

Rana, Pratibha

From: Kennedy, Michael
Sent: Thursday, February 17, 2011 4:25 PM
To: Rana, Pratibha
Subject: RE: Biotest- Request for feedback regarding manufacturing delays

Question1. I informed Biotest that a late submission of their data would likely result in either a major amendment extension of the clock or a CR letter depending on the actual timing of the submission and the current review status at the time of the submission.

Question 2. I informed Biotest that the scheduling of the PAI was solely a DMPQ issue.

Michael C. Kennedy PhD
Laboratory of Plasma Derivatives
Division of Hematology
Office of Blood Research and Review
Center for Biologics Evaluation and Research

From: Rana, Pratibha
Sent: Thursday, February 17, 2011 4:17 PM
To: Kennedy, Michael
Cc: Shields, Mark; Cagungun, Nannette
Subject: RE: Biotest- Request for feedback regarding manufacturing delays

Michael,
Thank you for letting me know. Since I was not invited to this teleconference please enter your minutes/notes from this meeting to the BLA. So we know what was discussed during this teleconference. This information is also beneficial for Nannette as well.

Thank you.
Pratibha

From: Kennedy, Michael
Sent: Thursday, February 17, 2011 4:13 PM
To: Rana, Pratibha
Subject: RE: Biotest- Request for feedback regarding manufacturing delays

Hi Pratibha,

I talked with the company this afternoon.

Michael C. Kennedy PhD
Laboratory of Plasma Derivatives
Division of Hematology
Office of Blood Research and Review

3/17/2011

Center for Biologics Evaluation and Research

From: Rana, Pratibha
Sent: Tuesday, February 15, 2011 4:42 PM
To: Kennedy, Michael
Subject: RE: Biotest- Request for feedback regarding manufacturing delays

Michael,
The Sponsor called again today to find out the status of the email he sent on February 8. Please let me know if we need to set up a teleconference.
Thanks
Pratibha

From: Rana, Pratibha
Sent: Thursday, February 10, 2011 10:35 AM
To: Kennedy, Michael
Subject: RE: Biotest- Request for feedback regarding manufacturing delays

I will wait to hear from you regarding this issue. Please keep me posted on when you plan to have the discussions or when I can set up the teleconference with the sponsor.

Thanks
Pratibha

From: Kennedy, Michael
Sent: Thursday, February 10, 2011 10:16 AM
To: Rana, Pratibha
Subject: RE: Biotest- Request for feedback regarding manufacturing delays

Pratibha,
I believe Dot and I will be having discussions with Biotest regarding the HBIG (b)(4) - I will discuss the BLA issues with them at that time. Please remember that before you send any comments to the sponsor they need to be approved by me.

Thanks,

Michael C. Kennedy PhD
Laboratory of Plasma Derivatives
Division of Hematology
Office of Blood Research and Review
Center for Biologics Evaluation and Research

From: Rana, Pratibha
Sent: Thursday, February 10, 2011 10:06 AM
To: Kennedy, Michael
Cc: Crim, James; Kennedy, Michael; Olin, Rebecca; Cagungun, Nannette; Scott, Dorothy; Frazier, Douglas;

3/17/2011

Jackson, Damia; Shields, Mark

Subject: RE: Biotest- Request for feedback regarding manufacturing delays

Michael,

Please advise regarding the Biotest BLA 125389/0. Or send me final comments to send to the sponsor.

Thanks

Pratibha

From: Olin, Rebecca

Sent: Wednesday, February 09, 2011 8:08 AM

To: Cagungun, Nannette; Scott, Dorothy; Frazier, Douglas; Jackson, Damia; Kennedy, Michael

Cc: Rana, Pratibha; Crim, James

Subject: RE: Biotest- Request for feedback regarding manufacturing delays

It would seem that the cleanest way to do this would be to withdraw the BLA and resubmit when they have all the data they need. My two cents.

From: Cagungun, Nannette

Sent: Tuesday, February 08, 2011 5:03 PM

To: Scott, Dorothy; Frazier, Douglas; Olin, Rebecca; Jackson, Damia; Kennedy, Michael

Cc: Rana, Pratibha; Crim, James

Subject: FW: Biotest- Request for feedback regarding manufacturing delays

Importance: High

Please see email below- regarding STN 103945 and STN 125389. Will DMPQ take this?

Thanks,

Nannette

From: Matthew Vaughn [mailto:MVaughn@biotestpharma.com]

Sent: Tuesday, February 08, 2011 4:03 PM

To: Rana, Pratibha; Cagungun, Nannette

Subject: Biotest- Request for feedback regarding manufacturing delays

Importance: High

Hi Pratibha, Hi Nannette,

Thank you for accepting my email. I will do my best to describe the current manufacturing (b)(4) (b)(4) that Biotest would like to urgently discuss with FDA. At the bottom of the email, I've included a few key questions.

For BIVIGAM (STN 125389): Due to unforeseen complications during implementation of the Phase 2 changes (ref. to BLA Section 2.2), we are currently experiencing a delay in our ability to re-start the IgG manufacturing facility in Boca Raton, FL. These complications apply specifically to the (b)(4) (b)(4). As previously communicated to FDA, Biotest planned to manufacture 2 additional conformance lots of BIVIGAM starting no later than February 2011 in order to submit a BLA amendment in late April/May 2011 (see BLA cover letter).

Additionally, (b)(4)

(b)(4)

(b)(4). As a result of this re-prioritization, the second set of conformance lots for BIVIGAM will not begin

3/17/2011

until late May 2011.

As a consequence, we are proposing submission of a BLA amendment to provide a new facilities and equipment section (Section 3.2.A) in late May/early June 2011. A subsequent BLA amendment, including all remaining results from the second set of conformance lots, i.e. comparability data would be submitted in August 2011.

(b)(4)

Proposed questions:

- 1) Due to the likelihood that the comparability data for the second set of BIVIGAM conformance lots will not be submitted until August 2011, how can FDA and Biotest jointly solve this timing issue considering that the PDUFA date is September 3, 2011?
- 2) Does FDA agree that we could submit a new Section 3.2.A in a separate BLA amendment in late May/early June to be followed by the comparability data in August? Would FDA be willing to schedule a PAI if Biotest submits a new Section 3.2.A in late May/early June 2011?

Thank you for your consideration of this information and we look forward to discussing this with the FDA in the near future.

Kind Regards,

Matt

Matthew T. Vaughn
Associate Director, Regulatory Affairs
Biotest Pharmaceuticals Corporation
5800 Park of Commerce Blvd., N.W.
Boca Raton, FL 33487
(561) 989-5712
mvaughn@biotestpharma.com

NOTICE: This e-mail message and any attachment to this e-mail contain confidential information that may be legally privileged. If you are not the intended recipient, you must not retransmit, convert to hard copy, copy, use or disseminate this e-mail or any attachments to it. If you have received this e-mail in error, please notify us immediately by return e-mail or by telephone at 561-989-5800 and delete this message. Please note that this electronic mail (and any related correspondence) is not intended to create and it does not create any legal rights, obligations or consequences between Biotest Pharmaceuticals Corporation and you or your company. Only those rights and obligations that are set forth in a definitive written agreement, executed by all parties in the manner provided for in such agreement, will create any legally binding rights, obligations or consequences. All agreements are subject to legal review and acceptance by signature of an authorized party of Biotest Pharmaceuticals Corporation before becoming final.

3/17/2011