Registration and Licensure

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C B
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Background Information

How Blood Regulation Began

- **1902 Biologics Control Act**
  - **Statutory authority to regulate biological products**
  - **Labeling, inspections, penalties**
- **1906 Food and Drug Act**
  - **Prohibited interstate commerce of misbranded & adulterated drugs and foods**

Laws and Regulations Governing Biological Products

- Food, Drug, and Cosmetic Act (FD&C Act)
- Public Health Service Act (PHS Act)
  - Sections 351 and 361
- Title 21 Code of Federal Regulations (CFR)
  - Drugs – Parts 210 and 211
  - Blood, Blood Components, and Blood Derivatives – Parts 606-660
  - Devices – Part 820
  - Human Tissues Intended for Transplantation – Parts 1270 and 1271

Additional Resources for Blood Regulation

- **Guidance documents**
  - FDA's recommendations (current thinking) on how to comply with statutes and regulations
  - Describes new policies and procedures
  - Developed under Good Guidance Practices (21 CFR 10.115)
  - Level 1 or Level 2 document
  - Not binding on FDA or regulated industry
  - Found on CBER website - http://www.fda.gov/cber/blood/bldguid.htm
- **CBER SOPPs and specific SOPs**

Regulated Blood Components

- **Blood components for transfusion**
  - Whole Blood, Red Blood Cells
  - Platelets, Platelets Pheresis
  - Fresh Frozen Plasma, Plasma Cryoprecipitate Reduced
  - Cryoprecipitated AHF
  - Irradiated, leukocyte reduced, divided, washed, frozen, deglycerolized, rejuvenated
- **Blood components for further manufacturing**
  - Source Plasma
  - Source Leukocytes
  - Recovered plasma

CBER

Registration

Outline - Registration

- Why must I register with FDA?
- How do I register with FDA?
- What does being registered mean?
- What will I be required to do?
- What are the FDA activities with registered facilities?
- Are there any exemptions to being registered?
- What are unregistered facilities required to do?

Federal Food, Drug and Cosmetic Act (1938)

- Supercedes the 1906 Food and Drug Act
- Adds control of cosmetics and therapeutic devices
- Manufacturers must prove drug is safe before marketing
- Penalties for violations now include court injunction
- Requires facility registration
- Authorizes manufacturing facility inspections (1953 amendment)

Registration

- Required under the FD&C Act
- Described in 21 CFR 607.7
- All owners or operators of establishments that engage in the manufacture of blood products must register with FDA
- Does not permit shipping of blood product in interstate commerce
  - May engage in intrastate shipment

Product Manufacture

- Defined in 21 CFR 607.3(d)
- Collection, preparation, processing, compatibility testing and other procedures of any blood product that meets the definition of a drug
- Includes testing, control procedures, labeling and repackaging of the blood products
- Manufacturing steps can be performed by entity that owns product or by a contractor

