

From: Do, Yu
Sent: Monday, January 11, 2016 9:16 AM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Friday, January 29, 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. Since this BLA is for a Primary Humoral Immunodeficiency indication (not for a (b) (4) related indication), please remove any mention of (b) (4) from the Package Insert as well as from the Drug Product release specifications.

2. As stated before during the October 7, 2014 pre-BLA Type B Meeting, FDA discourages the use of (b) (4) filters as these do not necessarily prevent particulates from going through or from reforming after filtration. Please remove any mention of using an (b) (4) filter from the Package Insert.

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 29, 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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