

From: Rana, Prati bha
Sent: Friday, September 11, 2015 7:25 PM
To: 'Vicki Chen'
Subject: 125574/0 Information Request

Dear Ms. Chen:

We are reviewing your submission to your BLA for Antihemophilic Factor (Recombinant), submitted on December 16, 2014. We are providing the following comments and request for additional information to continue our review.

1. Please provide all your monitoring reports for the following sites for Leopold I study:

- * Site # 14001 (United States)
- * Site #39001 (Israel)
- * Site #65001 (Hong Kong)

2. The clinical study report (CSR) section 5.3.5.2 (12954 Addendum) under "subjects enrolled more than once" provided subject numbers with same dates of birth. You stated that all the six subjects from Leopold I study who participated in Hong Kong site have the same dates of birth as the six subjects that participated in Leopold II study site #54005 (Dr. Sun, China). Please explain if they are the same subjects and submit medical history for these subjects that made them eligible to participate in the respective studies.

3. Please provide all monitoring reports for the following sites for Leopold II study:

- * All sites in China (sites #54001, 54002, 54003, 54004, and #54005)

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 September 25, 2015 referencing the date of this request.

The action due date for this file is December 16, 2015.

If you have any questions, please contact me at Prati bha.rana@fda.hhs.gov or (240) 402-8433.

Prati bha Rana

Prati bha Rana, M.S.
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