporarily closed due to repairs, relocation, damage due to extreme weather or disaster such as hurricane or earthquake
  - INACTIVE – EXEMPT: The establishment has been deemed exempt from registration as per criteria listed in 21 CFR 607.65

Registered and Licensed Blood Establishments (April 2026)

Registered only (e.g., hospital blood banks, transfusion services)	726
Licensed blood collection establishments (71 license holders)	1000
Licensed Source Plasma establishments (28 license holders)	1204

Facility Changes-

Relocations, Acquisitions and Voluntary Revocations, Mergers

Facility Relocation

Complete relocation of Facility to new location:

- The current facility's registration/FEI Number and compliance history will be transferred to the new location

Dividing Operations of Current Facility:

- The new facility will need a new FEI number
- approvals/licensure of the current facility do not transfer to the new facility

Facility Acquisitions and Voluntary Revocations

- New owners of acquired establishment must amend the establishment registration within 5 days of the change
- If applicable, contact FDA to determine if a new biologics license should be issued

Facility Mergers

- Union of two or more establishments to form a new legal entity
- Requires update of registration
- FDA issues new license number to new legal entity, when applicable
- Reference: *Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture*, Final Guidance, December 2014

Summary

- Blood establishments must register with FDA and list blood products in commercial distribution
  - Certain types of establishments are exempt from registration
  - Registrations are submitted electronically
- Facility moves, acquisitions, mergers require updates to registration or issuance of new registration number
  - Contact FDA (bloodregis@fda.hhs.gov) with questions

Registration Resources

- For more information on Blood Establishment Registration, visit FDA's/CBER Blood Establishment Registration and Product Listing webpage: https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing
- For inquiries regarding registration, please send an email to: bloodregis@fda.hhs.gov

Submitting a Biologics License Application (BLA) for Blood and Blood Components or Source Plasma

Miriam Montes, MS, MT (ASCP)SBB

Chief, Blood and Plasma Branch

FDA/CBER/OBRR

May 12, 2026

Objectives

1. Describe FDA regulatory requirements for the manufacture of blood and blood components, including Source Plasma
2. Identify testing, donor deferral and notification requirements for relevant transfusion-transmitted infections (RTTIs) and donor reentry recommendations
3. Explain the requirements and process for blood establishment registration
4. **Describe the steps in submitting a biologics license application (BLA) for blood and blood components**
5. Explain the BLA review process and common deficiencies in submissions
6. Describe the pre-license and pre-approval inspection process and common citations

What is a BLA?

A BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce

- Submitted by an applicant (manufacturer)
- Must contain information which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency

Original BLA versus BLA Supplement

Original BLA

- You are a **new entity** seeking to manufacture blood/blood components or source plasma
- Your organization has **no existing U.S. License Number**
- You are requesting a **new biologics license**
- Requires **pre-license inspection (PLI)**
- New U.S. License Number issued upon approval

BLA Supplement

- You are an **already-licensed entity** with an existing U.S. License Number
- You want to **add a new facility** under your existing license, which requires **pre-approval inspection (PAI)**
- You are making **manufacturing changes** to approved operations
- You want to **manufacture additional blood components** at your existing facility

BLA Supplement Types

- **Prior Approval Supplement (PAS)** - 21 CFR 601.12(b): **Substantial potential** to adversely affect safety or effectiveness; **FDA approval required before distribution**
- **Changes Being Effected in 30 Days (CBE-30)** 21 CFR601.12(c): **Moderate** potential to adversely affect safety or effectiveness; Submit at least 30 days before distribution
- **Changes Being Effected (CBE)** - 21 CFR601.12(c): **Moderate** potential to adversely affect safety or effectiveness; Implement immediately after FDA receives submission
- **Annual Report (AR)** 21 CFR 601.12(d): **Minimal** potential to adversely affect safety or effectiveness; No pre-approval required ; Submitted annually

[SUBSTANTIAL] Stop /wait for Approval ▶ [MODERATE] Caution ▶ [MINIMAL] Go Ahead

Examples of Supplements

Change	Example
Prior Approval Supplement (PAS)	Implementation of a new immunization program for Red Blood Cells or vaccines
Changes Being Effected in 30 days (CBE30):	Implementation of a new manufacturing process, such as leukoreduction of blood components or apheresis collections previuosly approved under a comparability protocol (CP)
Changes Being Effected (CBE)	Use of an FDA registered contract facility that currently performs manufacturing steps on blood products
Annual Report (AR)	Implementation of infectious disease test required or recommended by FDA, if directed by the relevant guidance document to report implementation in AR

Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture | FDA

When to Submit:

- The facility must register with FDA within 5-days after beginning operations or within 5-days after the submission of the BLA

  (21 CFR 607.21)
- Operations must be established:
  - Manufacturing has started
  - Personnel have been trained
  - Operations and processes have been validated, and all operations are compliant

Applicable regulations: 21 CFR 600.21 & 21 CFR 601.2

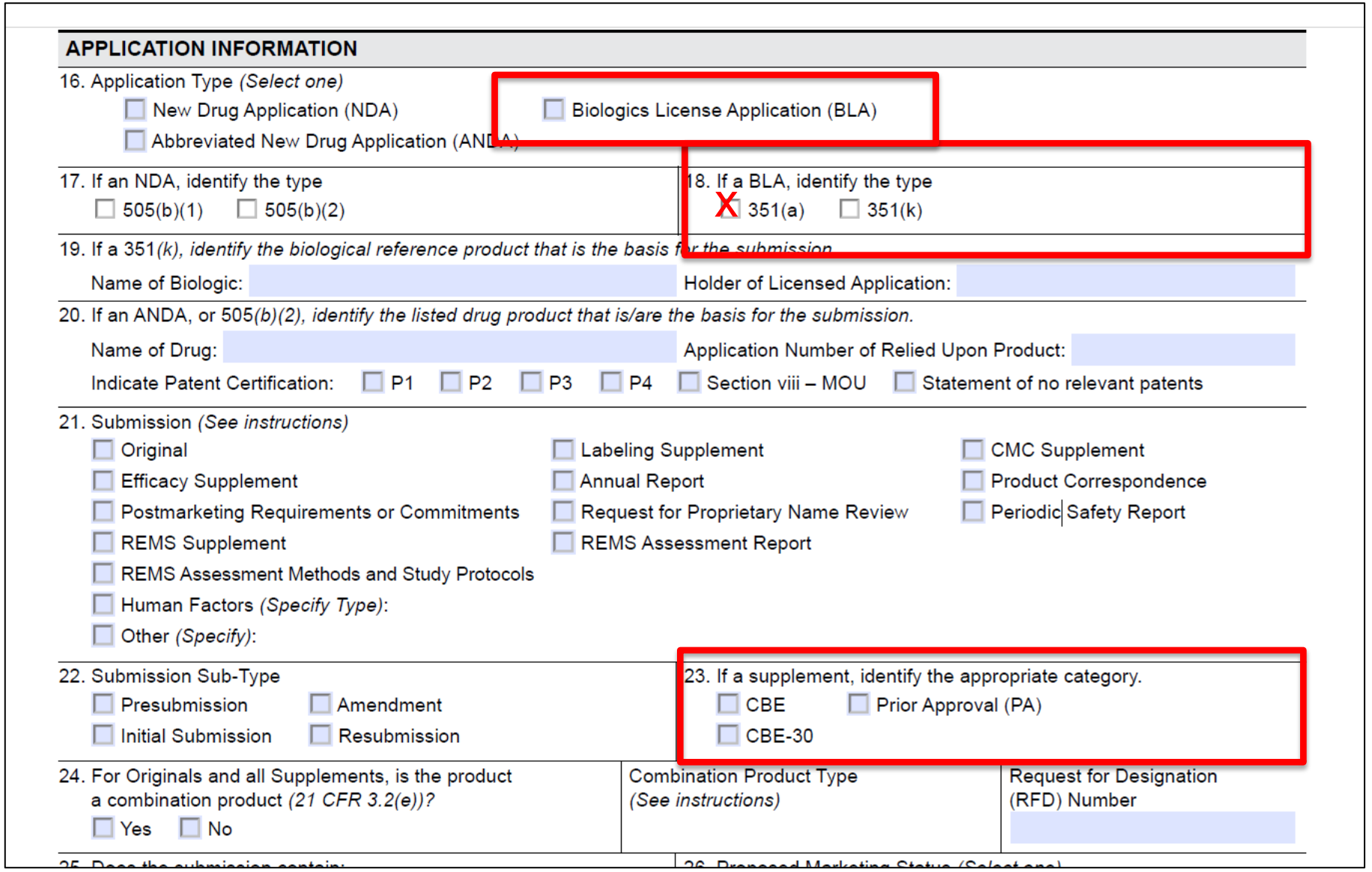
Pre-Submission Contact & Information Request