Manufacturer

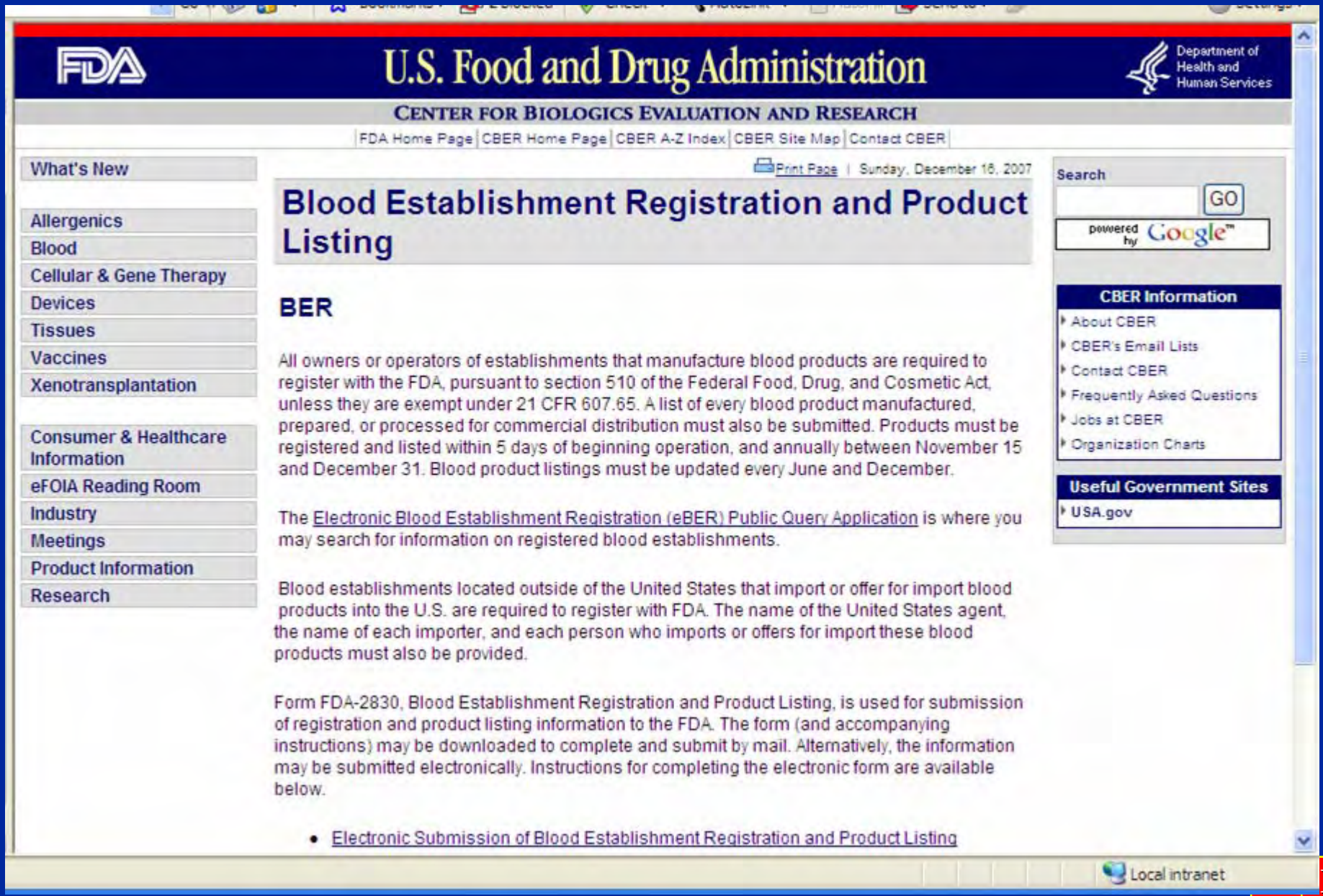
- Defined in 21 CFR 600.3(t)
- Legal person or entity engaged in the manufacture of products subject to licensure under PHS Act
- Manufacturer (licensed or unlicensed) assumes responsibility for compliance with applicable product and establishment standards, even if manufacturing is performed by contractor

Who Must Register?

- **Major Facilities**
  - Collection facility
  - Community blood bank
  - Component preparation facility
  - Hospital blood bank
  - Plasmapheresis center
  - Product testing laboratory
- **Auxiliary Facilities**
  - Distribution center
  - Donor center (Manual collection of Whole Blood)
- **Brokers**
  - who take possession and manipulate and/or relabel product

How do I register?

- **Submit registration form to CBER within 5 days after beginning manufacturing operations (21 CFR 607.21 & 607.22)**
- **FDA Form 2830: Blood Establishment Registration and Product Listing**
- **Complete a form for each facility and list all products in commercial distribution.**
  - **Include both licensed and unlicensed products**
- **Electronic registration (eBER)**
  - **http://www.fda.gov/cber/blood/bldreg.htm**
  - **Electronic registration will be required**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Blood Establishment Registration and Product Listing
BER
All owners or operators of establishments that manufacture blood products are required to register with the FDA, pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act, unless they are exempt under 21 CFR 607.65. A list of every blood product manufactured, prepared, or processed for commercial distribution must also be submitted. Products must be registered and listed within 5 days of beginning operation, and annually between November 15 and December 31. Blood product listings must be updated every June and December.
The Electronic Blood Establishment Registration (eBER) Public Query Application is where you may search for information on registered blood establishments.
Blood establishments located outside of the United States that import or offer for import blood products into the U.S. are required to register with FDA. The name of the United States agent, the name of each importer, and each person who imports or offers for import these blood products must also be provided.
Form FDA-2830, Blood Establishment Registration and Product Listing, is used for submission of registration and product listing information to the FDA. The form (and accompanying instructions) may be downloaded to complete and submit by mail. Alternatively, the information may be submitted electronically. Instructions for completing the electronic form are available below.
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Local intranet

