

Rana, Pratibha

From: Stockbridge, Lisa L
Sent: Monday, November 29, 2010 4:10 PM
To: Rana, Pratibha
Subject: RE: STN 125389/0 First Committee Meeting

All of the elements applicable to APLB review are present. This is fileable from our perspective.

Thanks,

LLS

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

From: Rana, Pratibha
Sent: Monday, November 29, 2010 3:53 PM
To: Stockbridge, Lisa L
Cc: Kennedy, Michael
Subject: FW: STN 125389/0 First Committee Meeting

Lisa,
Could you please send me a short email regarding the first committee meeting.
Thanks
Pratibha

From: Rana, Pratibha
Sent: Tuesday, November 23, 2010 3:36 PM
To: Stockbridge, Lisa L; Olin, Rebecca
Cc: Kennedy, Michael
Subject: RE: STN 125389/0 First Committee Meeting

Rebecca and Lisa,
Please let Michael know if you have any issues. Also send me an email regarding the submission.
We were waiting for you to call in since you had both accepted the meeting.
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, Iftexhar; Kim, Jessica
Cc: Kelly, Sondag
Subject: STN 125389/0 First Committee Meeting
When: Tuesday, November 23, 2010 3:00 PM-4:00 PM (GMT-05:00) Eastern Time (US & Canada).
Where: CBER Conf. WOC-1

This is the first committee meeting: (I will provide the call in number next week for those who cannot attend in person)

For STN 125389/0

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

The purpose of this meeting: (please see below)

- Ensure submission is complete
- Ensure a reviewer is assigned
- Identify if consult review is needed.
- Notify OBRR PeRC Representative
- Inspections Needed?
- BPAC eligible?
- Identify follow up activities to be completed before the filing meeting.