

Chris Turner
2001-05-07 06:07 PM

To: Siddika Mithani@HWC
cc:

Subject: Re: Synergy Group of Canada

Can I forward this sting to Dr. Phil Waddington to highlight the problems or do you prefer I just talk to him?
Please advise. Thanks!

----- Forwarded by Chris Turner/HC-SC/GC/CA on 05/07/2001 06:06 PM -----




Siddika Mithani



05/07/2001 02:42

To: Joan Korol@HWC
cc: Micheline Ho@HWC, Chris Turner/HC-SC/GC/CA@HWC, Patricia Maynard@HWC

Subject: Re: Synergy Group of Canada 

Sm


Joan Korol on 05/07/2001 02:37:36 PM

Joan Korol on 05/07/2001 02:37:36 PM



20 (1)(c)

To: Siddika Mithani@HWC
cc: Micheline Ho@HWC, Chris Turner/HC-SC/GC/CA@HWC, Patricia Maynard@HWC

Subject: Re: Synergy Group of Canada 

Thank you for providing this summary , Siddika,
Just one more question: regarding your last point ... could you elaborate or

you elaborate?

Can

Siddika Mithani




Siddika Mithani



2001/05/07 02:06

To: Joan Korol@HWC
cc: Micheline Ho@HWC, Chris Turner/HC-SC/GC/CA@HWC

Subject: Re: Synergy Group of Canada 

Joan,
As per my earlier conversation, I would like to clarify a few things.

000155

1) I have spoken to Bonnie Kaplan - she has called me to talk about IND submissions. She indicated that prior to initiating the trial, her group had spoken to ONHP (I believe in 1999/2000) where she was advised that clinical trials were not required for natural health products.

2) When she spoke to me, she said that this was a natural health product - therefore I suggested that she contact Phil Waddington's group.

3) When we discussed the possibility of filing an IND submission, I outlined all the requirements, and the elements that we review in terms of proposed clinical trials - which would include preclinical pharmacology/toxicology, pharmacokinetics etc. Based on our discussion, clearly, the product would not meet our requirements -

4) I indicated that our Bureau could not set different standards for natural health products and clinical trials. Clearly, the requirements for clinical trials for natural health products must be clarified at a higher level. A decision needs to be made as to whether these products and drugs are to be assessed by the same criteria and requirements. We also need to identify who is going to review and evaluate these clinical trials, in view of the fact that a Directorate has been created for Natural Health Products.

5) I indicated to Bonnie Kaplan that I don't have a problem in reviewing her IND submission - however,

I hope this information is useful.

20 (1) (c)

Siddika

Joan Korol on 05/07/2001 01:43:26 PM

Joan Korol on 05/07/2001 01:43:26 PM



To: Siddika Mithani@HWC
cc:

Subject: Synergy Group of Canada

Siddika, This is the e-mail received from Dennis.

I will e-mail him back confirming that you have not written to Bonnie Kaplan stating that "BPA was not responsible for monitoring this product" as was discussed by telephone earlier this morning.

You've mentioned that you spoke often to Bonnie Kaplan. Was an IND requested? If so was one provided for review?

Did you say that an IND would not have been approved?. If so, what was this based on?

----- Forwarded by Joan Korol on 2001/05/07 01:29 PM -----

 Dennis Shelley
2001/05/07 02:21 AM

To: Joan Korol
cc: Rod Neske, Miles Brosseau

Subject: Synergy Group of Canada

Last week I received 3 or 4 telephone calls from Mr. Tony Stephan of this company. They began following the receipt (I presume) to the warning letters that were signed off by Miles.

000156

for synergy



Joan Korol on 2001/05/09 08:22:47

To: Dennis Shelley/HC-SC/GC/CA@HWC
cc: Rod Neske/HC-SC/GC/CA@HWC, Miles Brosseau/HC-SC/GC/CA@HWC, Patricia Maynard@HWC, Daniele Dionne@HWC, Siddika Mithani@HWC

Subject: Re: Synergy Group of Canada

This is an update to your e-mail of May 7

We will be attempting to have a teleconference this afternoon . Details to follow

In addition to the information below, Siddika indicated that Bonnie Kaplan and Siddika had many conversations on the subject of the clinical study requirements. Bonnie Kaplan wrote to Siddika summarizing her understanding of the issue, Siddika did not agree to the content of Bonnie's letter (Bonnie's understanding of what was discussed), phoned Bonnie to tell her so but has not responded in writing. Siddika has discarded the letter from Bonnie.

