From: Pracht, Leigh
Sent: Thursday, May 22, 2014 10:35 AM
To: Steve McGregor
Subject: RE: STN 125426 Information Request for Emergent IXINITY

Importance: High

Mr. McGregor,

I hope all issues were appropriately covered in my absence; however, I am not certain as to whether these two additional requests were forwarded to you. If they have been, please disregard; if not, please respond by May 29, 2014.

1) Reporting the square-root transformed annualized bleeding rate could be misleading, although it may be acceptable to normalize the data by transformation during the statistical analysis. Please update your study report on annualized bleeding rate based on the original scale.

2 On page 100 of the clinical study report, it is stated that "In the prophylaxis treatment group, 42 subjects (68.9%) experienced a total of 286 bleeding episodes…" However, the summary table generated by program "EF_AL_T07.sas" indicates that the total number of bleeding episodes is 303. Please correct this inconsistency.

Best regards,

Leigh A. Pracht
Regulatory Project Manager
CBER/OBRR/IOD
WO Bldg #71; Room 4210; HFM-380
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
Telephone: 240-402-8343
Leigh.Pracht@fda.hhs.gov

From: Valencia, Iliana
Sent: Friday, May 09, 2014 5:55 PM
To: Steve McGregor
Cc: Pracht, Leigh
Subject: RE: STN 125426 Information Request for Emergent IXINITY

Mr. McGregor,

Dr. Jain, Dr. Feuerstein and Myself will be available to hold a call with you on Monday, May 12 @ 3:40-4:10 pm EST.

Please confirm if the time is acceptable. We will dial to the number provided below.

Sincerely,

Iliana Valencia
301-827-6161
Iliana.valencia@fda.hhs.gov

From: Steve McGregor [mailto:smcgregor@ebsi.com]
Sent: Friday, May 09, 2014 3:00 PM
To: Valencia, Iliana
Cc: Pracht, Leigh
Subject: RE: STN 125426 Information Request for Emergent IXINITY

Good afternoon Iliana,
We are working toward addressing the items listed below for Tuesday, May 13th. However we would like to discuss the 4th item (Secondary, tertiary, or intermittent prophylaxis) with the Agency and wonder a call could be scheduled for Monday, May 12th. Please let me know if this would be possible.

I can be reached by email or phone at 204-275-4646.

Kind regards,
Steve

Steve McGregor
Director, Regulatory Affairs
Biosciences Division

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*Cangene Corporation doing business as Emergent BioSolutions.

From: Valencia, Iliana [mailto:Iliana.Valencia@fda.hhs.gov]
Sent: Friday, May 09, 2014 10:52 AM
To: Steve McGregor

Cc: Pracht, Leigh
Subject: FW: STN 125426 Information Request for Emergent IXINITY
Importance: High

Mr. McGregor,
Please see information request below. I am resending this to you because my email to Ms. Koh did not go through.

Many thanks,

Iliana Valencia
301-827-6161
Iliana.valencia@fda.hhs.gov

From: Valencia, Iliana
Sent: Friday, May 09, 2014 10:44 AM
To: 'TKoh@inspirationbio.com'
Cc: Pracht, Leigh (Leigh.Pracht@fda.hhs.gov)
Subject: STN 125426 Information Request for Emergent IXINITY

Inspiration Biopharmaceuticals, Inc.
Attention: Ms. Tung Koh
July 31, 2012
Sent by email

Dear Ms. Koh:

We are reviewing your April 5, 2012 biologics license application (BLA) for Coagulation Factor IX (Recombinant). We are requesting the following information in order to continue our review:

1. Amendment 125426/0 Sequence e0024 contains a supplemental clinical study report of seven subjects treated with modified IB1001, with data cut-off date of 2014-02-28. Please update the supplemental clinical study report submitted in Sequence e0024 to include data from as many subjects as possible, and submit as an amendment to the BLA.

2. The proposed prescribing information submitted under 125426/0 Sequence e0019 does not contain any information about modified IB1001. Please update the prescribing information to include data from the clinical study of modified IB1001 and submit as part of the amendment to the BLA.

3. Please revise the package insert, where appropriate, to include data from pre- and post-modification versions of IB1001 and specify the source of data and/or version of product, e.g., (1) testing of IB1001 before modification, (2) comparability testing, (3) testing of IB1001 after modification, or other source.

4. Please remove the indication “Secondary, tertiary, or intermittent prophylaxis to reduce the frequency of bleeding episodes in adults and children ≥ 12 years of age with

hemophilia B (1).” Please remove any reference to this indication from the rest of the prescribing information.

Please submit your responses to this information request as amendments to this file by May 13, 2014 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is July 29, 2014.

Iliana on behalf of Leigh Pracht

Iliana Valencia, MS
Chief, Regulatory Project Management Branch
CBER/OBRR/IOD
301-827-6161
iliana.valencia@fda.hhs.gov