I concur with this review. M. Serabian 7/01/11

FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research
Office of Cellular, Tissue and Gene Therapies
Division of Clinical Evaluation and Pharmacology/Toxicology
Pharmacology/Toxicology Branch

BLA Filing Memorandum

BLA STN#: 125391 **AMENDMENT: #000**

Reviewer: ATM Shamsul Hoque, Sc.D.

Product Name: Hematopoietic Progenitor Cells, Cord Blood (HPC-C)
Product Proprietary Name: N/A

Proposed Use (Indication): Hematopoietic reconstitution in patients with hematological malignancies, ----------(b)(4)----------.

Sponsor: ClinImmune Labs, University of Colorado Cord Blood Bank
Sponsor's Point of Contact:
Sharon Miller/Brian Freed
University of Colorado Cord Blood Bank
12635 East Montview Blvd, Suite 300
Aurora, Colorado 80045
Tel: 303-724-0535
Fax: 303-724-1849
Email: sharon.miller@UCDenver.edu

Date Received (by DCC): 04-May-2011
Filling Decision: 24-June-2011
Filling Action (letter) Date: 15-July-2011
Date Review Completed: 23-June-2011; amended 27-June-2011; amended 01-July-2011

RPM: Ramani Sista
Committee Chair/CMC Reviewer: Yong Fan
CMC Reviewers: Lilia Bi, Safa Karandish, Fatima Abbasi, and Joydeep Ghosh
Medical Reviewers: Rachel Witten
Statistical Reviewer: Chunrong Cheng
Epidemiology Reviewer: A. Ou
Labeling Reviewer: Loan Nguyen and Lisa Stockbridge
DMPQ Reviewers: Mohammad Heidaran and Marion Michaelis
Bioresearch Monitoring Reviewers: Dennis Cato
Consult: N/A

Cross-referenced and/or related files:

----------(b)(4)----------

Synopsis:

This BLA submission was provided in an electronic submission format. This reviewer read and followed the designated Pharm/Tox Filing Checklist for BLAs (Appendix I, below). There is no Pharmacology/Toxicology section in this BLA submission. Section 4b1 of the submission (Chemistry, Manufacturing and Controls Section) contains details on: 1) the Cord Blood Unit (CBU) processing procedure using --(b)(4)-- validated methods (----------(b)(4)---------- (thus reduction) of red blood cells (RBCs), as well as for plasma volume reduction. The CMC section also contains details on: 1) ----------(b)(4)---------- 3) the CBU collection and storage bags, ----------(b)(4)---------- anticoagulant, ------(b)(4)-----. These bags, the anticoagulant, and the --(b)(4)-- are cleared/approved by FDA. This information will be reviewed by the CMC and DMPQ reviewers.

APPENDIX I

BLA Number: STN 125391-000

Applicant: ClinImmune Labs
University of Colorado

Stamp Date: 04-May-2011

Product Name: Hematopoietic Stem/Progenitor Cells, Cord (HPC-C)

BLA Type: Electronic Submission

Proprietary name: N/A

On **initial** overview of the BLA application for filing:

	Content Parameter	Yes	No	Comment
1	Is the pharmacology/toxicology section organized in accord with current regulations and guidelines for format and content in a manner to allow substantive review to begin?			Not applicable
2	Is the pharmacology/toxicology section indexed and paginated in a manner allowing substantive review to begin?			Not applicable
3	Is the pharmacology/toxicology section legible so that substantive review can begin?			Not applicable
4	Are all required (*) and requested IND studies (in accord with 505 b1 and b2 including referenced literature) completed and submitted (carcinogenicity, mutagenicity, teratogenicity, effects on fertility, juvenile studies, acute and repeat dose adult animal studies, animal ADME studies, safety pharmacology, etc)?			Not applicable
5	If the formulation to be marketed is different from the formulation used in the toxicology studies, have studies by the appropriate route been conducted with appropriate formulations? (For other than the oral route, some studies may be by routes different from the clinical route intentionally and by desire of the FDA).			Not applicable
6	Does the route of administration used in the animal studies appear to be the same as the intended human exposure route? If not, has the applicant submitted a rationale to justify the alternative route?			Not applicable

	Content Parameter	Yes	No	Comment
7	Has the applicant submitted a statement(s) that all of the pivotal pharm/tox studies have been performed in accordance with the GLP regulations (21 CFR 58) or an explanation for any significant deviations?			Not applicable
8	Has the applicant submitted all special studies/data requested by the Division during pre-submission discussions?			Not applicable
9	Are the proposed labeling sections relative to pharmacology/toxicology appropriate (including human dose multiples expressed in either mg/m2 or comparative serum/plasma levels) and in accordance with 201.57?			These sections will be reviewed in detail after review of all pharmacology/toxicology sections.
10	Have any impurity – etc. issues been addressed? (New toxicity studies may not be needed.)			Will be reviewed, as appropriate.
11	Has the applicant addressed any abuse potential issues in the submission?			Not applicable
12	If this BLA is to support a Rx to OTC switch, have all relevant studies been submitted?			Not applicable

IS THE PHARMACOLOGY/TOXICOLOGY SECTION OF THE APPLICATION FILEABLE? _YES_

If the BLA is not fileable from the pharmacology/toxicology perspective, state the reasons and provide comments to be sent to the Applicant:

- None at this time

Please identify and list any potential review issues to be forwarded to the Applicant for the 74-day letter:

- None at this time

ATM Shamsul Hoque, Sc.D July 1, 2011

Reviewing Pharmacologist/Toxicologist Date

Mercedes Serabian, MS, DABT July 1, 2011

Chief, PTB/Supervisor Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

MEMORANDUM

Date: July 1, 2011

To: BLA Committee

From: ATM Shamsul Hoque

Subject: STN 125391/000 Filing Action

I have reviewed aspects of Section 4.b.1 (Chemistry, Manufacturing and Controls) of ClinImmune Labs' BLA submission (STN No. 125391/000), which contains details on ----------(b)(4)----------, the collection and freezing bags, and the anticoagulant (b)(4). These components are cleared/approved by FDA and the in-depth review for these components will be conducted by the CMC and DMPQ reviewers. I find the application acceptable for filing.

ATM Shamsul Hoque, Sc.D.
(Signature of Committee Member)

Mercedes Serabian, M.S., DABT
(Supervisory Concurrence)