

Content of Amendment Discussed During Inspection Email - GLASSIA, February 23, 2010

From: Marszal, Ewa
Sent: Tuesday, February 23, 2010 9:30 AM
To: 'Dudu Nakar'; Ruth Wolfson
Cc: ----(b)(4)---; Doleski, Joseph (David); Ward- Peralta, Cherie
Subject: RE: Content of Amendment discussed during inspection

Dear Ruth and David,

I apologize for a delayed response. I have not had yet a chance to review my inspection notes; nevertheless, the list that you provided appears to cover most of the issues that still need to be looked at. We will let you know if we need anything else.

One thing that I do remember that is not included is safety information for the in-line filter needle. I think you planned to ask the manufacturer to send the information directly to us. Additional question that I have is about -(b)(4)----- . Does -----(b)(4)-

-----? If not, we will need information on extractables/leachables.

Please consolidate the response as much as possible, e.g., please provide items 1, 2, and 3 in one amendment.

Best wishes,

Ewa

From: Dudu Nakar [mailto:dudun@kamada.com]
Sent: Thursday, February 18, 2010 9:23 AM
To: Marszal, Ewa
Cc: Ruth Wolfson; ---(b)(4)----
Subject: FW: Content of Amendment discussed during inspection

Dear Ewa,

Thanks again for the valuable discussions during the inspection.

We would appreciate your input on the content of the upcoming amendment(s) we intend to submit as soon as possible covering the outstanding subjects discussed during the inspection as listed below.

We would like to send you the information as soon as it is available, thus the above information might be submitted in more than one submission.

These will include:

1) Validation of the -----(b)(4)----- step:

a. Validation protocol & report

b. Commitment to -----(b)(4)-----

2) --(b)(4)-- in lot size (----(b)(4)----):

- a. Uniformity of filling for -(b)(4)-
- b. Filter sterilization validation for -(b)(4)- volume
- c. Risk Assessment for the change
- d. Current long term stability data for the Drug Product and commitment to provide updated data in the BLA AR
- e. The updated chapters 3.2.P.3.2, 3.2.P.3.5 and 3.2.P.8 will be submitted with relevant information/data

3) Update final process parameter list (revised Q43) based on the agreements reached during the inspection.

a. -----(b)(4)-----

b. -----(b)(4)-----

c. -----(b)(4)-----

d. -----(b)(4)-----

4) Justification of -(b)(4)- potency

5) -----(b)(4)-----

6) Updated sections of the SOP for Out of Specification, as requested.

Looking forward hearing from you.

Kind Regards,

Ruthy and David

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