

26a_STN 1255740 Information Request.txt

From: Rana, Prati bha
Sent: Friday, May 22, 2015 9:43 AM
To: vicki.chen@bayer.com
Subject: STN 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 have the following request.

Sample and Reagent IR for 125574/0

1. Please provide 17 vials per lot of each of the following lots:

Drug Product Batch

Number

250 (IU)

Drug Product Batch

Number

1000 (IU)

Drug Product Batch

Number

3000 (IU)

(b) (4)

2. Please provide the most recent test results and the test date for each of the lots requested above, to the BLA.

3. For the (b) (4) assay, please provide conditioning material equivalent to 6 vials of 1000 IU PF and 3 vials of rVIII-PF-control.

4. For the Factor VIII chromogenic assay, please provide 3 vials of your internal standard

(b) (4) and 3 vials of "house positive control".

The samples and reagents should be shipped to:

Josephine Resnick

Regulatory Coordinator

Food and Drug Administration

Center for Biological Evaluation and Research

Division of Biological Standards and Quality Control

10903 New Hampshire Avenue

W075, G-717

Silver Spring, MD 20993-0002

Contact Karen Campbell at 240-402-9418 or Josephine Resnick at 240-402-7344 for questions on the shipment.

We request that these samples, reagents and documentation be sent by June 19, 2015.

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

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.
Regul atory Project Manager
email : prati bha. rana@fda. hhs. gov

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