

From: Do, Yu
Sent: Tuesday, March 08, 2016 5:24 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Tuesday, March 15, 2016):
Original BLA, BL 125590/0, Immune Globulin Intravenous (Human) [RI-002], ADMA Biologics, Inc.

Importance: High

Dear Ms. Myers:

We are reviewing your original July 31, 2015, submission to BLA 125590 for Immune Globulin Intravenous (Human). We are providing the following comments and request additional information to continue our review:

1. You wrote on page 9 of the Study Report Body under Module 5.3.5.2., "With no subjects experiencing a SBI during the study, RI-002 achieved the primary efficacy endpoint with the 99% upper confidence bound for the observed SBI rate per subject per year of <1.0."

a. What is the specific value (number) of this 99% upper confidence bound? Where in the submission can this 99% upper confidence bound be found?

b. Which particular SAS program, provided in this submission, was used to calculate this 99% upper confidence bound?

The review of this submission is ongoing and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by March 15, 2016, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is July 30, 2016.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov if you have any questions.

Sincerely,

Yu Do, M.S.
Regulatory Project Manager
FDA/OMPT/CBER/OBRR/RPMS
(240) 402-8343
yu.do@fda.hhs.gov

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