Registered-Only Blood Establishments

- 10-15% of transfused blood is prepared in unlicensed, registered-only blood banks
- CBER does not review product manufacturing submissions from registered-only facilities unless:
  - Request a “variance” (21 CFR 640.120)
  - Apply for a licensure (21 CFR 601.2)
  - Contract manufacturer of licensed products (61 FR 24227, 5/14/96)
- Manufacturing activities observed during FDA inspections conducted by field investigators

Responsibilities of Registration

- Each year manufacturer must update the registration by June 30 or December 31 (21 CFR 607.30)
- Send updates to FDA or enter into eBER
- Manufacturer is responsible for complying with FDA regulations and cGMPs (including labeling, BPD, and fatality reporting)
- Facility will be FDA inspected every 2 years

Exempt from Registration

- Described in 21 CFR 607.65
- Facilities that do not manufacture products
- Transfusion services that:
  - Only perform compatibility testing and transfusion
  - Do not routinely collect or process products
  - Only prepare recovered plasma for further manufacture or RBCs for transfusion from Whole Blood
  - Pool platelets & cryoprecipitate or do bedside filtration
  - Are approved for Medicare reimbursement
- Brokers who do not take possession or do not manipulate or relabel product

Exempt from Registration

- **Exemption written to omit duplication of inspections by Federal government health agencies (FDA & CMS)**
- **Responsibilities of unregistered facility**
  - **Must comply with FDA regulations and cGMPs (including labeling, BPD and fatality reporting)**
- **Inspections**
  - **Done under the authority of CMS (or other deemed status organization)**
  - **FDA can inspect “for cause” (e.g., fatality investigation)**

Licensure

Outline - Licensure

- Why must I be FDA licensed?
- How do I obtain an US License from FDA?
- What does licensure mean?
- What will I be required to do once I am licensed?
- What are the FDA activities with licensed facilities?

Public Health Service Act (1944)

- Expanded from 1902 Biologics Control Act
- Regulation of biological products and control of communicable diseases
- Defines biological product to include blood, blood components and derivatives
  - Regulates blood and blood components like drugs
- Section 351 – stipulates requirements for licensure
- Section 361 – requires control of communicable diseases

Section 351- PHS Act

- **No person shall introduce or deliver for introduction into interstate commerce any biological product unless:**
  - **A biologics license is in effect**
  - **Each package of biological product is plainly marked**
  - **Biological product is safe, pure, potent and effective**
  - **Facility where product is manufactured meets standards**
  - **Applicant consents to inspection**
- **Secretary establishes requirements for approval, suspension and revocation of biologics license**

Significance of Licensure

- Manufacturers who manufacture biological products for distribution into interstate commerce must be registered and licensed
- Signifies FDA approval of product and facility
- License number appears on label of products approved in application
- Allows shipment of product interstate in commerce
- 85 – 90% of blood products transfused in US are prepared in licensed blood establishments

Definitions

- BLA – Biologic License Application
- Application - Original submission requesting a U.S. license
- Supplement - Submission to request change to an existing approved license application
- Amendment - Information submitted to an unapproved application or supplement to revise or modify the submission
- Submission – Application, supplement, amendment, labeling, product correspondence

How do I get licensed?

- **Submit BLA form - Form FDA 356h: Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use**
  - **Must accompany every submission and correspondence sent to FDA**
- **Complete the chemistry, manufacturing and controls (CMC) section**
  - **Contains information pertinent to the review and approval of submission**

Contents of the Submission

Guidance for Industry

"For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h" (May 1999)

http://www.fda.gov/cber/gdlnes/cmcblood.htm

General Submission Content

- **Cover Letter**
  - Products requested for licensure, including anticoagulants, additional processing (leukocyte reduction, irradiation, etc.)
  - Collection, processing and testing instruments (model, version no.)
  - Infectious disease testing (list agents, test kits used)
  - Blood centers preparing products (address, registration number)
  - Description of personnel training
  - Contractors used (name, address, registration number, license number (if appropriate), services provided)

General Submission Content

- **SOPs**
  - Donor suitability, including donor deferral, donation interval (eg, RBC loss)
  - Collection procedures, including arm prep, donor monitoring
  - Donor history forms, including informed consent
  - Product manufacturing procedures, including QC, labeling, splitting, leukocyte reduction, irradiation, storage, shipping, equipment calibration, etc.
  - Adverse event and failure investigation
  - Quarantine and disposition of unsuitable products
  - Quality assurance program

General Submission Content

- **Records and Forms**
  - Donor selection, including questionnaire, informed consent, education materials
  - Product processing, collection information
  - Product quality control logs
- **Completed records and forms**
  - 2 consecutive months quality control
    - Apheresis Red Blood Cells (including leukocyte reduction)
    - Leukocyte reduced Red Blood Cells
    - Platelets and Platelets, Pheresis (including leukocyte reduction)
    - Each type of device at each center
  - Validation summary, including failure investigation

