



DEPARTMENT OF HEALTH & HUMAN SERVICES

MEMORANDUM

From: Wilson W. Bryan, M.D., (Acting) Director

Division of Clinical Evaluation and Pharmacology / Toxicology, OTAT, CBER

Date: December 20, 2016

NDA/ STN#: 125552

Applicant Name: MacoProductions S.A.S. (Macopharma)

Action Goal Date: December 30, 2016

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

Proprietary name: None

Indication: Collection of 40 – 250 ml of umbilical cord blood from either vaginal birth or within the sterile field of a cesarean section

Pharmacology / Toxicology Reviewer: Alex Bailey, Ph.D.

Pharmacology / Toxicology Branch Chief: Mercedes Serabian, DABT

Clinical Reviewer: John Hyde, Ph.D., M.D.

Clinical Branch Chief: Ilan Irony, M.D.

Material Reviewed / Consulted:

Pharmacology / Toxicology Review of Original Submission, 2/20/15

Clinical Review of Original Submission, 2/26/2015

General Medicine Branch Chief Memo, 1/24/2015

I appreciate Dr. Bailey's and Dr. Hyde's thoughtful pharmacology/toxicology and clinical reviews. I agree that this application raises regulatory management issues. I also appreciate Dr. Irony's summary supervisory memo. Based on the above reviews and memo, and considering the risks and benefits associated with this product for the collection of umbilical cord blood, I recommend approval of this NDA.