

From: Rana, Prati bha
Sent: Monday, February 29, 2016 3:41 PM
To: 'Vicki Chen'
Subject: 125574/0 Information Request
Attachments: word-file-of-working-version-package-insert.doc

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 make the changes in the Prescribing Information according to the attached word document containing additional comments. Please accept all those changes where agreement has been reached but leave your comments where further discussion is needed. Please submit both the clean and annotated versions of the revised labeling in Word and PDF formats.
2. Please provide a brief update on the back-up off-site facility for cell banks storage, i.e., if it remains [REDACTED] or if an alternative storage location has been identified.
3. Regarding your response dated February 18, 2016 (eCTD Sequence 0046): since the updates from the two epidemiological registry studies will be provided in the form of Periodic Benefit-Risk Evaluations Reports (PBRER), please note that it is required by the statute (21 CFR section 600.80) to submit Periodic Adverse Experience Report (PAER/PSUR) quarterly for 3 years after licensure and annually thereafter. Therefore, please ensure that you request a waiver from the FDA to use the PBRER format instead of the PSUR/PAER format as long as you submit copies of all non-expedited individual case safety reports received during the last PSUR reporting interval and a narrative identifying any change to the approved label. Please also ensure that you have an obligation to report doses distributed in the US every 6 months.

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 March 4, 2016, referencing the date of this request.

The Action Due Date for this file is March 16, 2015.

Prati bha Rana

Prati bha Rana, M.S.
Regulatory Project Manager

FDA/CBER/OBRR

12_1255740 Information Request.txt

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