General Submission Content

- **Product Quality Control Log Information**
  - Product description (e.g., product name, leukocyte reduced)
  - Type of collection (e.g., single, double, triple)
  - Collection and testing dates
  - Product specifications
  - Product testing results
  - Automated collection device (manufacturer, model number)
  - Product identification number
  - Collection center
  - Technologist identified
  - Evidence of QA oversight

General Submission Content

- **Labeling**
  - FDA form 2567
  - Circular of Information
  - Base label and product overlay labels for each product
  - 606.121((c)(13) – machine readable information
    - Unique facility identifier
    - Lot number relating unit to donor
    - Product code
    - ABO/Rh of donor
  - ISBT 128 or Codabar
    - ISBT – request 640.120 alternative procedure to 606.121(e)(1)(ii)

Shipping Products to CBER

- **What products are shipped**
  - **Platelets**
  - **Platelets, Pheresis**
- **When to ship products**
  - **After validation has been completed**
  - **After 2 months of QC has been completed**
  - **After all labeling and testing has been completed**
- **Scheduling shipment**
  - **Call CBER (Division of Hematology, Laboratory of Cellular Hematology (LCH)) at 301- 827- 3413**

BLA Application Review

Desk Review of Documents

- Review for completeness and accuracy
  - Product manufacturing consistent with regulations and product standards
  - Donor safety issues
- Assign submission tracking number (reference number) and notify applicant
- Applicant can prepare product but cannot distribute product in interstate commerce
- Communicate with applicant if need additional information or revisions (via telecon, letter)
- Conduct a pre-license inspection

Resources for FDA Review

- Regulations in the Code of Federal Regulations (CFR)
- Recommendations in FDA guidance documents
- Device Operator's Manuals
- Package Inserts for Reagents and Supplies
- Published scientific literature
- Some checklists available at: http://www.fda.gov/cber/blood/checklist.htm

BLA Application Review

Pre-License Facility Inspection

- Continuation of desk review
- FDA notifies applicant of inspection dates
- FDA observes product manufacturing consistent with regulations, commitments in application, product specifications and cGMPs
- FDA-483 (Inspectional Observations) is issued if we observe deficiencies
- Applicant must respond and acceptably address all cited observations

FDA Inspection

- **Observe Operations**
  - SOPs - procedures, personnel
  - Product manufacturing, labeling, storage
  - Equipment, computer systems
  - Physical facility – privacy, sufficient space
- **Review Records**
  - QA activities, training
  - Donor records, reactions, deferrals
  - Testing – infectious disease, QC, validation
  - Product manufacturing
  - Contractor responsibilities

Resources for B&P & Tissue Inspections

- **Compliance Program Guidance Manuals**
  - **Inspections of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories and Contractors (10/06)**
  - **Inspection of Source Plasma Establishments (10/06)**
  - **Inspection of Tissue Establishments (3/03)**
  - **Inspection of Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps) (7/05)**
- **Inspection or compliance references:**

http://www.fda.gov/ora

http://www.fda.gov/cber/cpg/cpg.htm

License Approvals

- **FDA approvals are very specific**
  - **Product specific**
  - **Facility specific**
- **Conditions for approval specified in approval letter**
  - **FDA no longer issues license certificates**
- **License number must appear on approved product labels**

Responsibilities of Licensure

- Maintain current and correct registration
- Comply with FDA regulations and cGMPs (including BPD and fatality reporting)
- Notify CBER of any changes to the approved license, including contractor changes (21 CFR 601.12)
- Facility will be FDA inspected every 2 years
- License may be suspended or revoked for failing to comply with regulations or applicable standards

Enforcement Actions

- Regulatory tools used by FDA to bring establishments who violate FDA laws into compliance
- License Suspension
- License Revocation
- Warning Letter (licensed and unlicensed)
- Seizure (products)
- Injunction (consent decree)
- Prosecution

Reporting Changes to BLA

21 CFR 601.12

Changes to an approved application:

"…an applicant shall inform … (FDA) about each change … established in the approved license application(s). Before distributing a product made using a change, applicant shall demonstrate … the lack of adverse effect of change … as they may relate to the safety or effectiveness of the product."

