

RECORD OF TELEPHONE CONVERSATION

Submission Type: NDA Submission ID: 125552/0 Office: OCTGT

Product:

Cord Blood Sterile Collection Bags with anticoagulant CPD

Applicant:

Macopharma

Telecon Date/Time: 22-September-2014/9:20 AM Initiated by FDA? Yes

Telephone Number: 866-906-9888

Communication Category(ies):

Sterilization/Container Closure Integrity Test

Author: RAMANI SISTA

Telecon Summary:

Sterilization\Container Closure Integrity Testing for manufacturing process

FDA PARTICIPANTS:

Ramani Sista

Ellen Huang

Marion Michaelis

NON-FDA PARTICIPANTS:

Ewa Wasik, Pharmacist, Quality Control Manager (Poland)

Magdalena Rataj, Quality Assurance Manager (Poland)

Aneta Leszczyńska, Microbiologist (Poland)

Przemysław Grzyski, Plant Manager (Poland)

Thomas Coneys, Quality Assurance Manager (France)

Heather Pratt, Regulatory Manager (Macopharma US)

Telecon Body

FDA requested information via email to which the sponsor provided their responses (attached to pdf) in Amendment BN125552/0/1. This telecom was organized to obtain clarifications to some of the sponsor responses.

1. Regarding the response to Information Request (IR) Question 1, FDA stated that it was not clear if there were any cold spots during the empty chamber temperature distribution study. FDA requested the sponsor to provide data regarding the presence of cold spots in their empty chamber studies. The sponsor

indicated that data was available and they could provide it. FDA added that a summary of the data was acceptable and they do not need to see the raw data.

2. Regarding IR Questions 2 and 6, FDA asked for the firm's rationale for the (b) (4). The sponsor stated that this is a (b) (4) the sterilization process. FDA asked if the (b) (4) was based on a specific standard reference method or a published paper. The sponsor indicated they devised this process and it was in their protocol. The firm also indicated that the (b) (4). FDA also asked the firm for their justification that (b) (4) is the worst-case condition. The firm indicated that they would provide a written rationale for FDA review.
3. Regarding IR Question 4, FDA communicated that if they plan on sterilizing less than the maximum load, that the sponsor will need to submit in a supplement in the future. The sponsor indicated they plan to do a minimum load sometime towards end of September. They will have a report available by end of October, which will be forwarded for FDA review as an amendment to this NDA.
4. Regarding IR Question 7, the sponsor indicated they will have data for the repeated runs for the (b) (4) sensors by end of October, which will be submitted for FDA review.
5. Regarding IR Questions 12 and 13, FDA asked since the units are (b) (4) the bags, how do they account for variability between operators? The sponsor indicated, they have filled over (b) (4) units this way and have validated this process. FDA also asked if they perform any other container closure integrity tests (CCIT) to support that the units are integral, such as a pressure test. The sponsor stated that they performed additional CCIT tests in their stability study protocol and normal, routine in-process and final physical integrity testing on the units. FDA requested a description of the testing with details in their response.
6. FDA asked the sponsor if the bags they use are 510(k) cleared and if yes to provide the numbers in their response. The sponsor responded that the bag materials, closures are cleared for irradiated products and the numbers are included in the submission. FDA asked if they could provide where in the submission are the numbers.
7. Regarding parametric release, FDA stated that since there is no established history with this facility, they cannot approve the sponsor for parametric release. FDA also referenced *FDA's Compliance Policy Guides Section 490.200 (Parametric Release – Parenteral Drug Products Terminally Sterilized by Moist Heat)* and *FDA's 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 sponsor stated that they do not plan to implement parametric release right away but are collecting a minimum of (b) (4) of data to support parametric release submission. FDA recommended the sponsor to look at the FDA's guidance and compliance policy guides regarding parametric release when they submit their request for parametric release. The firm also said that they are performing sterility testing of their final units. Furthermore, FDA asked the sponsor if have submitted their sterility test method to the submission. The firm stated that they will confirm if they have and will submit it if they have not yet done so.