

From: Hooban, Christopher  
Sent: Friday, May 29, 2015 10:12 AM  
To: 'stanley.ammons@octapharma.com'  
Subject: Information Request - BL 125587/0; Original BLA; Octapharma; ADD 14-APR-2016

Our Reference: BL 125587/0

Octapharma Pharmazeutika Produktionsges.m.b.H.

Dear Mr. Ammons:

We are reviewing your April 15, 2015 biologics license application (BLA) for Immune Globulin Intravenous, Human 10%. We determined that the following information is necessary to continue our review:

1. Please confirm the following interpretation made by the reviewer:
  - a. The interpretation of the last column, first row of Table 14.3.1.3 --- 38 (74.5%) 125 --- is that 38/51 (74.5%) subjects experienced a total of 125 AEs of any kind, and that based on Table 28, 89/125 (71.2%) of these events met the criteria of an Infusional AE.

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

Please submit your response to this information request as an amendment to this file by June 5, 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.

The action due date for this file is April 14, 2016.

If you have any questions, please contact me at (240) 402-8376 or christopher.hooban@fda.hhs.gov.

Chris Hooban  
Regulatory Project Manager  
OBRR/CBER/FDA  
U.S. Food & Drug Administration  
White Oak Building 71, Room 4257  
Office: (240)402-8376  
Mobile: (240)762-2266  
Email: christopher.hooban@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.