

Marszal, Ewa

From: Marszal, Ewa
Sent: Tuesday, May 11, 2010 12:38 PM
To: 'Ruth Wolfson'; Ward- Peralta, Cherie
Cc: (b)(4) Dudu Nakar; Scott, Dorothy; Pierce, Leland Ross
Subject: RE: URGENT Clarification being requested for the Fax of May 3rd, 2010

Dear Ruthy,

Regarding Item #9:

Thank you for the clarification. Our understanding was that 5-micron needle was used in-line during product administration. Since this is not the case, please clarify in the PI that the supplied filter needle should be used during product pooling. Also, since 5-micron needle appears to reduce the number of visible particles but does not eliminate their presence and the particles appear to reform after product passage through the needle, please recommend additional in-line filtration of the product through a 5-micron in-line filter (not supplied) during product administration. Please update the PI accordingly.

Regarding Item #7:

All licensed A1PI products are recommended to be infused within 3 hours after the vials are entered. In the case of the lyophilized products this time corresponds to 3 hours after reconstitution. A requirement that the products are administered within 3 hours of reconstitution is on the packaging of the lyophilized products. Limited storage time limits bacterial growth in case of contamination. We intend to implement this requirement for all liquid A1PI products as well in the absence of compelling data indicating that longer times were safe.

Best regards,

Ewa

From: Ruth Wolfson [mailto:RuthW@kamada.com]
Sent: Saturday, May 08, 2010 3:49 PM
To: Marszal, Ewa; Ward- Peralta, Cherie
Cc: (b)(4) Dudu Nakar; Scott, Dorothy
Subject: URGENT Clarification being requested for the Fax of May 3rd, 2010
Importance: High

Dear Ewa,

Kamada would appreciate receiving your clarifications for two of the items raised in the Agency's Fax of May 3rd, 2010:

- Item 9 - Kamada would appreciate if the Agency would clarify item # 9 since there was no use of an infusion set with an in-filter during the Phase II/III clinical study. Instead, we used a sterile 5 micron filter needle that was used to transfer the product from the syringe into the infusion bag, where the required ml of product were pooled. In other words, the product was filtered, each 50 ml vial with a new sterile filter needle, when transferred into and pooled in the empty IV bag prior to the infusion to the patient.
- Item 7 - Please clarify why does the Agency require that the "product brought to room temperature will be administrated within three hours of entering the vials".

If needed you can call me any time to my cellular phone at +972-52-4283223, or send me a mail and I will call you as soon as possible.

5/12/2010

Kind regards,
Ruthy