

From: Do, Yu
Sent: Monday, December 21, 2015 10:14 AM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Monday, January 11, 2016):
Original BLA, BL 125590/0, Immune Globulin Intravenous (RI-002), ADMA
Biologics, Inc.

Importance: High

Dear Ms. Myers:

We are reviewing your original July 31, 2015 submission to BLA 125590/0 for Immune Globulin Intravenous (Human). We are providing the following comments and request additional information to continue our review:

1. In your stability studies for (b) (4) (Sections 6.2.1 and 6.2.2 of Process Validation and/or Evaluation (b) (4) Stability), it was indicated that the (b) (4) results exceeded the maximum acceptance criteria of ? (b) (4) Please provide the details of these out-of-specification events and their corresponding investigation reports.
2. In your drug substance stability study, a dramatic change of the (b) (4) value was noticed for Lot (b) (4) tested at time points (b) (4) Please explain.
3. Please provide an update on your ongoing stability studies for drug products, along with the raw data, in an Excel spreadsheet.

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 January 11, 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/IOD/RPMS
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