

----- Forwarded by Jean Saint Pierre/HC-SC/GC/CA on 2002-06-07 12:00 -----



Jean Saint Pierre  
2002-03-14 10:37

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

cc: patricia\_maynard@hc-sc.gc.ca, Tony Halisky/HC-SC/GC/CA@HWC, Nada El-Defrawy/HC-SC/GC/CA@HWC, Bruce Wozny/HC-SC/GC/CA@HWC, Diane E. Brunet/HC-SC/GC/CA@HWC, Catherine Yen/HC-SC/GC/CA@HWC, France Dansereau/HC-SC/GC/CA@HWC

Subject: Re: SYNERGY Re: vitamins cure for ADD, ADHD, bi-polar disorder, etc. 

Joan;

You are correct: "I understand Jean Saint-Pierre is working with you (Dennis and Rod ) regarding this part" ( confirmation that Dr. Kaplan has stopped the 2 clinical trials related to this. Dennis is proceeding on this action and a response is expeted by end of this week.

All we want is evidence from Dr. Kaplan, who is acting as Sponsor/Qualified Investigator, that she is complying with Dr. Peterson's request to stop, in an appropriate manner, the 2 trials with that product. In essence, she has not received authorization to proceed with clinical trials, per Div. 5.

As far as importation of the product, for personal use, I will leave this with you, as it has no link to Clinical trials, as far as I know. Should it have, please let me know.

Merci, Jean

Joan Korol



Joan Korol  
03/14/2002 10:15 AM

To: Jean Saint Pierre/HC-SC/GC/CA@HWC  
cc:

Subject: SYNERGY Re: vitamins cure for ADD, ADHD, bi-polar disorder, etc.

FYI

----- Forwarded by Joan Korol/HC-SC/GC/CA on 03/14/2002 10:14 AM -----



Joan Korol  
03/14/2002 09:00 AM

To: Dennis Shelley/HC-SC/GC/CA@HWC  
cc: Rod Neske/HC-SC/GC/CA@HWC

Subject: SYNERGY Re: vitamins cure for ADD, ADHD, bi-polar disorder, etc.

Jean Saint Pierre 03/15/2002 09:04 AM

To: Dennis Shelley/HC-SC/GC/CA@HWC  
cc: Robert Peterson/HC-SC/GC/CA@HWC, Jean Lambert/HC-SC/GC/CA@HWC, Daniele Dionne/HC-SC/GC/CA@HWC, France Dansereau/HC-SC/GC/CA@HWC, Patricia Maynard/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC, Siddika Mithani/HC-SC/GC/CA@HWC

Subject: Synergy / EMPower+ - Dr Kaplan - Re: clinical trials stopped

Dennis, thank you for following up in obtaining confirmation that the unauthorized clinical trial, initiated by Dr. Kaplan, is, according to her statement below, stopped.

I suggest that this incident, opened in the Incident System, be closed.

Merci, Jean

DENNIS SHELLEY

**DENNIS SHELLEY**

03/14/2002 07:01 PM

To: Jean Saint Pierre/HC-SC/GC/CA@HWC  
cc: Rod Neske/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC, Miles Brosseau/HC-SC/GC/CA@HWC

Subject: clinical trials are on hold

I was able to with Dr Kaplan by phone today. She advised that she will be out of her office from tomorrow thru April 1st. I discussed the matter of a reply to the two letters From TPD that were shared with us (a tad later than we would have wished). In discussion with you I understood the issue was to be able to close the file of the CT issue within the larger issue of compliance and enforcement. Therefore I suggest to Dr. Kaplan that she send me an e-mail. She readily agreed to do this as a means of closure. Hence the enote below. She does make it clear that she is no longer engaged in any clinical trial of EM Power +.

Please share this with whomever you feel needs to know. Thanks. Unless otherwise advise I will not pursue further correspondence on this matter.

----- Forwarded by Dennis Shelley/HC-SC/GC/CA on 2002/03/14 15:54 -----



"Bonnie Kaplan" <Bonnie.Kaplan@calgaryhealthregion.ca> on 2002/03/14 15:51:05

To: Dennis Shelley/HC-SC/GC/CA@HWC  
cc:

Subject: clinical trials are on hold

---

Dear Mr. Shelley,  
Thank you for checking today about our response to Dr. Peterson's December 20 letter and the followup communication in January with Dr. Mitchell (Office of Medical Bioethics).

In response to Dr. Peterson's request, we stopped all clinical trial work with E.M.Power+. Each psychiatrist received information about his/her patient, and appropriate care changes were made. Copies of each letter, specifying the patients by name, reside in the Office of Medical Bioethics. We will not restart our clinical trial until Health Canada

000239

gives us permission

Bonnie Kaplan

--  
Bonnie J. Kaplan, PhD  
Professor, Dept of Pediatrics  
Univ of Calgary, Alberta Children's Hospital  
Phone: 403-229-7365 FAX: 403-543-9100

20 (1) (b) (c)

----- Forwarded by Jean Saint Pierre/HC-SC/GC/CA on 2002-06-07 12:00 -----



Jean Saint Pierre  
2002-03-15 09:12

To: Marie LaSalle@HWC, Solange Rivard/HC-SC/GC/CA@HWC, Francisco  
Fernandes/HC-SC/GC/CA@HWC, Randy Stephanchew/HC-SC/GC/CA@HWC  
cc:

Subject: Synergy / EMPower+ - Dr Kaplan - Re: clinical trials stopped

WOW! It must be Friday! This, below is good news. A confirmation that the unauthorized trial is finally stopped. I will spare you the zillions other docs on that file.

But, and there is always a "but", the file is not quite close. Some people involved in this are apparently importing this product under the personal importation directive. So you may hear of Customs alerts to stop importing this product. However, no clinical trials are involved there.

Jean

----- Forwarded by Jean Saint Pierre/HC-SC/GC/CA on 03/15/2002 09:05 AM -----



Jean Saint Pierre  
03/15/2002 09:04 AM

To: Dennis Shelley/HC-SC/GC/CA@HWC  
cc: Robert Peterson/HC-SC/GC/CA@HWC, Jean Lambert/HC-SC/GC/CA@HWC, Daniele  
Dionne/HC-SC/GC/CA@HWC, France Dansereau/HC-SC/GC/CA@HWC, Patricia  
Maynard/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC, Siddika  
Mithani/HC-SC/GC/CA@HWC

Subject: Synergy / EMPower+ - Dr Kaplan - Re: clinical trials stopped

Dennis, thank you for following up in obtaining confirmation that the unauthorized clinical trial, initiated by Dr. Kaplan, is, according to her statement below, stopped.

I suggest that this incident, opened in the Incident System, be closed.

Merci, Jean

000240