From: Steve McGregor <smcgregor@ebsi.com>
Sent: Monday, June 16, 2014 5:54 PM
To: Cagungun, Nannette
Cc: Feuerstein, Irwin
Subject: RE: Request for proposed and ongoing pediatric studies- Coagulation Factor IX (Recombinant)
Attachments: emfalert.txt

Dear Ms. Cagungun,

I am emailing to request an extension to the 10am EST deadline listed below for this amendment on proposed and ongoing pediatric studies, such that we are allowed until the close of business on June 17th to provide our response. This extension is needed to allow time to consider the first point listed below (denial of request for partial waiver of studies in subjects aged 0-27 days) prior to providing our responses to the items summarized under item #2.

I can be reached at 204-275-4646 should you wish to discuss this request for an extension.

Kind regards.

Steve M.

Steve McGregor
Director, Regulatory Affairs
Biosciences Division

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From: Cagungun, Nannette [mailto:Nannette.Cagungun@fda.hhs.gov]
Sent: Monday, June 16, 2014 4:50 PM
To: Steve McGregor
Cc: Feuerstein, Irwin
Subject: Request for proposed and ongoing pediatric studies- Coagulation Factor IX (Recombinant)
Importance: High

Our Reference: BL 125426/0

Dear Mr. McGregor,

We are reviewing your biologics license application (BLA) for Coagulation Factor IX

(Recombinant) and are providing the follow comments:

1. FDA has decided to deny your request for partial waiver of studies in subjects aged 0 - 27 days. Hemophilia B exists in patients in the 0 - 27 day age group, can be diagnosed, and can have clinical manifestations such as excess bleeding during surgery or trauma in the neonatal period. Please include in your studies subjects aged 0 - 27 days, where possible.

2. We reference our teleconference of 2014-06-04 where FDA requested, and Emergent agreed to submit, timelines for proposed and ongoing pediatric studies. We have not received these materials. Please submit the following:

a. Plan to request deferral of pediatric studies;
b. Summary table of planned clinical studies;
c. Timeline of the pediatric development plan.

Please submit these three items as an amendment to the file by 10:00 am tomorrow, June 17, 2014.

Please do not hesitate to contact me if you have any questions.

Sincerely,

Nannette Cagungun, MS, PD, RAC
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