- Original BLAs – Applicants are highly encouraged to contact OBRR before submission
- If an inspection is necessary, OBRR will send a request for information necessary for inspection upon receipt of the BLA or supplement
  - Note: Most licensed Source Plasma Centers (manufacturing supplements) already have these documents and usually submit them along with the supplement

What to Submit

- A signed Form FDA 356h: *Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use,* signed by Authorized Official (AO) https://www.fda.gov/media/72649/download
- Form FDA 2830: *Blood Establishment Registration and Product Listing* **(Original BLA & New Facilities)**
- Sufficient information about manufacturing processes consistent with applicable regulatory requirements

Form FDA 356h



APPLICATION INFORMATION

16. Application Type *(Select one)*
- ☐ New Drug Application (NDA)
- ☐ Abbreviated New Drug Application (ANDA)
- ☐ Biologics License Application (BLA)

17. If an NDA, identify the type
- ☐ 505(b)(1)
- ☐ 505(b)(2)

18. If a BLA, identify the type
- X 351(a)
- ☐ 351(k)

19. If a 351*(k), identify the biological reference product that is the basis for the submission.*

Name of Biologic:

Holder of Licensed Application:

20. If an ANDA, or 505*(b)(2), identify the listed drug product that is/are the basis for the submission.*

Name of Drug:

Application Number of Relied Upon Product:

Indicate Patent Certification: ☐ P1 ☐ P2 ☐ P3 ☐ P4 ☐ Section viii – MOU ☐ Statement of no relevant patents

21. Submission *(See instructions)*
- ☐ Original
- ☐ Efficacy Supplement
- ☐ Postmarketing Requirements or Commitments
- ☐ REMS Supplement
- ☐ REMS Assessment Methods and Study Protocols
- ☐ Human Factors *(Specify Type)*:
- ☐ Other *(Specify)*:
- ☐ Labeling Supplement
- ☐ Annual Report
- ☐ Request for Proprietary Name Review
- ☐ REMS Assessment Report
- ☐ CMC Supplement
- ☐ Product Correspondence
- ☐ Periodic Safety Report

22. Submission Sub-Type
- ☐ Presubmission
- ☐ Amendment
- ☐ Initial Submission
- ☐ Resubmission

23. If a supplement, identify the appropriate category.
- ☐ CBE
- ☐ Prior Approval (PA)
- ☐ CBE-30

24. For Originals and all Supplements, is the product a combination product *(21 CFR 3.2(e))?*
- ☐ Yes
- ☐ No

Combination Product Type *(See instructions)*

Request for Designation (RFD) Number

Form FDA 2830

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	FEI: DUNS: U.S. License Number:	REASON FOR SUBMISSION	DISTRICT OFFICE: Atlanta VALIDATED BY FDA
LEGAL NAME AND LOCATION:	REPORTING OFFICIAL:		U.S. AGENT:
OTHER NAMES USED IN THIS LOCATION:	TYPE OF OWNERSHIP: DONOR/RECIPIENT RELATIONSHIP:		ESTABLISHMENT TYPE:

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
WHOLE BLOOD	X							X	X			
RED BLOOD CELLS (RBC)				X	X	X		X	X			
CRYOPRECIPITATED AHF									X			
PLATELETS			X	X	X	X			X	X		
PLATELETS EXTENDED DATING			X	X	X	X			X	X		
PLASMA			X	X	X				X			
PF24 PLASMA				X					X			
PF24RT24 PLASMA									X			
FRESH FROZEN PLASMA			X	X	X				X			
LIQUID PLASMA				X	X				X			

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF BLOOD PRODUCTS AND LICENSED DEVICES	FEI: DUNS: U.S. License Number:	REASON FOR SUBMISSION	DISTRICT OFFICE: Atlanta VALIDATED BY FDA:
LEGAL NAME AND LOCATION:	REPORTING OFFICIAL:		U.S. AGENT:
OTHER NAMES USED IN THIS LOCATION:	TYPE OF OWNERSHIP: PARTNERSHIP		ESTABLISHMENT TYPE:

PRODUCT	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS	BACTERIAL TESTING	PATHOGEN REDUCED	POOLED
SOURCE PLASMA			X						X			

Submission Content

- **Cover Letter dated and signed by AO to include:**
  - Applicant legal name and address
  - Facility requesting approval (address and Registration Number)
  - Summary of the request (reason for the supplement)
  - BLA content summary (table of contents preferred)
  - Product names and manufacturing methods
  - Blood product validation plan and summary of validation results
  - Blood product quality control data for two consecutive months

Submission Content (cont'd)

- Applicable Standard Operating Procedures (SOPs)
- Container Labels (if applicable)
- Manufacturer's Instructions (package insert)
- Equipment Validation Documentation:
  - Installation Qualification (IQ)
  - Operational Qualification (OQ)
  - Performance Qualification (PQ)

Original BLA: SOPs

- **Medical Oversight:**
  - Medical supervision and Physician Substitute program
  - Serum Protein Electrophoresis/Syphilis testing and medical review

- **Donor Eligibility and Requalification:**
  - Donor selection and registration
  - Donor screening (donor eligibility and donation suitability)
  - Donor acknowledgement and informed consent
  - Donor physical examination process (Source Plasma)
  - Donor re-entry

Original BLA: SOPs (cont'd)

- **Collection Procedures**
  - Arm preparation
  - Blood product collection and management
  - Sample collection/testing for relevant transfusion-transmitted infections (RTTI)
  - Red blood cell loss management

Original BLA: SOPs (cont'd)

- **Donor Management, Counseling and Notification:**
  - Donor adverse events
  - Fatality Reporting
  - Donor deferral, notification and counseling
  - Lookback and consignee notification

Original BLA: SOPs (cont'd)

- **Product Management:**
  - Product labeling
  - Source Plasma quarantine hold procedure
  - Source Plasma and frequent plasma donation
- **Equipment & Supplies:**
  - Equipment quality control, calibration and maintenance
  - Storage and release of critical supplies

Original BLA: SOPs (cont'd)

- **Quality Systems:**
  - Quality assurance program
  - Management of deviations and internal assessments
  - Document management
  - Failure investigations and Biologic Product Deviations
  - Downtime procedures

How to Submit

- The Electronic Submissions Gateway (ESG):
  - Agency-wide solution for accepting electronic regulatory submissions that enables the secure submission of regulatory information for review. Instructions for setting up an ESG account can be found at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm
- Submissions may also be submitted electronically via email at CBERDCC_eMailSub@fda.hhs.gov

Secure Email

- CBER strongly encourages the use of secure email 🔒
  - If you do not have secure email, you will receive notification requesting authorization to use non-secure email for all communications related to the submission OR will be asked if you would like to establish secure email
  - To establish secure email, please follow the instructions in SOPP 8119 Use of Email for Regulatory Communications, Appendix A available at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm109645.htm

FDA Receipt and Assignment

- The FDA Document Control Center (DCC) will electronically receive, process, validate, and load application into the specific electronic system and assign a **Submission Tracking Number (STN)**
- DCC sends the supplement to OBRR and it is assigned to a Regulatory Health Project Manager (RHPM)

Note: The application will be routed based on the product name as reported by the applicant on the Form FDA 356h

Receipt & Assignment (cont'd)

- The RHPM sends the submission to the BPB Team Leads requesting assignment to the reviewer

- The BPB Team Leads assign the submission to a Consumer Safety Officer (CSO) and add the CSO to the review committee

Review Committee

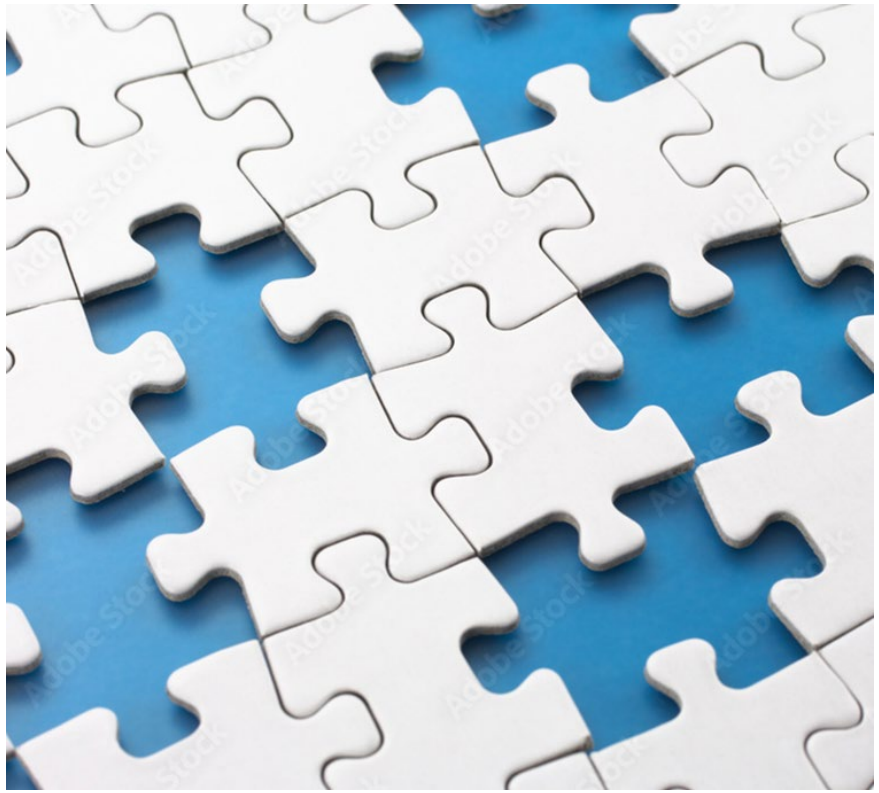
- **RHPM:** Manages the overall review process, including timelines for completion of regulatory and administrative actions, review committee meetings, communications related to the application
- **CSO:** Reviews of all components of submission, completes the appropriate documentation, creates a review memo, participates in review committee meetings, and enters information into the appropriate regulatory systems

