Blood Systems' Licensure of 5 & 7-day Platelets

Kathleen Hopping

Blood Systems, Inc.

Licensure of Apheresis Blood Products Workshop

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Changes to an Approved Application

- Steps to Use a Cleared Apheresis Device for Collection
  - Well defined plan
    - Description of change
    - Implementation plan
    - Number of affected locations
    - Anticipated roll-out
  - Validate and implement
  - Perform monthly quality control
  - Submit for licensure

Changes to an Approved Application

- FDA Reporting Categories
  - Comparability Protocol (CP)
  - Prior Approval Supplement (PAS)
  - Changes Being Effected 30 Days (CBE30)

BSI Gambro Trima Comparability Protocol (CP)

- Cover letter
- FDA Form 356h, *Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use*
- Information Required for CP Submission
- Relevant Standard Operating Procedures
- FDA Form 2567, *Transmittal of Labels and Circulars*
- Labels
- Two (2) consecutive months QC data

BSI Gambro Trima CP – Additional Requirements

- Description/Purpose
- Implementation/Roll-out plan
- Specific tests and validation protocols
- Acceptance criteria of product
- Actions taken if acceptable results not achieved
- Training program
- Quality assurance and quality control program
- Product submission sampling plan
- Proposed change in reporting category

Comparability Protocols - Advantages

- More expedient distribution of licensed product
- Easier implementation of a change across multiple facilities
- Decrease in number of product submissions to the FDA – Department of Hematology
- If clearly defined is a useful planning tool

Comparability Protocols - Disadvantages

- Useful only for discrete, specific manufacturing changes
- Strict adherence to all elements of comparability protocol after approval
- Technical innovations may render a CP obsolete

Regulatory Path for Licensed 7-Day Platelets

- What was included in submission
  - Cover letter
  - FDA Form 356h, *Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use*
  - Information Required for 7-Day Submission
  - Relevant Standard Operating Procedures
  - FDA Form 2567, *Transmittal of Labels and Circulars*
  - Labels

Regulatory Path for Licensed 7-Day Platelets

- Request exemption under 21 CFR 610.53(d) to 610.53(c) *Table of Dating Periods*
- Applies to collection facilities approved for 5-day on specified instrument
- Testing with the BacT/ALERT Microbial Detection Systems
- Platelets Pheresis, Leukocytes Reduced
- Reference Submission Tracking Numbers
- Post Marketing Surveillance Study

Regulatory Path for Licensed 7-Day Platelets

- Approval requirements:
  - GAMBRO BCT post marketing surveillance protocol
  - Two (2) consecutive months of Quality control data
  - Platelets, Pheresis, Leukocytes Reduced to the Division of Hematology (DH) for QC testing

Summary of BSI 7-Day Platelet Submissions

Legal Name & License Number	Type of Instrumentation	# of Affected Locations	Date of Submission	Date of Approval	Requires Platelet Submission to the FDA
BSI US Lic. # 183	Trima	22	09/02/2005	12/28/2005	Yes Completed
BSI US Lic. # 183	Amicus	9	10/05/2006	11/13/2006	Yes Completed
BSI US Lic. # 183	Trima	5	12/01/2006	01/03/2007	No
TCBB US Lic. #1706	Amicus	3	01/09/2007	02/05/2007	Yes
BCP US Lic. #1249	Trima	6	02/06/2007	06/18/2007	Yes
TCBB US Lic. #1706	Amicus	1 (Registered Facility Only)	06/08/2007	Pending with the FDA	No
BCP US Lic. #1249	Amicus	1	Pending in-house	NA	NA

Helpful Hints

- Keep open communication with all FDA staff involved in comparability protocol
- Respond to all deficiencies in a timely manner
- Keep Subject Matter Experts involved in the entire process

References

U.S. Department of Health and Human Services, Food and Drug Administration. (2001). Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture (Docket No. 99D-5046). Rockville, MD: Author.

U.S. Department of Health and Human Services, Food and Drug Administration. (nd). Information on the Regulatory Path for Gambro BCT 7-Day Platelets.