

From: Krammer, Marlene <marlene.krammer@octapharma.com>
Sent: Tuesday, April 28, 2015 8:56 AM
To: Hooban, Christopher
Cc: Rangetiner, Barbara; Ammons, Stanley; Cagungun, Nannette
Subject: RE: Request for Information - SDTM: BL 125077/332; Original BLA; Octapharma; ADD 14-APR-2016
Attachments: NGAM 2014 Submission Planning Checklist.docx

Dear Mr. Hooban,

I refer to your Email to Mr. Ammons of today. The study data tabulation model (SDTM) used within this submission is version 1.2. Please find enclosed to this Email the submission planning checklist where this information can be found on page 2. Please be informed that this document is enclosed in Module 1.2 of our original BLA submitted on April 15, 2015.

Kind regards, Marlene Krammer

Marlene Krammer
Manager
International Regulatory Affairs Department

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From: Hooban, Christopher [mailto:Christopher.Hooban@fda.hhs.gov]
Sent: Tuesday, April 28, 2015 8:30 AM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Request for Information - SDTM: BL 125077/332; Original BLA; Octapharma; ADD 14-APR-2016

Our Reference: BL 125077/332
Product: Immune Globulin Intravenous (Human) 10%, Panzyga
Indications: 1) Primary humoral immunodeficiency and 2) Chronic immune thrombocytopenic purpura

Dear Mr. Ammons:

Good morning. This email is in reference to your original BLA submitted on April 15, 2015 for Immune Globulin Intravenous (Human) 10%. The FDA would like to request information on the study data tabulation model (SDTM) used within the submission, specifically which version of SDTM was used to create the SDTM datasets. If you have any questions please contact me at (240)402-8376 or at christopher.hooban@fda.hhs.gov. Thanks for your time.

Chris Hooban
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