Valencia, Iliana

From: Valencia, Iliana
Sent: Friday, May 09, 2014 10:52 AM
To: 'smcgregor@ebsi.com'
Cc: Pracht, Leigh (Leigh.Pracht@fda.hhs.gov)
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
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301-827-6161
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