Three Reporting Categories

- Prior Approval Supplement [PAS] – 21 CFR 601.12(b)
- Changes Being Effected in 30 Days Supplement [CBE30] – 21 CFR 601.12(c)
  - Changes Being Effected Supplement [CBE] – 21 CFR 601.12(c)(5)
- Annual Report [AR] – 21 CFR 601.12(d)
- Reporting category depends on how the change will affect the product and FDA's experience with the change

Reporting Changes

Guidance for Industry

“Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture” (July 2001)

http://www.fda.gov/cber/gdlns/bldchanges.htm

Additional Manufacturing Requirements

Outline – Additional Requirements

- Labeling
- Contract manufacturing
- Biological Product Deviation reporting
- Fatality reporting
- “Variances”
- Current Good Manufacturing Practices

Labeling

- False or misleading labeling could result in misbranding of product
- Misbranding described in FD&C and PHS Acts.
- FDA can seize misbranded products and use in criminal cases
- CBER does not regulate commercial label manufacturers
- Labeling specifications in CFR:
  - Whole Blood components – 606.120 and 606.121
  - Source Plasma – 610.62 and 640.70

Cooperative Manufacturing Agreements

- **Shared manufacturing – both parties licensed to perform some manufacturing steps**
- **Divided manufacturing – both parties licensed to perform all manufacturing steps**
- **Short supply – unlicensed product (recovered plasma) to be manufactured into licensed product (21 CFR 601.22)**
- **Contract manufacturing – need not be licensed but performs manufacturing steps**

Contract Manufacturing

- **Manufacturer - need not perform all manufacturing steps or own facilities where steps are performed; may contract with others to perform manufacturing steps**
- **Contractor – manufacturer not under direct control of product owner, but who performs part or all of manufacturing steps as a service**
- **Cooperative manufacturing agreement – agreement between 2 or more manufacturers; describes responsibilities of each party**

Contracting Responsibilities

- Manufacturer is responsible for compliance of all manufacturing steps of their product, even if not performed in own facility
- Licensed manufacturers must notify CBER if using contractor or changing contractor (21 CFR 601.12)
- Contractor must manufacture product according to regulations, cGMPs and product standards
- Contractor must inform manufacturer of any changes in manufacturing
- Contractors performing manufacturing steps must be registered with FDA

Biological Product Deviation (BPD) Reporting

- All manufacturers report to FDA any event associated with manufacturing a product that adversely affects safety, purity or potency of the product and product was distributed (21 CFR 606.171)
- Applies to all facilities (licensed, unlicensed, transfusion services)
- Report electronically

  http://www.fda.gov/cber/biodev/biodev.htm
- Guidance document

  http://www.fda.gov/cber/gdlns/devbld.htm


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Biological Product Deviation Reporting (BPDR)
Includes Human Tissue and Cellular and Tissue-Based Product (HCT/P) Deviation Reporting
On November 7, 2000, the Food and Drug Administration published a final rule to amend the requirements of reporting errors and accidents in manufacturing of products. The rule amended the regulation at 21 CFR 600.14 for licensed biological products, and added a requirement at 21 CFR 606.171 applicable to all manufacturers of blood and blood components. The amended regulation at 21 CFR 600.14 and the new regulation at 21 CFR 606.171 require reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product or a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected. A manufacturer is required to report to the Center for Biologics Evaluation and Research (CBER), Office of Compliance
Reporting Questions Contact Page
Electronic Submission of Biological Product Deviation Reports (eBPDR)
Electronic Form Instructions
Latest System Changes
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Fatality Reporting

- All manufacturers report to FDA any fatality associated with blood collection or transfusion (21 CFR 606.170(b))
- Submit initial report within 7 days
- Applies to all facilities (licensed, unlicensed, transfusion services)
- Report electronically

