

From: Do, Yu
Sent: Wednesday, December 23, 2015 2:10 PM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Wednesday, December 30, 2015):
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. Please provide (b) (4) results of positive controls tested in the Bioburden Validation protocol (number VP-PQ-4008) and report (number VP-FR-4008R1).
2. For Sections 6.5 (Preparation of Samples) and 6.6 (Testing of Samples) of the Bioburden Validation protocol (number VP-PQ-4008):

Please clarify if the samples are inoculated with indicator microorganisms before or after (b) (4). In addition, please provide the complete procedure in detail.

3. For Section 6.9 (Results and Calculations) of the Bioburden Validation protocol (number VP-PQ-4008):

Calculations used for bioburden test results of the (b) (4) samples (section 6.9.1.1) should be the same as calculated for the (b) (4) samples (section 6.9.1.2), since (b) (4) is tested for all sample types. Please clarify the discrepancy in these sample calculations.

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 December 30, 2015, 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

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."