

Rana, Pratibha

From: Zhang, Pei
Sent: Friday, December 17, 2010 10:40 AM
To: Rana, Pratibha
Cc: Boxenbaum, Harold; Kennedy, Michael; Virata, Maria Luisa; Frost, Mitchell M; Olin, Rebecca; Ortega, Lillian; Ou, Alan C.; Quander III, Joseph; Stockbridge, Lisa L; Struble, Evi; Zhong, Lilin; Frazier, Douglas; Mikolajczyk, Malgorzata; Jain, Nisha; Mahmood, Iftekhar; Kim, Jessica; Kelly, Sunday
Subject: RE: STN 125389/0 Filing Meeting

Hi, Pratiba,

After initial reviewing CMC/Viral Validation section, this submission is fileable. Thanks!

Pei

From: Virata, Maria Luisa
Sent: Friday, December 17, 2010 10:28 AM
To: Rana, Pratibha; Kennedy, Michael; Boxenbaum, Harold; Frost, Mitchell M; Olin, Rebecca; Ortega, Lillian; Ou, Alan C.; Quander III, Joseph; Stockbridge, Lisa L; Struble, Evi; Zhong, Lilin; Frazier, Douglas; Mikolajczyk, Malgorzata; Zhang, Pei; Jain, Nisha; Mahmood, Iftekhar; Kim, Jessica
Cc: Kelly, Sunday
Subject: RE: STN 125389/0 Filing Meeting

Hi Pratibha,

Sorry that I didn't see your email as I was already on my way home.

Other than the viral NAT documents (for which I already asked you to send an IR to Biotest), I didn't see any other major deficiencies (re: product specifications, anti-Measles, anti-Diphtheria, (b)(4) etc) that would prevent filing of this submission.

Liza

From: Rana, Pratibha
Sent: Thursday, December 16, 2010 4:12 PM
To: Rana, Pratibha; Kennedy, Michael; Boxenbaum, Harold; Frost, Mitchell M; Olin, Rebecca; Ortega, Lillian; Ou, Alan C.; Quander III, Joseph; Stockbridge, Lisa L; Struble, Evi; Zhong, Lilin; Frazier, Douglas; Virata, Maria Luisa; Mikolajczyk, Malgorzata; Zhang, Pei; Jain, Nisha; Mahmood, Iftekhar; Kim, Jessica
Cc: Kelly, Sunday
Subject: RE: STN 125389/0 Filing Meeting

Thank you for your filing memo/emails.

Some of us call in but ended the meeting since there are no deficiencies and filing issues to be discussed.

Thanks
Pratibha

From: Rana, Pratibha
Sent: Thursday, December 16, 2010 2:28 PM
To: Kennedy, Michael; Boxenbaum, Harold; Frost, Mitchell M; Olin, Rebecca; Ortega, Lillian; Ou, Alan C.; Quander III, Joseph; Stockbridge, Lisa L; Struble, Evi; Zhong, Lilin; Frazier, Douglas; Virata, Maria Luisa; Mikolajczyk, Malgorzata; Zhang, Pei; Jain, Nisha; Mahmood, Iftekhar; Kim, Jessica
Cc: Kelly, Sunday
Subject: RE: STN 125389/0 Filing Meeting

Good Afternoon everyone,

I have to leave since my (b)(6)

I will call in for this meeting.

I am requesting that all of you send me an email as filing memo.

Please indicate weather you have any deficiencies. I will set the date for PMC T-28 day just in case if we need it.

If you all don't have any issues to discuss we may just satisfy this meeting via email.

Michael, Please let me know.

Thanks
Pratibha

From: Rana, Pratibha
Sent: Friday, November 12, 2010 4:30 PM
To: Rana, Pratibha; Kennedy, Michael; Boxenbaum, Harold; Frost, Mitchell M; Olin, Rebecca; Ortega, Lillian; Ou, Alan C.; Quander III, Joseph; Stockbridge, Lisa L; Struble, Evi; Zhong, Lilin; Frazier, Douglas; Virata, Maria Luisa; Mikolajczyk, Malgorzata; Zhang, Pei; Jain, Nisha; Mahmood, Iftekhar; Kim, Jessica
Cc: Kelly, Sonda
Subject: STN 125389/0 Filing Meeting
When: Thursday, December 16, 2010 4:00 PM-5:00 PM (GMT-05:00) Eastern Time (US & Canada).
Where: CBER Conf. WOC-400S

Filing meeting moved due to conflict with DH Holiday party on Friday, Please accept.

This is the Filing meeting meeting: Please attend in person, if you are unable to, **the call in info is below.**

For STN 125389/0

Product: Immune Globulin Intravenous (Human), Sponsor: Biotest Pharmaceuticals Corporation, Indication: Primary Immune Deficiency Disorders (PIDD)

- **The purpose of this meeting:**
- **If this BLA application is fileable.**
- **If there are any deficiencies.**
- **CRB assess applicants PREA Recommendation, Contact PREA rep.**
- **Telecon Date determined fro PMC, PMR, Labeling**
- **Filing memo is needed**

Passcodes:

Participant: (b)(4)

Dial in numbers

Toll Numbers

Toll Free Number

(b)(4)

(b)(4)

Please let me know if you have any questions.

Pratibha