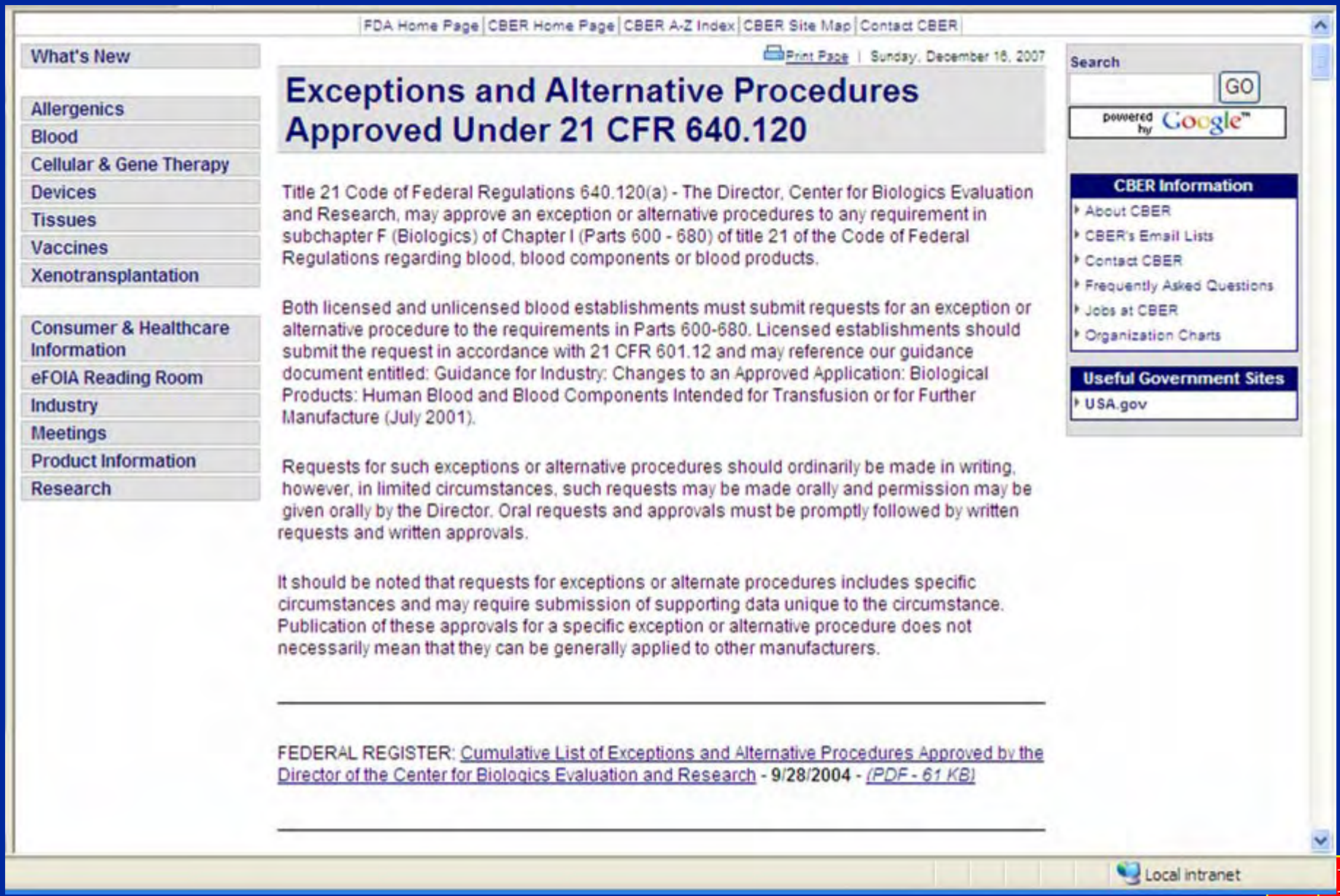
  fatalities2@.fda.hhs.gov
- Guidance document

  http://www.fda.gov/cber/gdlns/bldfatal.htm

“Variances”

- Alternative procedure or exemption (21 CFR 640.120)
- Submitted by both licensed and unlicensed manufacturers
- Request for procedure that is not consistent with regulation in the 600s
- Approved on case-by-case basis
- Must have approval before implement procedure or distribute products
- Examples on CBER website

http://www.fda.gov/cber/blood/exceptions.htm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Exceptions and Alternative Procedures Approved Under 21 CFR 640.120
Title 21 Code of Federal Regulations 640.120(a) - The Director, Center for Biologics Evaluation and Research, may approve an exception or alternative procedures to any requirement in subchapter F (Biologics) of Chapter I (Parts 600 - 680) of title 21 of the Code of Federal Regulations regarding blood, blood components or blood products.
Both licensed and unlicensed blood establishments must submit requests for an exception or alternative procedure to the requirements in Parts 600-680. Licensed establishments should submit the request in accordance with 21 CFR 601.12 and may reference our guidance document entitled: Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture (July 2001).
Requests for such exceptions or alternative procedures should ordinarily be made in writing, however, in limited circumstances, such requests may be made orally and permission may be given orally by the Director. Oral requests and approvals must be promptly followed by written requests and written approvals.
It should be noted that requests for exceptions or alternate procedures includes specific circumstances and may require submission of supporting data unique to the circumstance. Publication of these approvals for a specific exception or alternative procedure does not necessarily mean that they can be generally applied to other manufacturers.
FEDERAL REGISTER: Cumulative List of Exceptions and Alternative Procedures Approved by the Director of the Center for Biologics Evaluation and Research - 9/28/2004 - (PDF - 61 KB)
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cGMP Regulations

- **Manufacturers must control manufacturing process to ensure product quality (61 FR 20105)**
- **cGMP regulations provide direction for control and include concepts of:**
  - **Quality assurance**
  - **Quality control**
  - **Process validation**
- **Flexible to allow manufacturer to select most suitable methods**

Who Must Follow FDA cGMPs?

