BN 080041

InterSol Platelets Additive Solution

Fenwal, Inc

Ying Wang, PhD

Review Chemist

Office of New Drug Quality Assessment
Division of Premarketing Assessment III
Branch VI

CMC REVIEW OF BN 080041
For Center of Biologics Evaluation & Research

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CMC Review Data Sheet

1. BN 080041

2. REVIEW #: 1

3. REVIEW DATE: 9-Nov-2009

4. REVIEWER: Ying Wang, PhD

5. PREVIOUS DOCUMENTS:N/A

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original Submission	Aug. 4, 2008
Various Amendments	Feb.12, 2009, March 18, 2009, May 12, 2009

7. NAME & ADDRESS OF APPLICANT:

Name:	Fenwal, Inc.
Address:	Three Corporate Dr., Lake Zurich, IL 60047, USA
Representative:	Cheryl Chamberlain Roscher
Telephone:	847-550-7909

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: InterSol
b) Non-Proprietary Name: Platelets Additive Solution
c) Code Name/# (ONDQA only): N/A
d) Chem. Type/Submission Priority (ONDQA only):

- Chem. Type: 1
- Submission Priority: Regular

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)

10. PHARMACOL. CATEGORY: Solution to store blood product.

11. DOSAGE FORM: Injection Solution

CMC Review Data Sheet

12. STRENGTH/POTENCY: N/A

13. ROUTE OF ADMINISTRATION: Intravenous (to be used with AMICUS-derived apheresis platelet product, not be injected directly)

14. Rx/OTC DISPENSED: __√__Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__√__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT: N/A

CMC Assessment Section

The CMC Review for BN 080041

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

Chemistry, manufacturing and control (CMC) section of this CBER application has been requested for consult review to CDER. However, part of the CMC section such as container closure system and sterilization is still reviewed by CBER.

InterSol platelet additive solution is recommended for approval from CMC (ONDQA) perspective (portion evaluated in this review).

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of CMC Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

InterSol platelet additive solution is an isotonic solution designed to replace a proportion of the plasma used in the storage of platelets. It consists of various USP salt components with Water for Injection. The solution itself has no pharmacological effect. It is used to temporarily (up to 5 days) store the biological blood product (AMICUS-derived apheresis platelets).

B. Description of How the Drug Product is Intended to be Used

Platelet products stored in InterSol solution are transfused to patient with low platelet counts or to decrease bleeding. InterSol solution is not for direct intravenous infusion.

C. Basis for Approvability or Not-Approval Recommendation

Drug substances are several USP grade salts. Drug product is an isotonic solution consisting of several USP grade salts with water for injection. The proposed specification is standard for this type of the solution. Three stability batches manufactured at the commercial site at the commercial scale were submitted. One batch had -(b)(4)- month data at the storage condition ---(b)(4)---- and (b)(4) month data at the accelerated condition (----(b)(4)------). Two batches had (b)(4) month data at the storage condition and (b)(4) month data at the accelerated condition. The stability data support the proposed -(b)(4)- month expiration date.

III. Administrative

A. Reviewer's Signature:

Ying Wang, PhD

B. Endorsement Block:

Sarah Pope Miksinski, PhD, Branch Chief, Branch V, ONDQA

CMC Assessment Section

16 Pages determined to be not releasable: (b)(4)