



Patricia Maynard  
02/28/2002 02:41 PM

To: Joan Korol/HC-SC/GC/CA@HWC

cc:

Subject: Re: Synergy

well, sounds like he has taken this over.....  
Joan Korol



Joan Korol  
2002/02/28 02:02 PM

To: Patricia Maynard/HC-SC/GC/CA@HWC

cc:

Subject: Synergy

FYI

----- Forwarded by Joan Korol/HC-SC/GC/CA on 02/28/2002 02:01 PM -----



Jean Saint Pierre  
02/28/2002 12:01 PM

To: Siddika Mithani/HC-SC/GC/CA@HWC

cc: Philip Waddington/HC-SC/GC/CA@HWC, France Dansereau/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC

Subject: Synergy

20(1)(b)(c)

Siddika, thanks for forwarding the 6 page fax, which included:

4. Letter from Dr. Peterson to Dr. Mitchell, dated Feb 8 2002, stating that "future correspondence will be addressed to him"

(this letter refers to a letter dated January 28, 2002, or is it January 15?)

Based on the above, we have no documented evidence that the following was performed: an assessment of subjects , a transfer to appropriate professional/s who can place them on standard therapy, a notification of termination of the trial to subjects" and most importantly, that the clinical trial is stopped. Do you have additional information to confirm that this is the case?

If there is no evidence, the Inspectorate will initiate an investigation to verify the clinical trial is stopped.

I am looking forward to your reply.

Merci, Jean

000220



Health Canada  
Santé Canada

**Health Products and Food Branch Inspectorate**  
**Inspectorat de la Direction générale des produits de santé et des aliments**

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**Fax / Télécopie**

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**Date :** 2002-03-04

**From / De :** Jean Saint-Pierre

**Tel:** (613) 952-8173      **Fax:** (613) 952-9805  
**E-mail / Courriel:** jean\_saint\_pierre@hc-sc.gc.ca

**To / À :** Dennis Shelley

**Fax :** (604) 666-1398  
**Tel.:** (604) 666-3704

Number of page(s) / Nombre de page(s): 4, including this page

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**Subject / Sujet: Synergy**

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**Hello Dennis;      Attached are two letters:**

20 (1)(b)(e)

2. Letter (1 page, Ref. 02-100001-37) from Dr. Peterson to Dr. Ian Mitchell (REB) dated Jan 4, 2002, stating to #1 terminate the trial and #2 "ensure that these subjects are assessed and their care is transferred to an appropriate professional who can place them on standard therapy".


Action suggested is to obtain evidence that #1 and #2 have been complied with, from Dr. Kaplan.

Please let me know the outcome.

Regards, Jean

000221

To: France Dansereau/HC-SC/GC/CA@HWC  
cc: Jean Saint Pierre/HC-SC/GC/CA@HWC, Brian Gillespie/HC-SC/GC/CA@HWC, Philip Waddington/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC

Subject: Re: Synergy 


France,  
In response to your suggestion, I would imagine that it would be more appropriate to contact Dr. Kaplan rather than the Chair of the REB. Based on Division 5 of the Regulations, we have no jurisdiction or authority over the REB. Our authority extends only to the sponsor. The REB would not be responsible (as per our regulations) to ensure that the trial has stopped. I suggest that you contact Dr. Kaplan (the sponsor of the trial, as well as the principal investigator) to confirm that the trials have stopped. For your consideration,  
Siddika

France Dansereau



France Dansereau  
03/01/2002 08:46 AM

To: Siddika Mithani/HC-SC/GC/CA@HWC  
cc: Jean Saint Pierre/HC-SC/GC/CA@HWC, Brian Gillespie/HC-SC/GC/CA@HWC, Philip Waddington/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC

Subject: Re: Synergy 

Siddika

Thank you very much for your comments. I personally was not aware that it was the same person who informed us about EVA.  
Would you be more at ease if, instead of initiating an investigation, we just called the REB chair, as a follow up to his letter, to confirm that the clinical trial has stopped. That could be said in a diplomatic terms so not to upset anyone and from our part it would permit us to close this case.


Again, thank you very much for your cooperation.

Siddika Mithani



Siddika Mithani  
2002-02-28 10:02 PM

To: Jean Saint Pierre/HC-SC/GC/CA@HWC  
cc: Brian Gillespie/HC-SC/GC/CA@HWC, Philip Waddington/HC-SC/GC/CA@HWC, France Dansereau/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC

Subject: Re: Synergy 

Jean,  
I am concerned that you are asking for documented evidence regarding the termination of this clinical trial. This is a credible university centre, where the REB structure and composition exceeds beyond the regulatory requirements. The fact that a commitment has been made by the REB Chair that he will follow up with the investigator, there is no reason to doubt that appropriate steps have not been taken to ensure that the trial has been stopped. I would also like to point out that this was the same REB that wrote to us

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with regards to the Elk Velvet Antler proposal which they decided to put on hold based on their experience with the Synergy compound. The REB has been diligent in following our regulations and ensuring compliance with the regulatory requirements.

In my opinion, an investigation at this time for the purpose of "verifying that the clinical trial has stopped" is unnecessary - in fact it would be detrimental. NHPD and TPD have worked extremely hard to ensure that regulatory requirements are respected. We do have an ongoing dialogue with the sponsor to explore ways in which the issues identified during the review can be resolved.

If however, you are intending to investigate other aspects of Synergy and EM Power+ , I would not be in a position to comment.

For your consideration,

Siddika

Jean Saint Pierre



Jean Saint Pierre  
02/28/2002 12:01 PM

To: Siddika Mithani/HC-SC/GC/CA@HWC  
cc: Philip Waddington/HC-SC/GC/CA@HWC, France Dansereau/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC

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I am looking forward to your reply.

Merci, Jean

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