- **Manufacturers who manufacture biological products for distribution into interstate commerce**
  - **Must be registered and licensed**
- **Manufacturers who engage in intrastate commerce only**
  - **Must be registered**
- **Transfusion service facilities**
  - **Unregistered, unlicensed**

cGMP Regulations

- 21 CFR 210 and 211s - Finished Pharmaceuticals
  - First published in FR in 1963 (26 FR 6385)
- 21 CFR 606s – Blood and Blood Components
  - Final Rule published in 1975 (40 FR 53532)
- 21 CFR 820s - Medical Devices
- 21 CFR 1271s – Tissues (includes cGTP)

Blood establishments must follow 210, 211s and 606s

Why follow Drug cGMPs?

- 43 FR 18614 (May 28, 1974)
- Blood and blood components are used in diagnosis, prevention, treatment and cure of diseases in man
- Therefore blood meets definition of drug in section 201(g) of Federal Food, Drug and Cosmetic Act
- Blood products must meet all statutory requirements of FD&C Act

Quality Control Unit

- **21 CFR 211.22 - describes responsibilities and authority of QC unit**
  - **Approve/reject supplies, product, etc.**
  - **Review records**
  - **Investigate errors**
  - **Review and approve SOPs, validation protocols**
  - **Review changes in product, process, equipment, personnel, determine need for revalidation**
  - **Activities described in writing**

QC Unit
Additional Considerations

- Can be individual person or organizational element
- Does not need to perform all tasks, must ensure controls are implemented
- Review records for trending/corrective action; evaluate effectiveness of corrective action
- Accept/reject product produced by contractor
- Report results to organizational unit responsible for implementing change (e.g., management)

Quality Controls Considerations

- Don’t do quality activities just to satisfy regulatory authorities
- Identify root causes before addressing 483 observations
- Don’t respond to the 483 on a local basis
- Develop preventative actions, not just corrective actions
- Think strategically, not quick fix

FDA Quality Guidance Documents

- **Guideline for Quality Assurance in Blood Establishments (July 11, 1995)**
  http://www.fda.gov/cber/guidelines.htm
- **Guideline of General Principles of Process Validation (May 1987)**
  http://www.fda.gov/cder/guidance.htm
- **Guide to Inspections of Quality Systems (QSIT) (August 1999)**
  http://www.fda.gov/ora/inspect_ref/igs/qsit/default.htm

Summary

Registration vs. Licensure

- **Blood establishment must register if it manufactures biological product or performs a manufacturing step**
  - **Register electronically on CBER website**
  - **Intrastate commerce only**
- **Applicant must also hold an approved, un-revoked U.S. license if it wants to distribute the biological product across state lines (interstate commerce)**
  - **Submit documents for review**
  - **Undergo FDA pre-license inspection**
  - **Approvals are specific for product and facility**
  - **FDA license number on label of approved products**

Licensure Review Procedure

- **CBER reviews based on:**
  - **Regulations and Guidance Documents**
  - **Operator's Manuals and Package Inserts**
- **Submission should contain information for substantive review**
  - **Consult FDA regulations, guidance documents, and CBER review checklists**
  - **Consult operator's manuals and package inserts**
- **Some reviews may require platelet products sent to CBER for testing**
- **Facility inspections**

Responsibility or Activity	Licensed & Registered	Registered-Only	Unregistered
Interstate commerce	x		
Intrastate commerce	x	x	
Follow cGMPs	x	x	x
BPD reporting	x	x	x
Fatality reporting	x	x	x
FDA inspection	x	x	X* [CMS]
Annual registration	x	x	
Report under 601.12	x		

Five Layers of Blood Safety

- Selection of suitable donors
  - Donor education and risk factor screening
  - Medical interview and limited physical examination
- Use of deferral registries to identify unsuitable donors
- Infectious disease testing (HIV, HCV, HBV, HTLV, STS, WNV)
- Quarantining blood while verifying suitability and doing tests
- Monitoring, investigating and taking corrective actions to address manufacturing problems and adverse reactions

