

Information Request Email, May 13, 2013 - ALPROLIX

From: Thompson, Edward

Sent: Monday, May 13, 2013 11:01 AM

To: 'Nadine D. Cohen PhD (nadine.cohen@biogenidec.com)'

Cc: 'Dan Soroko'; Kirschbaum, Nancy (Nancy.Kirschbaum@fda.hhs.gov)

Subject: Information Request for BL 125444/0

Contacts: Nadine D. Cohen PhD

Dear Dr. Cohen:

We are reviewing your December 28, 2012 biologics license application (BLA) for Coagulation Factor IX (Recombinant), Fc Fusion Protein. We determined that the following information is necessary to continue our review:

For each analytical procedure used to control drug substance or drug product quality, please provide the following information in a table.

Attribute	Test	SOP Number and Title	Validation Report Number and Title
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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 May 27, 2013 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 December 28, 2013.

If you have any questions, please contact me at (301) 827-9167.

Sincerely,

Edward Thompson
Regulatory Project Manager
FDA/CBER/OBRR/DBA/RPMB

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