

From: Do, Yu
Sent: Thursday, January 14, 2016 3:23 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Friday, January 22, 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:

Bioburden for (b) (4)

1. The bioburden counts reported in validation report VP-FR-4008R1 and Information Request (IR) response dated January 8, 2016 (question 1) are average recovery counts of microorganisms inoculated in the test samples used during method qualification.

Please provide Colony Forming Unit (CFU) counts of initial inoculums to ensure that test samples were inoculated with (b) (4) CFUs and were compliant with regulatory requirements.

2. According to IR response dated January 8, 2016, your response to question 2 states, "The (b) (4) of validation protocol (number VP-PQ-4008) is a (b) (4) step to make the matrix suitable for use in the validation." However, (b) (4) SOP (number QC2092R9) does not state this (b) (4) to bioburden testing.

Please clarify this discrepancy and provide the preliminary method qualification data, indicating that the sample matrix is not suitable for the intended method without this (b) (4)

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 22, 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
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