

From: Do, Yu
Sent: Friday, February 19, 2016 10:12 AM
To: dmyers@malvernconsultinggroup.com
Subject: Information Request (Response Due by Friday, February 26, 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 for Immune Globulin Intravenous (Human). We are providing the following comments and request additional information to continue our review:

1. Please provide the following information or documents for the Agency to review:

* Analysis of particles that appeared at 12 months for Bivigam's lot (b) (4). In addition, please indicate if the particles identified for this lot is comparable to those of RI-002's Lot (b) (4).

* Investigation report for Bivigam's Lot (b) (4) regarding visual appearance OOS at 12 months (i.e., Biotest Investigation Number FR-2013-18 INV 9004: Visual particles in BIVIGAM vials (b) (4)).

* Stability testing and/or study performed for Lot (b) (4).

2. Please provide one vial (50 ml) per lot of the following (b) (4) final products for (b) (4) testing: (b) (4). The testing will be conducted for research purposes only and not for lot release. Please use the following address for shipping:

FDA/CBER/OBRR
Attn: Yonggang Wang/Nancy Eller/Dr. Dorothy Scott
Building 52, Room 4140
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: (240) 402-8236

Please notify Yonggang Wang (Yonggang.Wang@fda.hhs.gov), Dorothy Scott (Dorothy.Scott@fda.hhs.gov), and Nancy Eller (Nancy.Eller@fda.hhs.gov) when the samples are being shipped. Also, please include the tracking number in this notification.

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 26, 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/PPMS
(240) 402-8343
yu.do@fda.hhs.gov

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