



CBER REGULATORY REVIEW MEMORANDUM

Date 20 March, 2015

From Simleen Kaur,
Laboratory of Microbiology, In-Vivo Testing and Standards (LMIVTS)
Division of Biological Standards and Quality Control (DBSQC)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To New Drug Application (NDA) STN # 125552/0

Subject NDA: Consult Review of Compendial Sterility Assay

Through Dr. James L. Kenney, Chief, LMIVTS/DBSQC/OCBQ/CBER/FDA
Dr. William M. McCormick, Director, DBSQC/OCBQ/CBER/FDA

Applicant MacoProductions S.A.S

Product Cord Blood Sterile Collection bags with Anti-coagulant Citrate Phosphate Dextrose Solution USP (CPD)

Background

On October 16, 2014, DBSQC received a consult review request for sterility test performed on cord blood sterile collection bags with anti-coagulant Citrate Phosphate Dextrose Solution USP (CPD) and the collection bag (b) (4) submitted under STN 125552/0 manufactured by MacoProductions S.A.S. (MacoProductions).

MacoProductions requested approval for two configurations of cord blood sterile collection bags, MSC1207DD (300 mL collection bag containing 27 mL CPD) and MSC1208DD (300 mL collection bag containing 21 mL CPD). The collection bags will be manufactured at MacoProductions’s new facility in Poland. MacoProductions requested the parametric release of collection bags after sterilization using moist heat, which was initially reviewed by Division of Manufacturing and Product Quality (DMPQ). According to the FDA Guidance for Industry, “Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes (February 2010)”, the firm should have prior manufacturing experience and knowledge incorporated into the risk assessment. Since the Poland facility does not have compliance history with the FDA, DMPQ requested MacoProductions to perform sterility testing on the collection bags containing CPD. MacoProductions concurred to the request as submitted in IR response received 09 January, 2014 under amendment number STN 125552/0/2.

Review

Sterility Test Method Bacteriostatic and Fungistatic (B&F) Qualification

(b) (4)

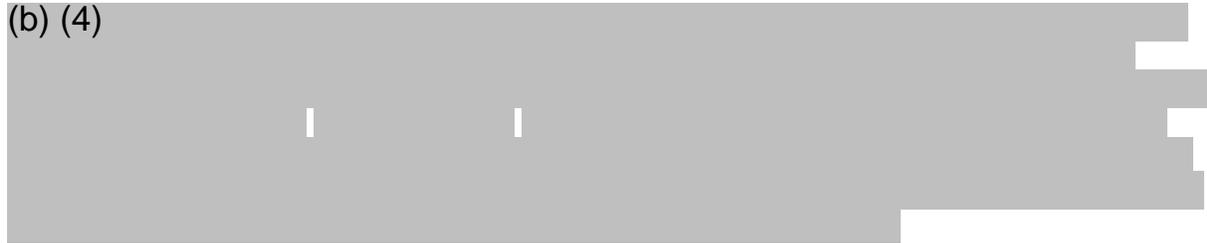
(b) (4)

(b) (4)

Sterility

(b) (4)

(b) (4)



Conclusions

After a thorough review of the information submitted in this NDA and response to information requests received January 5, January 19, February 24, and March 9, 2015, this reviewer finds that the proposed (b) (4) sterility test was qualified in accordance with (b) (4) by demonstrating that the anti-coagulant Citrate Phosphate Dextrose Solution USP in the cord blood sterile collection bags is suitable for the intended test method. CBER is waiting for MacoProductions to provide their sterility test qualification report on their (b) (4) to complete this review. This information was requested in an IR submitted on 09 February, 2015.