

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