From: Do, Yu
Sent: Wednesday, August 26, 2015 9:32 AM
To: 'Diane Myers'
Subject: Information Request (Nonclinical Studies): 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 determined that the following information is necessary to
continue our review:

1.   The issue of no nonclinical data was not raised and discussed during the pre-BLA
meeting. Therefore, such data need to be submitted in support of this BLA application.

Please submit the data from nonclinical studies as soon as possible.

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 7, 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.
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