Acknowledgment Letter

- OBRR will send an acknowledgement letter that confirms receipt of submission and provides key information:
  - 📋 **Submission Information:** Date submitted, and date received; Reason for submission; U.S. License Number; Supplement type and applicable regulation (e.g., CBE-30 under 21 CFR 601.12(c))
  - 📅 **Review Timeline:** Target goal date (based on availability of resources); Filing decision timeline (typically within 60 days of receipt)
  - 📝 **Administrative Requirements:** Submission tracking number (STN) - use on all future correspondence; Instructions for submitting additional information
  - ⚠️ **Important Clarifications:** Acknowledgement is not approval; or that we have reviewed the submission and data
  - 📞 **Contact Information:** RHPM name, phone, and email

Filing Review Process

- CSO examines submission to determine if it can be filed
- If the submission is scientifically or administratively incomplete, FDA will **refuse to file** and send a communication to the applicant



Why does FDA conduct Filing Reviews?

- Is a regulatory tool used to determine completeness of an application
  - Avoids unnecessary review of incomplete submissions
  - Prevents inefficient multiple-cycle reviews
  - Allow applicants to address critical deficiencies and resubmit a new application

Common Reasons for RTFs

1. **Administrative Incompleteness:** Clear omission of required information or sections (missing SOP's, validation, QC data)
2. **Scientific Incompleteness:** Missing critical data, information needed to evaluate safety, purity, and potency
3. **Inadequate Content/Presentation/Organization:** Information presented in a way that precludes meaningful review such as Illegibility, uninterpretable data, missing data references or protocols

What Does "Filing" Mean?

MEANS:	DOES NOT MEAN:
✅ The submission contains **sufficient information** to permit a substantive and meaningful review	❌ A license has been or will be issued
✅ CBER has determined the submission contains minimum required information to begin review	❌ The submission has been approved
✅ CBER will conduct a comprehensive evaluation of the submission	❌ CBER has evaluated the adequacy or quality of the data and information submitted
	❌ The facility or product meets all regulatory requirements for approval

What Happens Next?

- **If the BLA is Successfully Filed:**
  - CSO starts the interactive review process
  - CBER may request additional information as needed
  - Inspection Process (if applicable):
    - CSO will schedule a PLI for Original BLAs or PAI for supplements
    - Firm will be notified at least 30 days prior to the scheduled inspection
- **If Application is Not Filed:**
  - FDA will refuse to file (RTF) and send an **RTF letter** explaining deficiencies
  - Applicant must address deficiencies and resubmit

Additional Information for Inspection

If an inspection (PLI/PAI) is required OBRR will request additional information/data for review:

- **Data Timeframe**
  - **Source Plasma Centers:** Data since opening (~3 months) because facilities typically submit shortly after opening
  - **Blood Centers:** Data for last 6 months because facilities are usually operational longer before submitting
- **Self-Assessment**
  - Authorized Official must date, sign, and attest to the accuracy of the information submitted

Information Request Documents (PLI & PAI)

INFORMATION REQUEST FOR NEW SOURCE PLASMA CENTER APPROVALS

Name of firm: _____Reg#_____

Address: _____

STN: _____Authorized Official _____

Name/Title of Person Suppling Information_____

Please provide the documents requested below:

#	Request
1	**Self- Assessment:** Complete the attached New Source Plasma Center Information form, based on records for this center. Date and sign the form and return with the requested documents below. The Authorized Officials' signature attests to the completeness and accuracy of the information provided on the form.
2	**Deviations**
2.1	Summary of all major deviations that have occurred since the center opened. Include date of event, dates opened and closed (if applicable) and brief description
3	**Donor Adverse Reactions**
3.1	Summary of donor adverse reactions since opening that were classified as moderate or severe. Include the donor identification #, date and type of reaction.
3.2	Files for all reactions that resulted in calling 911, transport of the donor to the hospital or admission of the donor to a hospital; include the outcome and status of the donor – able to donate, temporarily deferred or permanently deferred
4	**Donors with Reactive Tests and Post Donation Information**
4.1	Summary of all donors identified as having reactive results for tests required under 21 CFR 610.40(a) including results of screening and confirmatory/supplemental tests
4.2	3 complete files each for donors serologically reactive for HIV, HBsAg, HCV or syphilis, including those with confirmed positive results (total = 12 files or fewer, if there are fewer than 3 donors with reactive results for any category) Include the actual test results, the dates the results were received, when the donor was deferred, donor notification records and the disposition/status of all units collected from these donors.
4.3	Summary of all donors deferred for post donation information since opening including the reason, disposition of units collected from the donor, and current status of the donor (permanently deferred, temporarily deferred or reinstated).
5	**Initial and Periodic Qualification of Donors**
5.1	Files for 2 applicant/new and 2 qualified/repeat donors showing results of initial and periodic SPE testing, dates testing performed and dates of physician substitute/physician review. If available, include at least one file for a donor who has been donating for > 6 months and one file for a donor who was deferred for having an abnormal SPE result and then was reinstated.

INFORMATION REQUEST FOR NEW BLOOD COLLECTION FACILITIES

Applicant: _____Reg#_____

Address: _____

STN: _____Authorized Official _____

Name/Title of Person Suppling Information_____

Please provide the documents requested below:

#	Request
1	Complete the attached New Blood Collection Facility Information request, based on records for this center. Date, sign and return with the requested documents below. The Authorized Officials' signature attests to the completeness and accuracy of the information provided.
2	**Deviations**
2.1	Provide a summary of all major deviations that have occurred for the last 6 months. Include date of event, dates opened and closed (if applicable) and brief description.
3	**Donor Adverse Reactions**
3.1	Provide a summary of donor adverse reactions for the last 6 months that were classified as moderate or severe. Include the donor identification #, date and type of reaction.
3.2	Provide records of adverse donor reactions for the last 6 months that resulted in outside medical care including 911 transport of the donor to the hospital or admission of the donor to a hospital; include the outcome and status of the donor – (permanently deferred, temporarily deferred, or reinstated).
4	**Donors with Reactive Tests and Post-Donation Information**
4.1	Provide a summary of all donors who donated at this center and were identified as having reactive results for tests required under 21 CFR 610.40(a) including results of screening and confirmatory/supplemental tests.
4.2	Provide one (1) complete record for each donor serologically reactive for HIV, HBsAg, HCV, HTLV I/II, or syphilis, including those with confirmed positive results (total = 5 files or fewer). Include the actual test results, the dates the results were received, when the donor was deferred, donor notification records and the disposition/status of all units collected from these donors.
5	**Summary of Biological Product Deviation Reports (BPDRs) for the last 6 months**

Information Request Overview

- **Records Request:**
  - Summary of major deviations (date of event, description, dates event was opened/closed)
  - Donor Adverse Reactions (moderate, severe, to include 911 transports)
  - Donors with reactive test results (results of screening and confirmatory/supplemental tests and donor notification records)
  - Post-donation information
  - Initial and Periodic Qualification of donors **(Source Plasma Only)**
  - Summary of Biological Product Deviation Reports **(Blood Centers ONLY)**

Other Information & Documents

- **Operational Details**
  - Date the facility opened for operations
  - Hours of operation (days/times facility is operational)
  - Number of employees to include number currently in training
- **Facility & Personnel Documentation**
  - Organizational chart
  - Floor plan
  - Staff job descriptions

Other Information & Documents (cont'd)

- **Management and Medical Personnel**
  - Management staff (key leadership positions)
  - Name of Responsible Physician (must be licensed in the jurisdiction where the facility is located) (21 CFR 630.3(i)(1))
  - Other medical personnel (must be licensed in the jurisdiction where the facility is located) (21 CFR 630.3(g)(2))
    - For Source Plasma facilities - Physician substitutes (medical profession (i.e. RN, EMT, LVN, paramedic) and expiration date of license and CPR certification)

