

Tilghman, Tracy

From: Tilghman, Tracy
Sent: Thursday, August 09, 2012 1:49 PM
To: 'tkoh@inspirationbio.com'
Cc: Pracht, Leigh
Subject: Reference BL# 125246

Importance: High

Our Reference: BL 125426/0

Inspiration Biopharmaceuticals, Inc.
Attention: Ms. Tung Koh
August 9, 2012
Sent by email

Dear Ms. Koh:

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

1. Please submit your Pharmacovigilance/Risk Management Plan in ICH format by August 30, 2012.

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 responses to this information request (Attn: Leigh Pracht) by August 30, 2012 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 February 4, 2013.

If you have any questions, please contact me at (301) 827-9427 or Leigh Pracht (301) 827-6116.

Sincerely,

Tracy Tilghman, MPH

Lieutenant, United States Public Health Service
Regulatory Project Manager
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