

From: Do, Yu
Sent: Monday, February 01, 2016 3:25 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Friday, February 05, 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 125590/0 for Immune Globulin Intravenous (Human). We are providing the following comments and request additional information to continue our review:

Bioburden for (b) (4)

1. Please provide an estimated date of completion for repeat bioburden qualification study to include evaluation of (b) (4) as mentioned in the Information Request (IR) response dated January 22, 2016.

2. According to Item 2 in the ADMA response dated January 22, 2016, bioburden samples used in (b) (4) qualification study are (b) (4) to remove endogenous organisms. This (b) (4) step, however, is not performed during bioburden testing. CBER finds this unacceptable since matrix qualified was not identical to the production matrix, as the removed endogenous organisms may have impacted the method qualification.

Therefore, CBER requests either adding a (b) (4) step before bioburden testing in the production process or repeating the (b) (4) qualification study without this (b) (4) step.

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 February 05, 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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