

## Memorandum

**From:** Kimberly Benton, Ph.D., Deputy Director, Division of Cellular & Gene Therapies  
Raj Puri, M.D., Ph.D., Director, Division of Cellular & Gene Therapies, OTAT, CBER

**Date:** December 19, 2016

**NDA/ STN#:** 125552

**Applicant Name:** MacoProductions S.A.S.

**Date of Submission:** April 30, 2014 (original submission); June 30, 2016 (response to FDA Complete Response letter dated March 30, 2015)

**Action Goal Date:** December 30, 2016

**Proprietary Name/ Established Name:** N/A

**Non-Proprietary Name:** Sterile Cord Blood Collection kit containing anticoagulant solution of Citrate Phosphate Dextrose Solution (CPD), USP

**Indication:** The bags are indicated for the collection of 40 – 250 ml of umbilical cord blood from either vaginal birth or within the sterile field of a cesarean section.

**Product Reviewers:** Mercy Quagraine, Ph.D.

**Branch Chief:** Steven Oh, Ph.D.

**Material Reviewed/ Consulted:** CMC Review of Resubmission dated December 7, 2016

I agree with the recommendation for approval as stated in the CMC review memo dated December 7, 2016, and have no additional comments.

---

Kimberly Benton, PhD

---

Raj Puri, MD, PhD