

From: Hooban, Christopher  
Sent: Monday, May 18, 2015 11:29 AM  
To: 'Krammer, Marlene'  
Subject: RE: STN 125587/0; Original BLA Application

Received.

Thanks.

From: Krammer, Marlene [mailto:marlene.krammer@octapharma.com]  
Sent: Monday, May 18, 2015 7:05 AM  
To: Hooban, Christopher  
Cc: Ammons, Stanley; Rangetiner, Barbara; Cagungun, Nannette  
Subject: RE: STN 125587/0; Original BLA Application

Dear Mr. Hooban,

I refer to your Email to Mr. Ammons dated May 15, 2015 in regards to STN 125587/0. We would like to clarify as follows:

Studies NGAM-01 and NGAM-05 (extension study to NGAM-01) for PID were completed in June 2012 and September 2012 respectively. Study NGAM-02 for ITP was completed in July 2013. Prior to filing the BLA Octapharma asked for a pre-BLA meeting (CRTMS #9173).

Based on the feedback received from FDA to the summary validation report and the issues encountered during the validation, Octapharma manufactured new validation batches (consistency batches) in 2014 to provide evidence for consistency and robustness of the commercial scale manufacturing process implemented at the site in Lingolsheim, France. FDA also recommended submitting a comparability study proposal followed by a conformance batch manufacturing study. The comparability study proposal was submitted on June 13, 2014 as amendment #031 to BB-IND #14121. FDA informed us on August 1, 2014 that the comparability study may proceed as written in our study proposal.

Please let us know in case you have any additional questions.

Kind regards,

Marlene Krammer  
Manager  
International Regulatory Affairs Department

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From: Hooban, Christopher [mailto:Christopher.Hooban@fda.hhs.gov]  
Sent: Friday, May 15, 2015 7:40 AM

To: Ammons, Stanley  
Cc: Cagungun, Nannette  
Subject: STN 125587/0; Original BLA Application

Our Reference: BL 125587/0

Mr. Ammons,

Good morning. Would you please provide:

1. Clarification as to why there was almost a three year interval between completion of the final study reports for NGAM-1 and 2 and submission of the BLA to FDA.

A reviewer for this BLA requested the information by the end of the month (29 MAY) to assist in the review. Thanks for your time and please feel free to email or call me if you have any questions.

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OBRR/CBER/FDA  
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