Contact Information

- **Mailing Address**

  Director, Division of Blood Applications, OBRR, CBER, FDA
  HFM-370
  c/o Document Control Center, HFM-99
  1401 Rockville Pike, Suite 200N
  Rockville, MD 20852-1448
- **Telephone – (301) 827-3543**
- **Fax – (301) 827-3534**
- **Blood and Plasma Branch Consumer Safety Officers**

Blood and Plasma Branch Consumer Safety Officers

- Karan Blum
- Judy Ciaraldi
- Marla Cohen
- Lore Fields
- Diane Hall
- Jennifer Jones
- Rosia Nesbitt
- Faye Vigue
- Cecilia Watson
- Hoi May Wong
- Ken Zemann

- Branch Chief – Leslie Holness, MD

Helpful Website Addresses

- **General CBER information**
  http://www.fda.gov/cber/
- **Guidance Documents**
  http://www.fda.gov/cber/guidelines.htm
- **Other useful information**
  http://www.fda.gov/cber/reading.htm
- **Forms (356h, 2830, 2567)**
  http://forms.psc.gov/forms/FDA/fda.html


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FDA Awards Seven Contracts for Women's Health Research
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Hot Topics

- Influenza Virus Vaccine 2006-2007 Season
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Useful Government Sites
- CDC National Immunization Program
- FDA's Critical Path to New Medical Products
- FDA Centennial
- MedWatch
- Pandemic Flu
- Vaccine Adverse Event Reporting System (VAERS)
- FIRSTGOV

Updated: September 6, 2006

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Electronic Reading Room (eFOI)

The CBER Reading Room provides access to documents posted on the CBER website. These documents are ones frequently requested by the public through the Freedom of Information Act. Many documents are also available by e-mail and in printed copy.

Product Approval Information

- Licensed Products
- 510K Devices
- PMAs (Premarket Approval Devices)
- NDA (New Drug Applications)
- Postmarketing Study Commitments
- Transfer of Therapeutic Products to CDER (2003)

Compliance, Surveillance and Enforcement

- Clinical Investigator Inspection List
- Compliance Program Guides for CBER
- NIDPOE (Notice of Initiation of Disqualification Proceedings and Opportunity to Explain) Letters
- Recalls / Withdrawals
- Warning Letters
- Violative Advertising & Promotional Labeling for Approved Biological Products
- Other Compliance Actions

Product Safety & Availability

- Information Sheets
- Letters to Industry / Healthcare Providers / Clinical Investigators
- Safety Information
- Adverse Event Reporting System (AERS) - CDER
- Vaccine Adverse Event Report System (VAERS)
- Shortages

Meetings

- Advisory Committees
- Minutes from Workshops & Open Public Meetings
- Presentations

Talk Papers & Press Releases

Additional Documents Available from FDA

- FDA's Electronic Freedom of Information Reading Room
- Handbook for Requesting Information and Records from FDA
- Compliance Program Guidance Manual - Office of Regulatory Affairs
- Compliance Policy Guides Manual - Office of Regulatory Affairs
- Dockets Management - Official repository for the administrative proceedings and rule-making documents for FDA
- Inspection Guides - Office of Regulatory Affairs

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CDC's MMWR
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  - **www.fda.gov/emaillist.html#biologics**
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New items posted to FDA's Center for Veterinary Medicine (CVM) website

Biologics

Blood Guidances
Guidance documents related to blood products and blood establishments, links to information about blood publications and FDA's Blood Action Plan

Blood Products Advisory Committee
Information on current and past meetings of the Blood Products Advisory Committee

Cellular, Tissue and Gene Therapies Advisory Committee
Information on current and past meetings of the Cellular, Tissue and Gene Therapies Advisory Committee (Formerly Biological Response Modifiers Advisory Committee)

FDA Patient Safety News (video)
Broadcasts for hospitals and other medical facilities in the U.S. featuring information on new drugs, biologics and medical devices, FDA's safety notifications and product recalls, and protecting patients when using medical products

MedSun
Adverse event reporting program for the clinical community to identify, understand, and solve problems with the use of medical devices.

Tissue Related Documents
Guidance, rules and related documents on Human Cells, Tissues, and Cellular and Tissue Based-Products

What's New at CBER
New Items posted to the Center for Biologics Evaluation and Research website

Consumer Health Information

FDA & You
FDA newsletter on medical products and health topics for teens, parents and educators

CBER