

Rana, Pratibha

From: Stockbridge, Lisa L
Sent: Thursday, December 16, 2010 3:40 PM
To: Rana, Pratibha; Kennedy, Michael; Boxenbaum, Harold; Frost, Mitchell M; Olin, Rebecca; Ortega, Lillian; Ou, Alan C.; Quander III, Joseph; Struble, Evi; Zhong, Lilin; Frazier, Douglas; Virata, Maria Luisa; Mikolajczyk, Malgorzata; Zhang, Pei; Jain, Nisha; Mahmood, Iftekhar; Kim, Jessica
Cc: Kelly, Sonda
Subject: RE: STN 125389/0 Filing Meeting

Good Afternoon,

Here are my first impressions of this submission:

- 1) This submission contains no SPL.
- 2) The PI is quite deficient even though there was an attempt to put it into PLR format.
- 3) The proposed carton/container formatting is not consistent with the regulations.

Lack of SPL does not affect fileability. However, I would suggest that you request that the sponsor provide the file for review.

Thanks,

LLS

Lisa L. Stockbridge, Ph.D.
Branch Chief
CBER/OCBQ/DCM/APLB
301-827-6226

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, Sonda
Subject: RE: STN 125389/0 Filing Meeting

Good Afternoon everyone,
I have to leave since [REDACTED] (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