



July 19, 2016

Our STN: 125552/0

RESUBMISSION ACKNOWLEDGEMENT

MacoProductions S.A.S.
Attention: Ms. Heather Pratt
3675 Crestwood Parkway, Suite 260
Duluth, GA 30096

Dear Ms. Pratt:

We have received your June 28, 2016, resubmission to your biologics license application for Cord Blood Sterile Collection Bags containing the Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD) on June 30, 2016.

The resubmission contains additional CMC/Product Quality information that you submitted in response to our March 30, 2015, complete response letter, and your responses to the observations on the Form FDA issued at the conclusion of the pre-licensure inspection.

We consider this a complete response to our action letter. Therefore, the goal date is December 30, 2016.

If you have any questions, please contact me at 240 402 8354.

Sincerely yours,

Ramani Sista, Ph.D., RAC, CQA
Regulatory Management Staff
Office of Cellular, Tissue & Gene Therapies
Center for Biologics Evaluation and Research