Other Information & Documents (cont'd)

- **Donor Screening**
  - Donor History Questionnaire (full and abbreviated)
  - Donor educational materials
  - High-risk and travel posters
  - Medication list
  - Donor informed consent forms
  - Donor notification letters

Other Information & Documents (cont'd)

- **Equipment:**
  - Donor screening equipment in use and validation
  - Collection equipment in use and validation
  - Product storage equipment in use and validation
  - Equipment operator's manuals (as applicable)
- **Computer Systems: Blood Establishment Computer Software (BECS)System information**
  - Includes Computer-Assisted Self-Interview (CASI) Validation documentation (administered on site, remote or both)
  - Program and functions including system name and version
  - 510(k) clearance number

Other Information & Documents (cont'd)

- **Product Information**
  - Products collected and intended use
  - For Blood Centers: Number of donations listed by product type
  - For Source Plasma centers: Number of donors, number of donations and total number of units collected
- **Contract Facilities:**
  - Testing laboratory
  - Product storage
  - Biohazard waste disposal
  - Product transport services

Other Information & Documents (cont'd)

- **Storage Capacity & Temperature Control (Source Plasma Centers)**
  - Freezer storage capacity,
  - Core freezing temperature maintained
  - Validation date of freezer
- Temperature monitoring system in use (specify system type/manufacturer)
- Frequency of alarm activations
- Number of temperature excursions (if applicable)
- Contingency plan if power outage occurs

Successful BLA Submission Dos and Don'ts

Do	Don’t
✅ **Complete all required forms** - ensure every field is filled out accurately	❌ **Submit incomplete forms** - missing information delays filing
✅ **Submit relevant documents only** - include what's required and applicable to your facility	❌ **Submit everything hoping it's right** - quality over quantity
✅ **Contact OBRR before submission** - highly encouraged to confirm requirements	❌ **Assume all documents apply** - only submit what's relevant to your application
✅ **Review for completeness** - verify all required information is included	❌ **Skip the pre-submission contact** - CBER can provide guidance on requirements

Timeline ⏱️

- The review timeline begins upon CBER receipt of the application
- Blood establishments are not subject to PDUFA and do not pay user fees
- There are no statutory requirements for review timelines
- However, CBER's practice is to follow PDUFA guidelines for non-user fee applications
  - For example, an Original BLA has a 12-month review clock

Summary: Key 🔑 Takeaways

- **When to Submit:**
  - **Original BLAs:** New entities with no U.S. License Number; facility operational minimum 3 months; **BLA Supplements:** Licensed entities adding new facilities or making manufacturing changes
- **Before You Submit:**
  - **Highly encouraged:** Contact CBER; Ensure facility is registered, operational, validated, and compliant; Collect minimum 3 months of data (Source Plasma) or 6 months (Blood Centers for supplements)
- **What to Submit:**
  - Forms: FDA 356h (signed by AO), FDA 2830
  - Cover letter with facility details and summary
  - Relevant SOPs, validation documentation, equipment information
  - BECS/CASI information with 510(k) clearance numbers
  - Donor materials and facility documentation

Summary: Key 🔑 Takeaways

- **Submission Process:**
  - Submit via ESG or email (secure email encouraged)
  - DCC assigns STN and routes to OBRR
  - RHPM and CSO assigned to review committee
  - Acknowledgement letter sent confirming receipt
- **Filing & Review:**
  - Filing review completed within 60 days Filing ≠ Approval or data evaluation
  - RTF issued if submission incomplete or inadequate
  - Review timeline: ~12 months for Original BLAs (based on PDUFA guidelines, resources permitting)

Remember !

- ✓ Complete all forms accurately
- ✓ Submit only relevant documents
- ✓ Contact CBER with questions
- ✗ Don't submit incomplete information
- ✗ Don't assume "more is better"

Contact Information

- **Discuss Your Plans (Pre-Submission Meetings)**
  If you would like to discuss your plans before submitting a supplement, we recommend requesting a meeting to review your approach and questions.
  Contact: Cherry.Geronimo@fda.hhs.gov
  (For information on scheduling a meeting with OBRR)
- **Supplements Under Active Review**
  For questions related to a supplement currently under review, please contact the **Regulatory Health Project Manager (RHPM)** listed in your Acknowledgement Letter
- **General Inquiries (No Meeting Requested)**

  Please email us at: CBEROBRRBPBInquiries@fda.hhs.gov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Biologics License Application Review Process

Camilla Smith, BS, BB(ASCP)SBB, CQA(ASQ)

Lead Consumer Safety Officer, Blood and Plasma Branch

OBRR/CBER/FDA

May 12, 2026

Objectives

1. Describe FDA regulatory requirements for the manufacture of blood and blood components, including Source Plasma
2. Identify testing, donor deferral and notification requirements for relevant transfusion-transmitted infections (RTTIs) and donor reentry recommendations
3. Explain the requirements and process for blood establishment registration
4. Describe the steps in submitting a biologics license application (BLA) for blood and blood components
5. **Explain the BLA review process and common deficiencies in submissions**
6. Describe the pre-license and pre-approval inspection process and common citations

Goal for the BLA Review Process

- **CBER's Goal:** Provide efficient and effective reviews for all new license applications (original BLA) and supplements (established firms, BLS)
- **Applicant's Goal:** Create an application can be readily reviewed and is likely to satisfy regulatory requirements
  - FDA will determine whether a submitted application meets requirements for approval of the manufacturing process for the product
  - FDA may send the applicant questions (Information Requests (IRs))
  - Active applicant involvement is ESSENTIAL during the review process

Successful BLAs for Blood Components and Source Plasma

Demonstrate compliance with the following:

- Code of Federal Regulations (21 CFR 600 -799)
- Guidance documents (www.fda.gov/bloodguidances)
- Operator's Manuals for devices (21 CFR 606.65(e))
- Package Inserts for reagents and supplies (21 CFR 606.65(e))

Avoid Potential Delays

✗ Don’t submit SOPs or documents that are not relevant to the manufacturing process or change

✓ Always include a cover letter

✓ Submit all documents that are referenced in your SOPs

✓ Make sure SOPs are consistent with the package insert, operator’s manual and current Code of Federal Regulations (CFR)

✓ Implement a Blood Establishment Computer Software (BECS) for donor and product record keeping

Key BLA Review Steps

- Perform comprehensive review and document findings
- Send information request to obtain additional information or clarification
- Present findings and preliminary regulatory recommendation at mid-cycle meeting
- Conduct inspections if applicable
- Finalize review memo and request compliance check
- Letter to applicant with regulatory decision

Materials Reviewed

- Cover Letter
- Table of Contents
- Form FDA 356h
- Form FDA 2830
- Container Labels (if applicable)
- Circular of Information(if applicable)
- Chemistry, Manufacturing Controls (CMC) Information
  - Standard Operating Procedures
  - Validation Summary and Data
  - Quality Control (blood centers)
  - Other applicable documents (PI, OM)

Materials Reviewed

The Cover Letter:

- Signature of the Authorized Official
- Name of facility requesting approval: registration number and/or license number
- Clear explanation of request
- Reference relevant previously approved SOPs, comparability protocols (BLS)

Common Mistakes in the Cover Letter

- Not signed by an authorized official
- Does not have a current date
- Registration number of the facilities where the manufacturing processes will occur are not included
- Describes an obsolete process

Labeling Material Reviewed

- Container Labels and Circular of Information (COI)
  - 21 CFR 606.121, 21 CFR 606.122
- Copies of each container label used at the establishment (full face container label)
- Display license number (BLS)
- Only submit facility specific pages in your COI

SOPs Reviewed

- Relevant Standard Operating Procedures approved by the Responsible Physician
- Schedules and procedures for equipment maintenance and calibration
- Complaints and investigations of adverse reactions arising from blood donation
- Personnel responsible for the collection, processing, compatibility testing, storage or distribution
  - adequate in number, educational background, training and experience

Common Mistakes in SOPs

- SOPs with major changes are submitted in an Annual Report
- SOPs are submitted to FDA without a new version number, or evidence that it was approved by your Responsible Physician
- Acronyms are not defined
- Failure investigation steps are missing, the role of the quality unit is not addressed
- SOPs are not consistent with the device manufacturer's instructions or operator's manual
- SOPs are not relevant to the manufacturing process change in the supplement

Validation and Quality Control Data Review

- Validation summary and data, and two consecutive months of Quality Control

For example, FDA recommendations for leukocyte reduction are found in:

Recommendations in the FDA Guidance for Industry, September 2012, Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion

Additional Information Reviewed

- Donation type (Volunteer, Paid)
- BECS
- Collection device(s)
- Physician Substitute Program (Source Plasma)
- Position descriptions
- Medical oversight
- Form FDA 2830 (Registration)
- QA unit and corporate duties
- List contract services
- List of equipment
- Donor informed consent
- SOPs and Operator Manual

Comparability Protocol

- Submitted initially as a Prior Approval Supplement (PAS) and may be combined with a product manufacturing supplement
- Describes specific tests and validation studies and acceptable limits to achieve/demonstrate lack of adverse effects
- Once approved, allows for a lower reporting category for the same change, using the same device, implemented in an affiliated center
  - PAS (12 months) downgraded to a CBE-30 (6 months)
- Example: Implementation of the manufacture of Apheresis Red Blood Cells using the same device

Without a Comparability Protocol

Applicant requests implementation for manufacture of Apheresis Platelets at seven centers using instrument X

- Center 1 develops SOPs, performs testing, validation, training.
- Center 1 submits PAS
- FDA reviews and approves implementation, Center 1 may begin interstate distribution of the licensed product
- To implement change at remaining centers, the applicant must submit a PAS each time to obtain approval for each facility to implement interstate distribution

With a Comparability Protocol

Applicant requests implementation for manufacture of Apheresis Platelets at seven centers using instrument X

- Center 1 develops SOPs, performs testing, validation, training
- Center 1 submits the PAS with a request for a CP
- FDA reviews and approves the CP and implementation of the change at Center 1
  - Future implementation of the CP may be reported as a CBE30 provided it follows the plan in the CP
  - CBE30 only applicable if the additional facility has an inspectional history

Comparability Protocol Review

- FDA Form 356h / Cover Letter
  - Request a CBE30 downgrade for subsequent implementation at affiliated facilities
- SOPs / Records and Forms
- Quality Control (QC) logs
- Labeling information
- Description of the change, implementation plan and training
- Tests and validation protocols
- Product acceptance criteria
- Quality assurance oversight
- Validation Summary and two months of QC data
- QC testing procedures / sampling plan / Actions for failed results

Inspection Ready?

- When an inspection is required, all inspection related information is included in the review file
- If a 483 is issued, written responses to all 483 items should be submitted to CBER
- Inspection findings are documented and reviewed for inspection classification
  - Inspection findings are considered when making final regulatory decisions

BLA Review: Possible Outcomes

- **Approval**
  - The establishment and the manufacturing process for the product meet the applicable regulatory requirements
- **Complete response (CR)**
  - When single cycle approval is not achievable, CBER may issue a CR letter
  - Deficiencies identified in submission
  - Unsatisfactory or unresolved inspection findings

Approval letter

- For Original BLA:
  - Describes products manufactured, name of facility, license number, applicable labeling
- For BLA supplements:
  - Describes manufacturing change and product, name of facility (or facilities), applicable labeling

Complete Response (CR) Letter

- The CR letter lists all deficiencies identified and recommends actions necessary to address the deficiencies
  - A CR response stops the review clock
- The applicant must submit a response (Resubmission) within 1 year or withdraw the application
  - The review clock restarts only when the responses satisfactorily address all issues in the CR letter

Complete Response Letter

- If a response is not received from the applicant within 1 year:
  - FDA may consider such failure to respond as a request to withdraw the application or supplement
  - FDA will notify the applicant in writing, and the applicant will have 30 days to respond (e.g., request an extension of time for resubmission)
  - If the applicant fails to respond, the application or supplement will be deemed to be withdrawn, and FDA will send a withdrawal letter

21 CFR 601.3(a)

Compliance Check

- A review of each manufacturing location included in the BLA or supplement
- For each location affected by the manufacturing change, a review is performed to ensure there are no ongoing or pending investigations or compliance actions
- Applies to all BLAs and supplements, except minor labeling changes
- Must be completed before issuance of a license or approval of a supplement

Compliance Check (cont'd)

- OBRR will request a compliance check after determining that the application can be approved
- FDA inspections must be completed and closed before the compliance status can be determined
- Office of Compliance and Biologics Quality (OCBQ) performs the compliance check
- OCBQ may not recommend approval of a submission when the compliance status is unacceptable

Actions after the Compliance Check

- If the compliance check is acceptable, the RPM drafts the approval letter
- If a compliance check is unacceptable, the approval process stops
  - A CR Letter is sent to the applicant
  - The review clock is stopped

Review Timelines

Supplement	Timeline
Prior Approval Supplement (PAS)	9-12 months
CBE – 30, CBE	6 months
Annual Report (AR)	6 months
Special Labeling Supplement – CBE	5 months

Responsibilities after Licensure

After licensure :

- Place the license number on container labels
- Distribute licensed products interstate (out of state), if you choose
- Approvals are specific to site, product, method, and product
- Comply with FDA regulations on cGMP including fatality reporting and biological product deviation

Responsibilities after Licensure

- Maintain current and correct registration and product listing information
- Notify CBER of any changes to the approved license, including contractor changes
- Be prepared for FDA inspections
- Submit an annual report each year listing changes in the product, production process, quality controls, equipment, facilities, or responsible personnel that have a minimal potential to have an adverse effect

Summary: Key 🔑 Takeaways

- It is essential to submit all relevant documents for review
  - Allows for comprehensive and timely review
- Review process is interactive and FDA may request additional information or clarification
- OBRR will perform inspections if applicable
- A compliance check is required before approval of an application
- Regulatory decisions- Approval or Complete Response
- Licensed establishments should be aware of responsibilities after approval


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Pre-License and Pre-Approval Inspection Process, Expectations, and Common Citations

Cathy McGraw , MSN RN

Consumer Safety Officer, Blood and Plasma Branch

CBER/DBCD/OBRR

May 12, 2026

Objectives

1. Describe FDA regulatory requirements for the manufacture of blood and blood components, including Source Plasma
2. Identify testing, donor deferral and notification requirements for relevant transfusion-transmitted infections (RTTIs) and donor reentry recommendations
3. Explain the requirements and process for blood establishment registration
4. Describe the steps in submitting a biologics license application (BLA) for blood and blood components
5. Explain the BLA review process and common deficiencies in submissions
6. **Describe the pre-license and pre-approval inspection process and common citations**

What Is An Inspection?

- **Investigations Operations Manual 5.1.2:** An establishment inspection is a careful, critical, official examination of a facility to determine its compliance with the laws and regulations administered by FDA
  - Investigations Operations Manual | FDA

Types of Inspections

- Purpose:
  - Verify data integrity, ensure compliance with cGMP, and confirm facility readiness
- Pre-License Inspection (PLI):
  - Conducted before approval of a biologics license application (BLA)
- Pre-Approval Inspection (PAI):
  - Specifically for biologics facilities before BLA approval

Regulatory Foundation

- **Primary Purpose:**
  - Assess facility compliance with federal statutes and regulations (FD&C Act, PHS Act, 21 CFR)
- **Key Regulatory Authority:**
  - **PHS Act 351(a)(1)**
  - **42 USC 262(a)(2)(C):**
    - C) The Secretary shall approve a biologics license application—
      - (i) on the basis of a demonstration that—
        - » (I) the biological product that is the subject of the application is safe, pure, and potent; and
        - » (II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and
        - » (ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c)

  - 42 USC 262 - Regulation of biological products

Regulatory Foundation

- **21 CFR 601.20(d): *Inspection—compliance with requirements***
  - A biologics license shall be issued or a biologics license application approved only after inspection of the establishment(s) listed in the biologics license application and upon a determination that the establishment(s) complies with the standards established in the biologics license application and the requirements prescribed in applicable regulations

Pre-Approval Inspections

- **Pre-approval inspections are usually conducted as part of a Prior Approval Supplement (PAS) for:**
  - Major changes that have substantial potential to adversely affect product safety or effectiveness
  - Changes where product distribution cannot occur before FDA approval
  - Based on acceptable CBER compliance check
  - Compliance checks draw on prior inspection history to confirm that establishments are consistently adhering to all applicable federal laws, regulations, and guidelines, ensuring a thorough and informed review process

When Is An Inspection Needed?

