



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 125552

March 30, 2015
COMPLETE RESPONSE

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, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cord Blood Sterile Collection Bag, Anticoagulant Citrate Phosphate Dextrose Solution (CPD).

We acknowledge receipt of your amendments dated June 19, July 23, September 17, October 9 and 27, December 19 and 29, 2014.

We also acknowledge receipt of your amendment dated March 18, 2015, which was not reviewed for this action. You may incorporate applicable sections of the amendment by specific reference as part of your response to the deficiencies cited in this letter.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

PRODUCT QUALITY

1. Please identify all the impurity (b) (4) on the CPD (b) (4) and establish limits on the amounts that should not be exceeded in the drug CPD. We request that impurity profile assessment and impurity specifications will be a part of your product release criteria.
2. Information on the qualification report for sterility testing of (b) (4) requested on February 9, 2015 is still outstanding.

PRESCRIBING INFORMATION

3. Submit draft labeling that addresses our proposed revisions in the attached comments on labeling. Prior to resubmitting the labeling, use the SRPI checklist to correct any formatting errors to ensure conformance with the format items in regulations and guidances. In addition, submit updated content of labeling [21 CFR 314.50(l)(1)(i)] in

structured product labeling (SPL) format as described at
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

4. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should include annotations that support any proposed changes.

FACILITY INSPECTION

5. During a recent inspection of the MacoProductions Polonia SP Zo.o., the Poland facility (UT. Szwajcarska 22, 54-405 Wroclaw, Poland) manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA Guidance for Industry, “Formal Meetings Between the FDA and Sponsors or Applicants,” May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

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

Sincerely,

Stephanie Simek, Ph.D.,
Deputy Director
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research

ENCLOSURE: Labeling