From: Pracht, Leigh
Sent: Wednesday, August 08, 2012 10:05 AM
To: Tung Koh
Subject: RE: Information request re: STN 125426/0

Hello Tung,

I checked with some of my IT consultants and found that the data must be in xpt format. There are several reasons, the most important being that, as all the prior data was presented in xpt, in order for the data to be joined together in our analysis system, this too must be xpt.

Thanks,

Leigh

From: Tung Koh [mailto:TKoh@inspirationbio.com]
Sent: Tuesday, August 07, 2012 6:14 PM
To: Pracht, Leigh
Subject: RE: Information request re: STN 125426/0

Dear Leigh,

One quick question regarding the information request below. Instead of .xpt table, can we provide the requested data in Excel worksheet?

Thank you.

Best regards,

Tung

Tung Koh

Sr. Director, Regulatory Affairs

Inspiration Biopharmaceuticals, Inc.

Corporate - One Kendall Square

Building 1400 East

Cambridge. MA 02139

Email: tkoh@inspirationbio.com

Tel: +1 (949) 394-8815

eFax: +1 (800) 524-1901

From: Pracht, Leigh [mailto:Leigh.Pracht@fda.hhs.gov]
Sent: Tuesday, July 31, 2012 6:57 AM
To: Tung Koh
Subject: Information request re: STN 125426/0

Our Reference: BL 125426/0

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:

Please provide an .xpt table with the following data fields for every Anti-CHO titer collected in every patient:

- Date collected
- Date analyzed
- Titer
- Normal/abnormal
- Assay used

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 as amendments to this file by August 14, 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) 827-6116.

Sincerely,

Leigh A. Pracht
Regulatory Project Manager

FDA/CBER/OBRR/DBA

WOC1; RM562N; HFM-380
1401 Rockville Pike
Rockville, MD 20852
Telephone: 301-827-6116

Fax: 301- 827-2857

Leigh.Pracht@fda.hhs.gov