- **Examples requiring PLI or PAI:**
  - Opening a new blood collection facility
  - Opening a new Source Plasma facility
  - Initiating a new program (e.g., RBC Immunization Program)
  - Adding a new collection-site with a specific manufacturing process to a facility without an inspectional history
  - BLA supplements based on new technologies or complex changes with impact on product

Pre-Inspection Notification Process

- **Timeline:**
  - After the blood establishment has been in operation for sufficient timeframe to demonstrate its ability to manufacture the product or complete the process for which licensure approval is being sought (21 CFR 600.21):
    - **Notification:**
      - The Authorized Official will be notified by email approximately 30 days in advance
    - **Information Provided:**
      - Inspection dates and time, location, and inspector name(s)

Pre-Inspection Notification Process

- **Facility should provide:**
  - Names and phone numbers of key staff for emergency contact
  - Special instructions (e.g., parking, parking fees, area construction)
  - Ensure blood collections and/or processes pending licensure are scheduled during inspections

Pre-Inspection Preparation

- **Recommendations:**
  - Review application data and ensure alignment with actual operations
  - Conduct internal audits and mock inspections
  - Prepare documentation (records, validation reports, quality control records, SOPs)
  - Ensure key personnel availability
  - Designate conference room or designated area

On-Site Inspection Process

- **Start of Inspection:**
  - FDA presents credentials and Form FDA 482 (Notice of Inspection)
  - Introductions
  - Discussion of inspection scope and schedule
  - Review of organizational structure
  - Tour of the establishment

On-Site Inspection Process: Review

- **During the Inspection:**
  - Standard Operating Procedures (SOPs)
  - Informed Consent / Donor Acknowledgement / Apheresis Consent
  - Deviations / CAPA Records
  - Post Donation Information
  - Donor Adverse Events
  - Donor Deferrals

On-Site Inspection Process: Review

- Validation of Equipment / Processes
- Adequate equipment qualification
  - Installation Qualification (IQ): Installation and configuration of the equipment.
  - Operational Qualification (OQ): Does the equipment operate correctly?
  - Performance Qualification (PQ): Does the equipment perform as intended consistently?
- Quality Control and Maintenance Records (e.g., Product, Equipment)
- Serum Protein Electrophoresis (SPE) Results

On-Site Inspection Process: Review

- Relevant Transfusion-Transmitted Infection (RTTI) Reactive Test Results
- Donor Notification / Donor Counseling
- Temperature Records / Temperature Excursions
- CPR Certification
- Responsible Physician / Physician Substitute Licensure
- Inspect and copy as needed any required records
- Make appropriate recommendations of actions needed

Note: This is not an all-inclusive list

On-Site Inspection Process: Observations

- During inspections, we typically look at several key areas, though the specific focus can vary
- Eyes-on visual observation of all operational methods used to manufacture product to be licensed, including but not limited to:
  - Registration
  - Donor Screening
  - Physical Exams
  - Donor Eligibility
  - Donor Privacy
  - Collections
  - Labeling
  - Processing
  - Storage

End of Day Meeting

- Daily inspection summary
- Key observations and findings
- Deficiencies or areas of concern
- Outstanding items / follow-up needed
- Next steps and schedule for next day

Inspection Closeout Meeting

- **Discussion Items/Non-Reportable Observations**
  - **Minor Regulatory Deficiencies:**
    - Deviations from regulations may be noted when the potential impact on product quality or safety is not immediately apparent or significant enough to warrant inclusion on Form FDA 483
  - **Guidance Document Deviations:**
    - Practices that deviate from FDA guidance documents (which are recommendations rather than requirements) may be discussed

Inspection Closeout Meeting

Future Follow-Up Items:

- Issues identified for review or monitoring during the next inspection

Open Dialogue:

- These discussions provide an opportunity for both the inspector and facility to engage in open dialogue, allowing the facility to clarify practices and the inspector to express the basis for any concerns

Inspection Closeout Meeting

Form FDA 483: Inspectional Observations:

- **Issued to** most senior official on-site at the time of inspection
- **Purpose:**
  - Notifies the facility of significant objectionable conditions related to products and/or processes that are observed during the inspection.
- **Basis for issuance:**
  - Reflects the inspector's judgment that the practices observed could result in the release of unsafe products
- **Response:**
  - The facility should provide a written response addressing the 483 observations within 15 days

Responding to Form FDA 483

We recommend the following:

- Provide written response within 15 days
- Address root cause, not just symptoms
- Include corrective and preventive actions with timelines
- Demonstrate management commitment
- Provide evidence of implementation when possible
- Be specific and avoid vague commitments

What Happens After The Inspection Is Completed?

- Respond to Deficiencies, If Applicable (e.g., response to Form FDA 483)
- Establishment Inspection Report (EIR) / Review
- Endorsement
- Compliance Check(s)
- Approval Letter

Potential Outcomes

Possible Classifications:

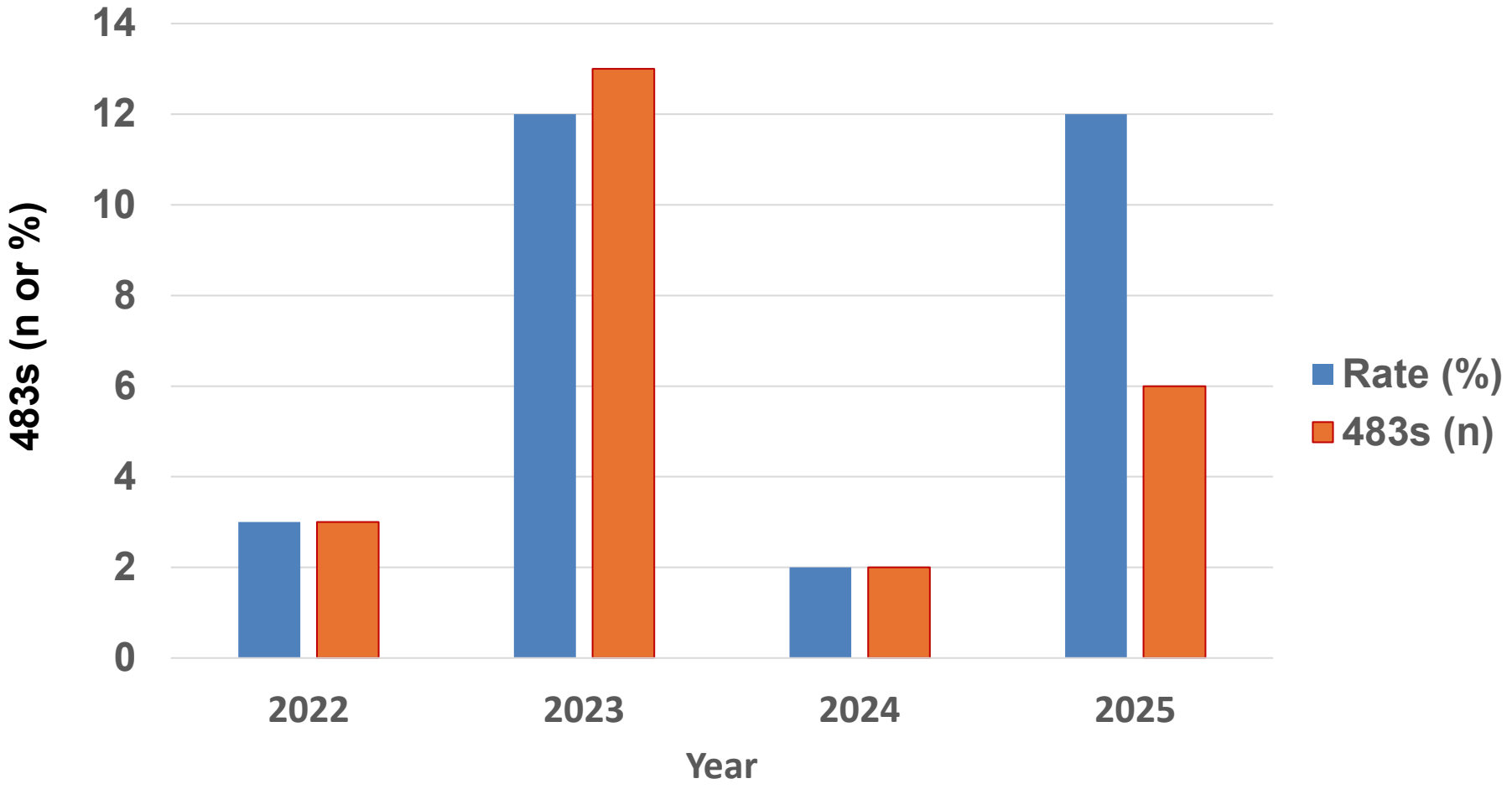
- **No Action Indicated (NAI)**:
  - Indicates a facility is in an acceptable state of compliance
- **Voluntary Action Indicated (VAI)**:
  - Indicates the inspection found objectionable conditions or practices but the agency has determined the facility can voluntarily correct its deficiencies and will not recommend any action
- **Official Action Indicated (OAI)**:
  - Indicates a facility is in an unacceptable state of compliance

Impact on Approval

Potential Consequences:

- **Complete Response Letter (CR)**:
  - Application not approved until deficiencies resolved
- **Withhold recommendation:**
  - Approval delayed pending re-inspection
- **Application approval:**
  - If deficiencies are minor and adequately addressed

483 Citations, 2022-2025



Common 483 Citations

Lookback

- **21 CFR 610.46(a)(1):**
  - The firm failed to notify the consignee within 3 days of discovering a donor who tested reactive for anti-HIV-1/2 and confirmed positive (H1P2N) on their donation. The firm's SOP does not include the appropriate steps to take when units collected at two or more centers are involved in a lookback case or which location or corporate is responsible for notifying consignees

