

From: Maruna, Thomas
Sent: Friday, June 17, 2016 11:07 AM
To: 'Denloye, Aderonke O'
Cc: Mahmood, Iftekhar; Landow, Laurence; Reed, Jennifer
Subject: RE: 17-June-2016 Information Request (Labeling) - BLA 125596.0 - Please Respond by 24-June-2016

Ms. Denloye,

Please add these clinical pharmacology edits to your June 24, 2016 response.



Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
FDA/CBER/OBRR/IO
thomas.maruna@fda.hhs.gov
Office: (240) 402-8454

From: Denloye, Aderonke O [<mailto:Ade.Denloye@shire.com>]
Sent: Friday, June 17, 2016 10:48 AM
To: Maruna, Thomas
Subject: RE: 17-June-2016 Information Request (Labeling) - BLA 125596.0 - Please Respond by 24-June-2016

Dear Thomas:

I received your recalled message which indicated that you wanted the response by 30Jun2016, so thanks for the clarification, we'll work towards the 24th Jun submission date.

Best regards,
Aderonke Denloye

From: Maruna, Thomas [<mailto:Thomas.Maruna@fda.hhs.gov>]
Sent: Friday, June 17, 2016 7:37 AM
To: Denloye, Aderonke O
Subject: RE: 17-June-2016 Information Request (Labeling) - BLA 125596.0 - Please Respond by 24-June-2016

The response date is June 24, 2016. I attempted to recall and resend the message. Please include the revised AE tables.

Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
FDA/CBER/OBRR/IO
thomas.maruna@fda.hhs.gov
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From: Denloye, Aderonke O [<mailto:Ade.Denloye@shire.com>]
Sent: Friday, June 17, 2016 10:35 AM
To: Maruna, Thomas
Cc: Landow, Laurence; Struble, Evi
Subject: RE: 17-June-2016 Information Request (Labeling) - BLA 125596.0 - Please Respond by 24-June-2016

Dear Thomas:

I am acknowledging receipt of the redlined PI and the response date of 30 Jun 2016.

Best regards,

Aderonke Denloye, MPH
Associate Director, Global Regulatory Affairs

Shire
One Baxter Way
Westlake Village, CA 91362 USA
+1 805 372 3053 desk
+1 805 372 3052 Facsimile
ade.denloye@shire.com
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Baxalta, now part of Shire

From: Maruna, Thomas [<mailto:Thomas.Maruna@fda.hhs.gov>]
Sent: Friday, June 17, 2016 7:01 AM
To: Denloye, Aderonke O
Cc: Landow, Laurence; Struble, Evi
Subject: 17-June-2016 Information Request (Labeling) - BLA 125596.0 - Please Respond by 24-June-

2016

Importance: High

Baxalta US Inc.
Attention: Ms. Aderonke Denloye
June 17, 2016
Sent by email

Dear Ms. Denloye:

We are reviewing your September 14, 2015 biologics license application (BLA) to treat primary immune deficiency disorders associated with defects in humoral immunity for the following:

| STN | Name of Biological Products |
|------------|--|
| 125596/0 | Immune Globulin Subcutaneous (Human), 20% Solution |

Please find the attached revised labeling for your review.

Please submit your responses as an amendment to this file by June 24, 2016 referencing the date of this request.

Please also include the revised AE tables concerning differences between the CSR tables and the PI for adverse events in your amendment.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for these files is September 13, 2016.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
Lieutenant, U.S. Public Health Service
Senior Regulatory Management Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
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