Siddika Mithani 2001/05/07 02:42

To: Joan Korol@HWC
cc: Micheline Ho@HWC, Chris Turner/HC-SC/GC/CA@HWC, Patricia Maynard@HWC

Subject: Re: Synergy Group of Canada

Sm

Joan Korol on 05/07/2001 02:37:36 PM



Joan Korol on 05/07/2001 02:37:36 PM

To: Siddika Mithani@HWC
cc: Micheline Ho@HWC, Chris Turner/HC-SC/GC/CA@HWC, Patricia Maynard@HWC

20(1)(c)

Subject: Re: Synergy Group of Canada

Thank you for providing this summary , Siddika,
Just one more question: regarding your last point ... could you elaborate on

you elaborate?

Can

000161



Joan Korol on 05/17/2001 03:20:53 PM

To: Siddika Mithani@HWC
cc: Patricia Maynard@HWC

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN

Thank you Siddika,
I will insert this into the reply . Our Legal Counsel will review the whole letter before it goes out.
...joan
Siddika Mithani

Siddika Mithani 2001/05/17 03:15

To: Joan Korol@HWC
cc:

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN

For your consideration:

While Dr. Mithani acknowledged the fact there is currently no regulatory framework for the review and evaluation of clinical trials with natural health products, she also discussed with you the information that would be required to be submitted for an Investigational New Drug Submission. Clearly, based on your discussions with her regarding the current requirements for IND submissions, this type of data was not available.

I hope this is useful.

Joan Korol on 05/17/2001 10:10:53 AM

Joan Korol on 05/17/2001 10:10:53 AM



To: Siddika Mithani@HWC
cc: Philip Waddington@HWC, Chris Turner/HC-SC/GC/CA@HWC, David Clapin@HWC, Patricia Maynard@HWC

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN

That's fine . Just put that in the wording you would like to see iin the letter.
Thx
...joan
Siddika Mithani

Siddika Mithani 2001/05/17 09:38

To: Joan Korol@HWC
cc: Philip Waddington@HWC, Chris Turner/HC-SC/GC/CA@HWC, David Clapin@HWC, Patricia Maynard@HWC

000197

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN 

Joan,

I am at a loss to respond to Dr. Kaplan's letter. My conversation with her was based on the fact that I would be happy to review her submission, although, upon further questioning, she did not have the data that would be required for the IND submission.

Siddika

Joan Korol on 05/17/2001 09:32:14 AM

Joan Korol on 05/17/2001 09:32:14 AM



To: Siddika Mithani@HWC, Philip Waddington@HWC
cc: Chris Turner/HC-SC/GC/CA@HWC, David Clapin@HWC, Patricia Maynard@HWC

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN

Please provide your para that can be inserted as a response to address the reference to you in the letter form B. Kaplan's lawyer. We are meeting to discuss this letter tomorrow,

..joan

----- Forwarded by Joan Korol on 2001/05/17 09:26 AM -----

Joan Korol on 2001/05/11 10:58:29 AM



To: Siddika Mithani@HWC, Sharon Chard/HC-SC/GC/CA@HWC, Philip Waddington@HWC
cc: Chris Turner/HC-SC/GC/CA@HWC, David Clapin@HWC, Patricia Maynard@HWC, Daniele Dionne@HWC

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN

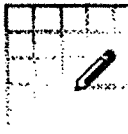
Attached for your review and response is a copy of the correspondence dated May 8, 2001 from Legal Counsel representing Bonnie Kaplan.

