



MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: STN 125657

Product(s): HPC – Cord Blood

Applicant: MD Anderson Cord Blood Bank

Teleconference Date/Time: April 9, 2018 / Noon-1PM Initiated by FDA? Yes

Telephone Number: 713-794-1908

Author: Joyce Rockwell

FDA Participants:

Joyce Rockwell, Consumer Safety Officer, OMPT/CBER/OCBQ/DMPQ/MRB1
Bradley Dworak, PhD, Consumer Safety Officer, OMPT/CBER/OCBQ/DMPQ/MRB1
Sarah Lee, RPM, OMPT/CBER/OCBQ/DMPQ/ARB
Mercy Quagraine, Biologist, CBER/OTAT/DCGT
Heba Degheidy, MD, PhD, Visiting Associate, CBER/OTAT/DCGT

Non-FDA Participants:

Jeffrey Wilson, Associate Director
Donna Reieux, Quality Assurance Manager
Erin Eaton, Operations Manager

Teleconference Purpose:

1. DMPQ Follow-up to Information Request dated 1/10/2018
2. DMPQ Follow-Up to 483 Responses
3. OTAT Follow-Up on BLA Review Issues

Teleconference Summary:

- Each BLA review committee member conveyed their issues to the firm.
- Mr. Jeffery Wilson explained that some of the information FDA requires would be provided in the next amendment that will be sent via the Electronic Gateway this week, next week at the latest.

- Each BLA review committee member explained what information needs to be submitted to CBER, by which method, and expected target date.
- The meeting minutes for the product office issues will be documented in a separate teleconference meeting minutes' memo. These minutes' captures just the outstanding DMPQ issues.

Action Items:

- Joyce Rockwell requested the following to be submitted as an official amendment to the BLA:
 - Summary of results for the (b) (4) process qualification runs performed using the revised media fill procedure (483 Observation 6).
 - Revised *Media Fill* procedure (S 002.019) (483 Observation 6).
 - Submit additional data to support the (b) (4)-day expiration date for the (b) (4) (Information Request #6).
 - Submit revised flow diagrams for personnel, supplies and reagents, laboratory waste since Corridor Room (b) (4) is incorrect, should be (b) (4) (Information Request #10).
- Bradley Dworak requested the following to be submitted as an official amendment to the BLA:
 - A revised *Test Results Entry* procedure (S 006.008) explicitly stating that subsequent testing results from (b) (4) are to be manually updated and not automatically overwritten (483 Observation 4).
 - A revised *Informatics Change Control* procedure (S 010.017) that details the risk assessment procedure including the risk factors used, risk scale, and implications/interpretation for each risk level (Information Request #17).