

From: Rana, Pratibha
Sent: Monday, July 23, 2012 12:39 PM
To: Ammons, Stanley
Cc: Barbara Rangetiner; Simone Meindl
Subject: STN 125416/0 Information Request

Attachments: Picture (Enhanced Metafile).html
Our Reference: STN 125416/0
Octapharma USA, Inc.

Attention: Stanley Ammons

Dear Mr. Ammons:

We are reviewing your December 22, 2011 biologics license application (BLA) for Pooled Plasma, Solvent Detergent Treated (Human). We are providing the following comments and request for additional information to continue our review:

Clinical:

"In the figure below from UNI-101, please define the 'no remark' group in each arm and explain how subjects were placed into this category and its impact on the study data as it is unclear from the submission."



Picture (Enhanced
Metafile).ht...

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 August 6, 2012 referencing the date of this request.

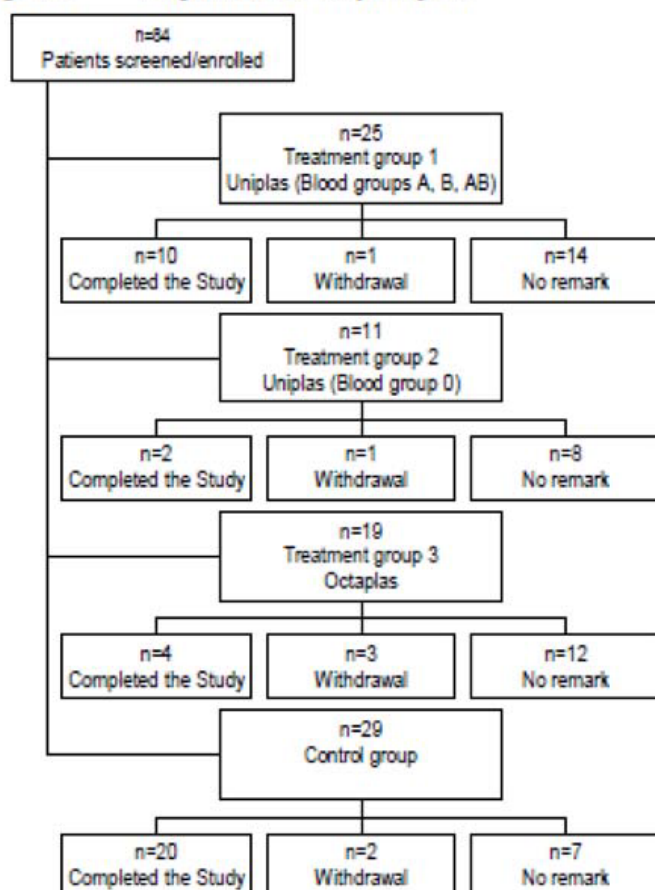
The action due date for this file is October 22, 2012.

If you have any questions, please contact me.

Sincerely,
Pratibha Rana
Pratibha Rana, M.S.
Regulatory Project Manager

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Figure 1 Disposition of Study Subjects

For further details please refer to:

- Summary tables – Patients disposition: [Section 14.1, Table 1](#)
- Summary tables – Trial termination: [Section 14.1, Tables 9.1-9.2](#)
- Individual patient data listings – Discontinued patients: [Section 16.2.1](#)

10.2 PROTOCOL DEVIATIONS

Patient No. 49, allocated to treatment arm 3 (Octaplas), received in addition to Octaplas also 2 units of Uniplas.

Patients No 68, allocated to receive Uniplas, was treated with Octaplas.

For further details please refer to:

- Summary Tables – Protocol Deviations: [Section 14.1, Table 2](#)
- Individual patient data listings – Protocol deviations: [Section 16.2.2](#)