



NDA 125552

June 26, 2014

FILING COMMUNICATION

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 (FDCA), for Cord Blood Sterile Collection Bag, Anticoagulant Citrate Phosphate Dextrose Solution (CPD).

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is **Standard**. Therefore, the user fee goal date is April 30, 2015.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

Our filing review is only a preliminary evaluation of the application and is not indicative of issues that may be identified during our review. If you respond to such issues during this review cycle, we may not consider your response before we take an action on your application.

We request that you submit the following information:

PRODUCT INFORMATION

Cited Literature

1. You did not establish whether the bags used in the supporting studies in the literature citations are the same as those proposed for NDA. Hence, it is uncertain if the bags used in the cited literature are the same as those considered under NDA.
2. The cited literature studies do not support the whole range of holding conditions (temperature and time duration) proposed by the sponsor. The sponsor proposes a temperature range of (b) (4) for 48 hours, but the cited studies cover 8°C for 24 -80 hours and 18°C – 26°C for 24 hours.

(b) (4) Studies

3. For the (b) (4) studies, the anticoagulant, CPD, used contained *ascorbic acid*; this is different from the CPD used in the cord blood collection bags under NDA. It is uncertain, whether the collection bags used in the studies are the same as those proposed under NDA.

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

Sincerely,

Raj K. Puri, M.D., Ph.D.
Director
Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research