

STN 125348 Fibrocell Telecon Summary 2-16-2011

Attendees

Fibrocell

Declan Daly, CEO
John Maslowski
Karen Donhauser
Joe Kocis

CBR International

Jeanne Novak
Dana Weinberger
Kevin Hennegan
Michael Strauss
Briana Woods
Dave Hines

FDA

Terrig Thomas
Don Fink

A Telecon was arranged to discuss CMC issues raised during the review of the responses to the CR letter comments.

Response to CR comment #2

Shipping Validation Studies: Based on the results of the shipping validation studies presented in the response to the CR letter, we do not agree to an expiration of -----(b)(4)----- lots met all release specifications after 24 hours, but -(b)(4)- deviated with regard to cell count by a margin of -----(b)(4)----- . Consequently, based on these studies, we consider 24 hours to be the maximal time from shipping to administration of the product. As the proposed expiration of -----(b)(4)----- may exceed 24 hours, please be advised that the expiration used on the commercial injection vial must include the hour of expiry, which must not exceed 24 hours post-shipment.

Fibrocell: *The sponsor agreed to indicate the hour of expiry, not to exceed 24 hours, on the final product label and will submit an example of such in an amendment to the BLA.* -----(b)(4)-----

Response to CR comment #8

Hold Time specification of Drug Product-Injection

The specification of -(b)(4)- for time from Bulk Drug Substance----- (b)(4)----- is not acceptable. The specification should be based on the times used for the lots shipped under shipping validation EX-GTR-143. Please submit this information to the BLA.

Fibrocell: *Under the shipping validation study, EX-GTR-143, the period of time from (b)(4) to shipping of the final product was -(b)(4)-- and the time of shipment was*

6:00pm. The sponsor agreed to submit this information to the BLA and to amend the SOP and MBR to accommodate a maximum time of -(b)(4)- from (b)(4) to shipment. FDA asked whether the shorter time frame would be sufficient to allow for potential system failures. At the time of the PLI the Quality Control laboratory lacked sufficient instrument redundancy to compensate for errors encountered during performance of final product release testing. Fibrocell said it is currently validating additional instruments which should prevent any delay in final product shipment due to an instrument failure that might occur during release testing.

Response to CR comment #6

Passage rules for Confluence Specifications of ---(b)(4)---

---(b)(4)---

Fibrocell agreed with our suggested proposal of -----(b)(4)-----
-----.

Fibrocell will implement agreed upon changes in accordance with documented Change Control procedures and submit for review the rationale and justification for each change in an amendment to the BLA.