

From: Mahmood, Iftekhar
Sent: Wednesday, September 16, 2015 10:35 AM
To: Do, Yu
Subject: RE: Filing Review Memo for Clinical Pharmacology: Original BLA, BL 125590/0, ADMA Biologics, Inc., Immune Globulin Intravenous (Human) (RI-002) (ADD: July 30, 2016)
Attachments: Filingcheck(125590).doc

Hi Yu,
I talked to Sandy and we will work together to come up with filing checklist for clinical pharmacology. I have attached the filing memo with this e-mail.
Thanks
Iftekhar Mahmood

From: Do, Yu
Sent: Wednesday, September 16, 2015 10:21 AM
To: Mahmood, Iftekhar
Subject: RE: Filing Review Memo for Clinical Pharmacology: Original BLA, BL 125590/0, ADMA Biologics, Inc., Immune Globulin Intravenous (Human) (RI-002) (ADD: July 30, 2016)

Hi, Iftekhar, Sandy is available to talk with you now whenever you are ready.

From: Mahmood, Iftekhar
Sent: Wednesday, September 16, 2015 9:53 AM
To: Do, Yu
Subject: RE: Filing Review Memo for Clinical Pharmacology: Original BLA, BL 125590/0, ADMA Biologics, Inc., Immune Globulin Intravenous (Human) (RI-002) (ADD: July 30, 2016)

Hi Yu,
Please ask Sandy for clinical pharmacology checklist. If you are looking for the response for three questions then the response are as follows:

1. This application can be filed
2. There is no deficiency but PK data need to be reanalyzed by the sponsor.
3. From clinical pharmacology perspective there is no innovative work in this submission.

If these are three response you are looking for then I can load it now but there will be no supervisory concurrence.

Thanks
Iftekhar Mahmood
Will you please send me your number so that I can call you.

From: Do, Yu
Sent: Wednesday, September 16, 2015 9:19 AM
To: Mahmood, Iftekhar
Subject: RE: Filing Review Memo for Clinical Pharmacology: Original BLA, BL 125590/0, ADMA Biologics, Inc., Immune Globulin Intravenous (Human) (RI-002) (ADD: July 30, 2016)

Hi, Iftekhar, I can request one from the Review Management (Sandy Menzies), but I don't know if it would be available for you to use any time soon. It would be more efficient for you to write a review memo for now.

I need you to complete this task, including EDR upload, no later than 5 days before the filing date, September 29, 2015.

Since you are currently on leave, is there anyone else who might help you in this regard? I am sorry again, but I want to make sure we don't miss the deadline.

Yu

From: Mahmood, Iftekhar
Sent: Wednesday, September 16, 2015 9:13 AM
To: Do, Yu
Subject: RE: Filing Review Memo for Clinical Pharmacology: Original BLA, BL 125590/0, ADMA Biologics, Inc., Immune Globulin Intravenous (Human) (RI-002) (ADD: July 30, 2016)

Hi YU,
There should be a clinical pharmacology checklist like other disciplines. I am taking time off and will not be able to send you the filing checklist. Do you know who is responsible for creating the checklists?
Thanks
Iftekhar Mahmood

From: Do, Yu
Sent: Wednesday, September 16, 2015 8:51 AM
To: Mahmood, Iftekhar
Subject: Filing Review Memo for Clinical Pharmacology: Original BLA, BL 125590/0, ADMA Biologics, Inc., Immune Globulin Intravenous (Human) (RI-002) (ADD: July 30, 2016)
Importance: High

Dear Iftekhar:

I am afraid this modified version of the filing checklist would not be adequate as it only contains a filing decision along with application information.

Since there is no filing checklist template for clinical pharmacology, you need to draft a filing review memo with more details and have it concurred by supervisor no later than this Friday, September 18, 2015. The filing review memo should address the following objectives:

1. Identify and document missing, incomplete, or inaccessible information to make a determination if the application is acceptable for filing or should be recommended for a "Refuse To File" (RTF) action
2. Identify and document other deficiencies to send to the applicant in the filing letter or deficiencies identified letter (e.g., missing statistical programs and datasets or missing draft labeling in the correct format)
3. Assist reviewers in planning their review of the submission (e.g., identification of new or novel techniques or issues (e.g., novel legal or policy issue or need for consultant reviews)

Sorry, Iftekhar, for any inconveniences and late notice. Please let me know if you have any questions. Thank you so much.

Yu

From: Mahmood, Iftekhar

Sent: Monday, September 14, 2015 11:16 AM

To: Do, Yu

Subject: Filing checklist

Hi Yu,

I have attached a modified version of filing checklist. Hope this will work. I may not be able to attend the meeting.

Thanks

Iftekhar Mahmood