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## Memorandum

**Date:** January 10, 2024

**To:** Jennifer H. Albert, BSN, RN  
CBER/OTAT/DRPM/RPMB1

Prateek Shukla, MD  
CBER/OTAT/DCEPT/GMB1

**From:** Michael Brony, Pharm.D.  
CBER/OCBQ/DCM/APLB

**Through:** Lisa L. Stockbridge, Ph.D.  
CBER/OCBQ/DCM/APLB

**Subject:** Labeling Review  
**RegeneCyte (HPC, Cord Blood)**  
**STN # STN 125764/0**

Sponsor: StemCyte, Inc.

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**Background:** The sponsor submitted:

New Approval  
 Efficacy supplement  
 Prior Approval Supplement (PAS) Amendment  
 Major Amendment

Submission contains:

Prescribing Information (PI)  
 Patient Package Insert (PPI)  
 Package and/or container labels  
 Other (Medication Guide)

Resubmission Date: November 9, 2023

Action Due Date: May 9, 2024

## **APLB Comments/Recommendations**

On January 7, 2022, StemCyte, Inc. submitted a licensing application for RegeneCyte (BLA 125764). Its proposed indication is for the use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

Complete response letter sent January 20, 2023.

The file was resubmitted November 9, 2023.

APLB has reviewed the draft prescribing information (PI) and package and container labels from a promotional and comprehension perspective and have the following comments.

### **PRESCRIBING INFORMATION**

Please ensure that the **FULL PRESCRIBING INFORMATION** reflects the regulatory sections and subsections of **THE TABLE OF CONTENTS**. This includes the correct numbering for the regulatory sections and subsections.

#### **CONTRAINDICATIONS**

Is RegeneCyte contraindicated in patients with known hypersensitivity to dimethyl sulfoxide (b) (4) (DMSO), Dextran 40 or plasma proteins? If so, to be consistent with all other HPC label, we recommend adding the following statement under the CONTRAINDICATIONS section.

#### **DRUG ABUSE AND DEPENDENCE**

To be consistent with other HPC labels, please delete this section.

#### **HOW SUPPLIED/STORAGE AND HANDLING**

To be consistent with the other HPC labels, we recommend removing the **Instructions for Preparation for Infusion** subsection and placing it at the end of the **PATIENT COUNSELING INFORMATION** section.

If you have any questions regarding this review please contact Michael Brony, Pharm.D. at 240-402-8898.

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Firm name: StemCyte, Inc

History

Prepared: M. Brony 1/10/24  
Comments: L. Stockbridge  
Revised: M. Brony  
Comment: L. Stockbridge  
Revised: M. Brony  
Concur: L. Stockbridge 1/11/24  
Final: M Brony 1/11/24

Concurrence box:

Name	Name/ Date
M. Brony	
L. Stockbridge	