Please provide your response to the third / fourth paragraph as applicable, by May 16, 2001. I will collate the responses and the draft letter will be reviewed by our Legal Counsel prior to responding to Lynn Mc Rae Legal Counsel for Bonnie Kaplan,



LegalResponseforKa

The following has been collated for your information :



Dennis Shelley
2001/05/07 02:21 AM

000198



Joan Korol on 2001/05/18 08:10:42 AM

To: Patricia Maynard@HWC
cc:

Subject: re: Synergy Group & research (Bi-polar disorders)

Can we discuss?
Sharon Chard



Sharon Chard
2001/05/17 07:20 PM

To: Joan Korol@HWC
cc: Philip Waddington, Heather Throop@HWC, Peter Chan@HWC, Sharon Chard/HC-SC/GC/CA@HWC

Subject: re: Synergy Group & research (Bi-polar disorders)

Although I haven't been able to complete my search of all the records I have gone from the start of the transition Team in 1999 -until May, 2000 and can find no evidence that I spoke with Dr. Kaplan. I had a telephone conversation with Tony Stephen who briefed me as in the e:mail below and wanted to find out how to go about getting access to the research funding (\$3 million over 3 years). It was my understanding that he was setting up a research consortium and wanted to apply for the research funding. At the time I spoke with him and the subsequent call the only item from perspective that had research on the agenda was the Research Conference scheduled for Novemeber 1999 in Halifax to determine the priorities. I was and still am fully aware of the F&D Act, Interim DIN Enforcement procedures and the lack of a NHP regulatory framework and do not believe I would have sent a letter or made the statements attributable to me. Certainly I would never have indicated I was the Director of TPP since at that time I was RD of HPB Atlantic Region and the chair of the Natural Health Products Transition Team. As stated previously I have not had an opportunity to go through my records but my staff tell me I am above-all consistent so

Sharon

----- Forwarded by Sharon Chard/HC-SC/GC/CA on 05/17/2001 08:10 PM -----



Sharon Chard
05/17/2001 04:41 PM

To: Sharon Chard/HC-SC/GC/CA@HWC
cc:

Subject: re: Synergy Group & research (Bi-polar disorders)

For me.

Sharon

----- Forwarded by Sharon Chard/HC-SC/GC/CA on 05/17/2001 04:42 PM -----



on 09/22/99 01:34:28 PM

19(1)

To: Sharon Chard

000200

cc:

Subject: re: Synergy Group & research (Bi-polar disorders)

Sharon,

I understand you've spoken with Tony Stephen on this. They now have 4 universities involved, and I will be receiving an 'Executive Summary' in the near future.

Can you find out from Dr Losos who in the HPB (hopefully excluding the TPP), he would like to have as a contact point to be kept abreast of the ongoing research and results?

I'm trying to build as many bridges as I can, and Tony & David (Synergy Group) have agreed to provide info, data and updates on their project to Dr Losos' contact point so that Health Canada will be (confidentially, of course) apprised and updated.

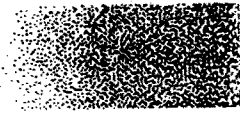
Hopefully, we can head off most of the possible or potential roadblocks and sticking points.



- att1.htm

19(1)

000201



Philip Waddington

2001/05/18 09:05:11 AM

To: Joan Korol@HWC
cc:

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN

Joan,
I apologize for not replying sooner. I will be at the meeting in person and look forward to seeing you at 3:00.

For input, I have nothing specific to add to a reply letter, above what I am sure you have already received with respect to addressing the legal issues of the letter (distribute is sale, etc.).

One thing I would like to clarify, is that in their letter they state that I, "*acknowledge the dilemma that arises from the fact that the product is not within the TPD's mandate, but that NHPD does not yet have the legislated regulatory authority to deal with these products.*" However, what I did was acknowledge that the product is within the TPD's mandate, and that NHPD does not yet have the regulatory framework in place to deal with these products. ... just for clarity.

I am looking forward to seeing the letter you draft in reply.
Thanks,
Phil

Joan Korol on 05/17/2001 09:32:14 AM



Joan Korol on 05/17/2001 09:32:14 AM

To: Siddika Mithani@HWC, Philip Waddington@HWC
cc: Chris Turner/HC-SC/GC/CA@HWC, David Clapin@HWC, Patricia Maynard@HWC

Subject: Re: WARNING LETTERS TO SYNERGY & KAPLAN

Please provide your para that can be inserted as a response to address the reference to you in the letter form B. Kaplin's lawyer. We are meeting to discuss this letter tomorrow,

..joan

----- Forwarded by Joan Korol on 2001/05/17 09:26 AM -----

Joan Korol on 2001/05/11 10:58:29 AM



000204