

Information Request Email, June 27, 2012 - Octaplas

From: Rana, Pratibha
Sent: Wednesday, June 27, 2012 4:40 PM
To: Ammons, Stanley
Cc: Rangetiner, Barbara
Subject: STN 125416/0 Information Request (6-27-2012)
 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:

1. Upon further review and in consideration of the intended use of OctaplasLG® as an alternative to FFP for all its clinical indications, FDA requests that Octapharma revise the final product release specification as indicated in the following table.

Parameter	Rationale for Revision	Recommended Limit	Conformance Lot Range
Protein S	----- (b)(4) ----- -----	---(b)(4)---	----- (b)(4) ----- --
α_2 -antiplasmin (A2PI)	----- (b)(4) ----- -----	---(b)(4)---	----- (b)(4) ----- -----
Factor V	----- (b)(4) -----	---(b)(4)---	----- (b)(4) -----
Factor XI	----- (b)(4) -----	---(b)(4)---	---(b)(4)---
Fibrinogen	----- (b)(4) -----	---(b)(4)---	---(b)(4)---
Factor II (Prothrombin)	----- (b)(4) ----- -----	---(b)(4)---	----- (b)(4) ----- -----
Factor X	----- (b)(4) ----- -----	---(b)(4)---	----- (b)(4) ----- -----
Factor VII	----- (b)(4) ----- -----	---(b)(4)---	----- (b)(4) -----
ADAMTS13	----- (b)(4) -----	---(b)(4)---	----- (b)(4) -----

2. Regarding -----(b)(4)----- report titled, "____(b)(4)-----
----- (b)(4)-----, Safety, Leachables and Extractables:

- although the report presented some data on extractables and potential leachables, there was no explanation of the data as they related to potential toxicity if leached into the product
- line listings in appendix 1 are illegible

Please provide a meaningful discussion of the safety of the -----(b)(4)--- -----(b)(4)-

Please submit your response to this information request as an amendment to this file by July 18, 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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