RTTI Testing, Donor Notification, and Counseling

- **21 CFR 610.40(e):**
  - The establishment failed to further test each donation, found to be reactive by a donor screening test, using a licensed, approved, or cleared supplemental test, when available. If no such supplemental test is available, you must perform one or more licensed, approved, or cleared tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status

RTTI Testing, Donor Notification, and Counseling

- **21 CFR 630.40:**
  - The firm does not include all of the required information in the notification and counseling message provided to a donor who is deferred or determined to be ineligible for donation for having reactive results in testing performed for Relevant Transfusion-Transmitted Diseases (RTTI) on a Source Plasma donation. Specifically:
    - The firm's notification letter does not clearly state that the donor is deferred and ineligible to donate again based on the reactive screening result performed by the firm's contract laboratory.
    - The firm does not always include all of the additional test results obtained in testing performed on the donation sample for the viral marker that caused the donor to be deferred

RTTI Testing, Donor Notification, and Counseling

- **21 CFR 630.40:**
  - The firm does not provide the following information to donors who are deferred for reactive screening test results for Relevant Transfusion-Transmitted Infections (RTTI), if the donors do not return to the collection center as requested by the firm:
    1) That the donor is deferred or determined not to be eligible for donation and the reason for that decision.
    2) The types of donations that the donor should no longer donate.
    3) The results of tests for evidence of infection due to RTTI that were a basis for deferral, including results of further/additional testing performed, and
    4) Where appropriate, information concerning medical follow-up and counseling

Responsible Physician

- **21 CFR 640.65(2)(i):**
  - Reinstatement of Donors into the plasmapheresis program deferred for abnormal SPE/Total Protein test results are not performed by your Responsible Physician (RP).

- **21 CFR 640.65(2)(i) & 21 CFR 630.3(i)(1)(3):**
  - Reinstatement of donors into the plasmapheresis program deferred for abnormal Serum Protein Electrophoresis (SPE)/Total Protein test results are not performed by a Responsible Physician (RP) licensed to practice medicine in the jurisdiction where the collection establishment is located.

Current Good Manufacturing Practice (cGMP)

- **21 CFR 606.60(a):**
  - The firm did not recalibrate the 1350-gram weight used to perform daily quality control (QC) checks of the weigher scale on the cell separator device according to the schedule in the spreadsheet and as recommended by the facility that performs calibration of equipment for the firm.

  - The firm did not conduct a Performance Qualification (PQ) study of the freezers (-80 ℃ and -35 ℃) prior to use, to determine the core freezing time for units of Source Plasma. The freezers have been used to initially freeze and store Source Plasma units collected since the center opened without completing the initial freezer qualification to demonstrate this equipment performs as it was designed, to ensure compliance with manufacturing requirements for Source Plasma.

Failure to Follow SOPs

- **21 CFR 606.100(b):**
  - Supplies are not always used in a manner consistent with the instructions provided by the manufacturer. The firm did not follow the SOP which stated that reagents and supplies are to be stored at the temperature recommended by the manufacturer/vendor, and the storage temperature is to be monitored
  - The firm does not always follow their Standard Operating Procedure (SOP) for Donor Notification and Counseling concerning required documentation. The SOP states that a copy must be made of the Donor Notification Letter to maintain with the file. As a result, there is no way to determine from the records what results were provided to the donors

Failure to Follow SOPs

- **21 CFR 606.100(b):**
  - The firm does not always follow SOP and operator's manual instructions when performing QC of the refractometers. During morning QC observation, a technician covered the refractometer with their hand to block ambient light, a step not outlined in the SOP and inconsistent with the operator's manual, which specifies that shielding from ambient light should only occur states that the user should shield the surface area from ambient light or move the instrument to a new location only when an error code is displayed or remove the instrument from service

Failure to Follow SOPs

- **21 CFR 606.100(b) & 606.160(a)(1):**
  - Staff do not always follow the firm's standard operating procedures for performing steps in the manufacturing process and do not always document results of work performed concurrently when the work is performed

Personnel

- **21 CFR 606.20(b):**
  - The firm does not have an adequate number of personnel. Specifically, the center lacks permanent employees in critical positions to include: 1) the center director; 2) quality assurance supervisor and 3) physician substitutes. During an inspection we cannot adequately assesses personnel as they are not present or trained as necessary to assure competent performance of their assigned functions

Operational Readiness

- Conduct thorough self-assessments
- Ensure application-facility alignment
- Train staff on inspection readiness
- Maintain robust quality systems year-round
- Practice data integrity principles daily
- Foster culture of compliance and transparency

Inspection Preparation Resources

- FD&C Act and PHS Act 351(a)
- 21 CFR Part 600 -680
- Operator's Manuals and Package Inserts
- Compliance Program Guidance Manuals
- Compliance Policy Guides
- Investigations Operations Manual
- Guidance Documents

References

- FDA/CBER Blood Guidances: Blood Guidances | FDA
- 21 CFR Subchapter F: Biologics: Part 600-680:
  - eCFR :: 21 CFR Chapter I Subchapter F – Biologics
- Compliance Program Guidance Manual: Chapter 42 - Blood and Blood Components: Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors- 7342.001
- Compliance Program Guidance Manual: Chapter 42 – Blood and Blood Components: Inspection of Source Plasma Establishments, Brokers, Testing Laboratories, and Contractors - 7342.002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Questions Submitted to FDA

First-time BLA Applicants (1)

- **For first-time BLA applicants, what are the most common deficiencies identified during FDA's review?**

First-time BLA Applicants (2)

What general timelines should applicants expect from original BLA submission through licensure decision?

Labeling

- **When submitting a BLA supplement that references a prior application, what are FDA's expectations for resubmitting unchanged labeling versus cross-referencing labeling from a previous submission, particularly when adding new apheresis collection sites and the product label does not change?**

Inspection Readiness

How should a new establishment with limited operational experience prepare for and demonstrate readiness for an FDA inspection?

Inspections

Please describe FDA's current practices regarding pre-license and pre-approval inspections (PLI/PAI), including typical inspection notification timelines and the most common inspectional citations observed at new blood collection establishment?

Facility and Product Licensure (1)

Can a single submission request approval of both a new facility and licensure of products collected at that facility, or does FDA prefer these actions to occur separately or in a specific order?

Facility and Product Licensure (2)

Please provide guidance on addressing Certificates of Inspection (COI) during BLA review.

Comparability Protocol

For establishments that already hold an approved BLA, may a comparability protocol reference the existing licensed application rather than being included in a new BLA?

Changes to an Approved Application (1)

What is the current FDA-recommended process for adding a new collection facility to an existing establishment license and licensing products collected at that site?

Changes to an Approved Application (2)

Why is the addition of a new blood or apheresis collection center generally considered a "major change" requiring a Prior Approval Supplement (PAS) under 21 CFR 601.12(b), when the new site will operate under the same approved policies, procedures, quality system, and organizational oversight as existing licensed facilities?

Changes to an Approved Application (3)

Are there any circumstances under which adding a new blood or apheresis platelet/RBC collection site could be considered a moderate change appropriate for a CBE 30 under 21 CFR 601.12(c) and an inspection would not be performed?

Changes to an Approved Application (4)

We understand the requirement to notify CBER of substantial changes in SOPs, materials, testing, or equipment for processing source plasma donors.

Could you clarify whether minor changes, such as formatting adjustments to internal process documentation or forms used for donor processing, require notification?

Resubmission Requirements

What are the common reasons BLAs are delayed or do not result in approval on first review?

When is formal resubmission of a BLA required?

Form 356h (1)

Form 356 h contains many fields that are confusing and may not apply to blood and blood products.

- **Can you explain the rationale and applicability of form 356h to blood and blood products?**

- **Is it possible to create a form specific to blood products?**

Form 356h (2)

What are the minimal requirements for blood products that should be included on the form?

Can you clarify which entries on the current form are necessary or applicable specifically for blood products?

Communication (1)

Is there a pre-BLA process available for blood centers to address questions and receive feedback in real-time?

Communication (2)

What is the best way for a blood center to obtain the latest status of their submission?

Communication (3)

Please describe any best practices for communicating with the RHPM about my submission.

Resources

What is the most effective way for firms to stay up to date on FDA guidance updates, regulation changes, etc., that directly affect the Source Plasma industry?

Are there specific resources or tools you can recommend?

Donor Deferral Registry and Donor Reentry

How does FDA respond to complaints from blood donors (and on occasion, Congress on behalf of their constituents) who request to be removed from the National Donor Deferral Registry (NDDR) and ask to be reentered as donors?


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Public Webinar: FDA Review of Biologics License Applications (BLA) for Blood and Source Plasma

Closing Comments

Anne Eder, M.D, Ph.D.

