NDA 125552/0 **December 21, 2016**

NDA APPROVAL

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

Dear Ms. Pratt:

Please refer to your New Drug Application (NDA) dated April 22, 2014, received April 30, 2014, and your amendments, June 19, July 23, September 17, October 9 and 27, December 19 and 29, 2014, March 18, 2015, March 7, June 28, and December 15, 2016, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sterile Cord Blood Collection Unit with Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD), 27 milliliters for MSC1207DD and 21 milliliters for MSC1208DD .

We acknowledge receipt of your amendment dated June 28, 2016, which constituted a complete response to our March 30, 2015, action letter.

This new drug application provides for the use of Sterile Cord Blood Collection Unit with Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD) for collection up to 250 milliliters of umbilical cord blood for MSC1207DD and up to 200 milliliters of umbilical cord blood for MSC1208DD.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the instructions for use). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 15, 2016, submission containing final printed carton and container labels.

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 125552**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with Final Printed Labeling (FPL) that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

ADVISORY COMMITTEE

Your application for Sterile Cord Blood Collection Unit with Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD) was not referred to an FDA advisory committee because this drug is not the first in its class.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ramani Sista, Regulatory Project Manager, at (240) 402 8354.

Sincerely,

Wilson W. Bryan, M.D.
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosure(s): Content of Labeling
Carton and Container Labeling