

From: Do, Yu
Sent: Tuesday, September 15, 2015 11:52 AM
To: 'dmyers@malvernconsultinggroup.com'
Subject: Information Request (Response Due by Wednesday, September 23, 2015):
Original BLA, BL 125590/0, Immune Globulin Intravenous (RI-002), ADMA
Biologics, Inc.

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. CBER finds the bioburden qualification report (number VP-FR-3376) incomplete since it does not include evaluation of (b) (4)

Please provide the results of (b) (4) tested in (b) (4) using (b) (4)

Sterility Testing for Drug Product (DP)

2. CBER finds the Bacteriostasis and Fungistasis (B&F) report (procedure no. STP0078 REV 03) for qualification of sterility test incomplete since it does not include evaluation of (b) (4) during the qualification study, which is outside the incubation duration required by (b) (4)

CBER requests B&F qualification study to be repeated in accordance with requirements of (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 September 23, 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/IOD/RPMS
(240) 402-8343

yu.do@fda.hhs.gov

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