Director, Office of Blood Research and Review
CBER, FDA

May 12, 2026

U.S. Blood Establishments

Products	License Holders (n)	Registered-only (n)	Establishments (n)
Source Plasma	**28**	--	**1204**
Blood and Components	**71***	--	**1000**
	--	**721**	**721**

*** Of these, 4 provide about 50-60% of US blood supply**

FDA, April 15, 2026

Workshop Objectives (Redux)

What you need to know about ….

1. Regulatory requirements
2. RTTI testing, donor deferral, notification, reentry

What you need to do…

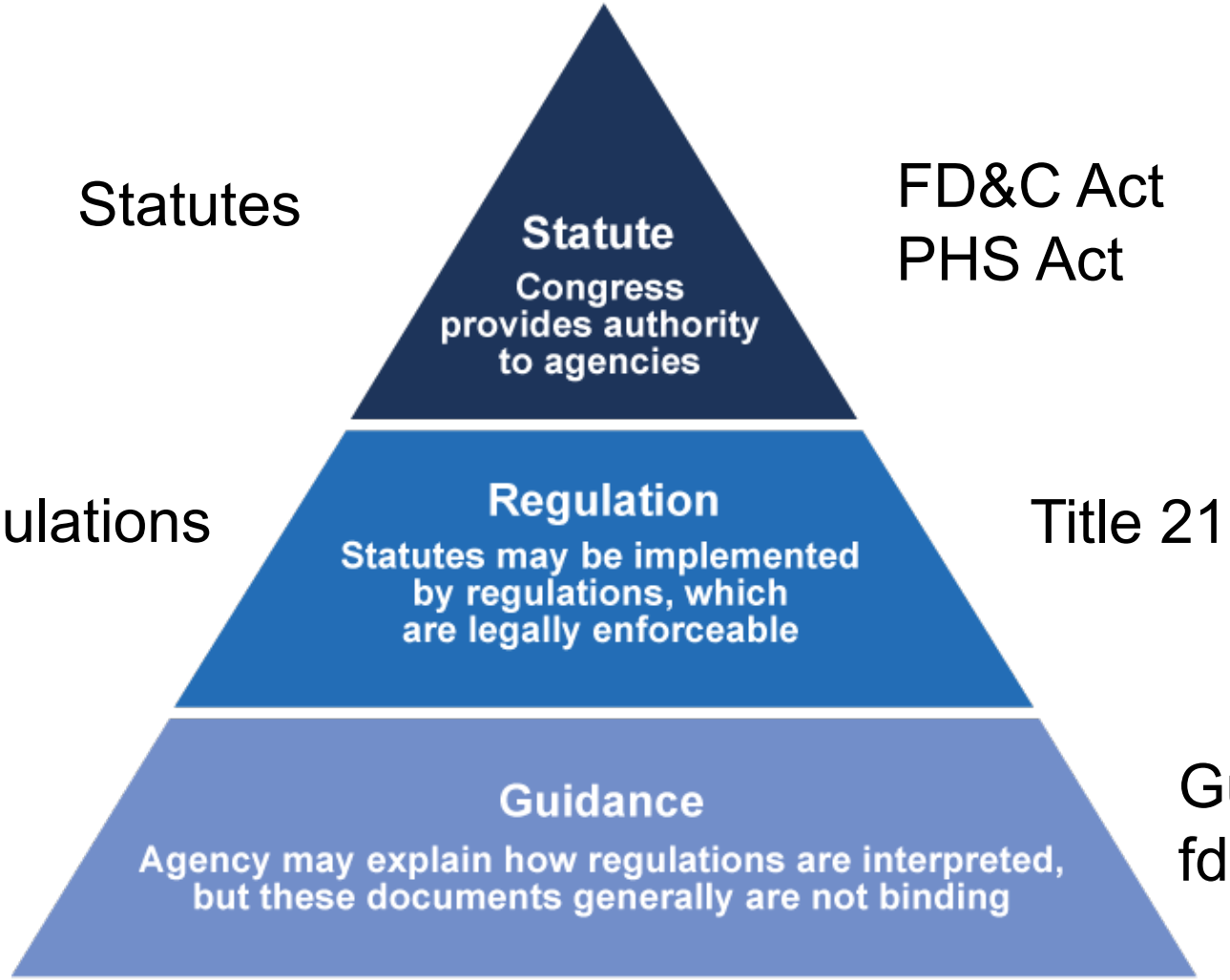
3. To register
4. To submit a BLA
5. During the BLA process (to avoid common deficiencies)
6. During an inspection (to avoid common citations)

Q & A with Do's and Don't

Statutes, Regulations, Guidance

Statutes

FD&C Act
PHS Act



Regulations

Title 21 CFR

Guidance

Guidance for Industry
fda.gov

Source: GAO analysis of regulatory authority | GAO-18-436T

RTTI Testing, Donor Deferral, Reentry

- **FDA recommends donor reentry to maintain donor pool**
- FDA continues to monitor for emerging TTIs and adjust RTTI screening requirements and recommendations based on current science
- Please check regularly FDA blood guidances and FDA biologics safety and availability communications to stay informed on current recommendations and emerging safety concerns

Registration Resources

- For more information on Blood Establishment Registration, visit FDA's/CBER Blood Establishment Registration and Product Listing webpage: https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing
- For inquiries regarding registration, please send an email to: bloodregis@fda.hhs.gov

BLA Submission : Key 🔑 Takeaways

- **When to Submit:**
  - **Original BLAs:** New entities with no U.S. License Number; facility operational minimum 3 months; **BLA Supplements:** Licensed entities adding new facilities or making manufacturing changes
- **Before You Submit:**
  - **Highly encouraged:** Contact CBER; Ensure facility is registered, operational, validated, and compliant; Collect minimum 3 months of data (Source Plasma) or 6 months (Blood Centers for supplements)
- **What to Submit:**
  - Forms: FDA 356h (signed by AO), FDA 2830
  - Cover letter with facility details and summary
  - Relevant SOPs, validation documentation, equipment information
  - BECS/CASI information with 510(k) clearance numbers
  - Donor materials and facility documentation

BLA Submission : Key 🔑 Takeaways

- **Submission Process:**
  - Submit via ESG or email (secure email encouraged)
  - DCC assigns STN and routes to OBRR
  - RHPM and CSO assigned to review committee
  - Acknowledgement letter sent confirming receipt
- **Filing & Review:**
  - Filing review completed within 60 days Filing ≠ Approval or data evaluation
  - RTF issued if submission incomplete or inadequate
  - Review timeline: ~12 months for Original BLAs (based on PDUFA guidelines, resources permitting)

BLA Review Process : Key 🔑 Takeaways

- Submit all relevant documents for review
  - Allows for comprehensive and timely review
- Review process is interactive and FDA may request additional information or clarification
- OBRR will perform inspections if applicable
- A compliance check is required before approval of an application
- Regulatory decisions- Approval or Complete Response
- Licensed establishments should be aware of responsibilities after approval

When Is An Inspection Needed?

- **Examples requiring PLI or PAI:**
  - Opening a new blood collection facility
  - Opening a new Source Plasma facility
  - Initiating a new program (e.g., RBC Immunization Program)
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- Compliance Program Guidance Manuals
- Compliance Policy Guides
- Investigations Operations Manual
- Guidance Documents

Resources

- Blood Guidances:
  –https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances

- CBER Guidance Agenda:
  –https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/guidance-agenda-guidance-documents-cber-planning-publish-during-calendar-year-2024

Contacts for OBRR Issues:

Specific Questions about your OBRR regulatory submission(s); or to request Type C pre-submission meeting

- Regulatory Health Project Manager (RHPM)
  or Cherry.Geronimo@fda.hhs.gov

General Questions about blood manufacturing, guidance documents:

- BPB Inquiries mailbox:
  CBEROBRRBPBInquiries@fda.hhs.gov

Contact CBER

For Other Issues

CBER inquiries

OCOD@fda.hhs.gov

Industry.Biologics@fda.hhs.gov

Send Us Your Feedback

- Please submit feedback about the workshop or questions after the event to CBERPublicEvents@fda.hhs.gov,
- Include **“OBRR Webinar 2026”** in the subject line.
- We will review feedback and post the presentations on the event page in a few weeks.

Thank you!

Back Row: Dr. Orieji Illoh, Mona Amin, Patricia Weddington, Brooke Spridgen, Camelita Bibby, Jaime Perry

Front Row: Christi Ann Samella, Camilla Smith, Barbara Peoples, Rick McBride (Retired), Thaddeus Nnabue, Miriam Montes, Michelle Gutierrez, Cathy McGraw, Dr. Wendy Paul

Blood and Plasma Branch

Not pictured: CSO/BPB: Racquel East, Dionne Cook, and Deborah Corpening; RPMS: Alpa Shah, Cherry Geronimo