

Information Request Email - GLASSIA, November 3, 2009

Sent: Tuesday, November 03, 2009 1:19 PM

To: '----(b)(4)----'

Subject: RE: Kamada STN 125325/0 - Information Request Hello -(b)(4)-

Response to Question 1: Since the PK questions are directly related to the PK data, It is best for FDA to discuss the information within the meeting. After checking FDA participants schedules, we would like to hold the meeting either on Wednesday, Nov 4 at 10:00 am eastern time or on Friday, Nov 6 at either 9:30 or 10:00 am, please confirm today, which of these days is better for Kamada participants to hold the meeting.

Response to Question 2: Kamada may provide a response as to when the conformance lots would be provided to FDA, but FDA requests the lots be provided as soon as possible to facilitate the review of the BLA submission.

Thanks
Cherie

From: ---(b)(4)---- [mailto:------(b)(4)-----]
Sent: Tuesday, November 03, 2009 8:19 AM
To: Ward- Peralta, Cherie
Subject: RE: Kamada STN 125325/0 - Information Request
Importance: High

Hi Cherie,

1. Will it be possible for the Agency to provide the PK questions in advance of the discussions with Kamada? (Kamada is checking with one last participant regarding scheduling).
2. In your October 23 fax, a response was requested by November 9, unless stated otherwise (see attached for a copy of the fax). Can I clarify whether the lot release samples need to be received by FDA by November 9 or is providing a defined delivery date for the samples by November 9 acceptable? A prompt response regarding this matter would be greatly appreciated.

-(b)(4)-

From: Ward- Peralta, Cherie [mailto:Cherie.Ward-Peralta@fda.hhs.gov]
Sent: Thursday, October 29, 2009 4:18 PM
To: ----(b)(4)---
Subject: Kamada STN 125325/0 - Information Request

Hello -(b)(4)-

Last week, I sent you an information request requesting for the submission of conformance lots to the Product Release Branch, could you please include the following sample of lots -----(b)(4)----- (3 samples per lot) within the submission to the Product Release Branch and include a reference to BLA submission number.

Also, FDA would like to schedule a telecon with the PK specialist from Kamada to discuss the PK information provided in the submission. Could you provide me the best time for Kamada to hold this meeting with our reviewers, and conference call in number?

If you have any questions, please contact me.

Thanks

Cherie Ward-Peralta
Regulatory Project Manager
HFM-380 FDA/CBER
Office of Blood Research and Review
Division of Blood Applications
301-827-9170 fax 301-827-2857
Email: cherie.ward-peralta@fda.hhs.gov

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