



Robert_Peterson@hc-sc.gc.ca on 2001/04/05 12:21:32 PM

To: Peter Chan@HWC
cc: Philip Waddington@HWC
Subject: Re: Clinical Trial In Alberta

Peter:

Info on Clin trials is on the Web site. E-mail or correspondence to Clin Trials Unit C/O Dr. Mithani would be next best route. There are many telephone calls which will get answered, but often refer people to the Web site for answers to questions.

Bob

Peter Chan
2001-04-05 10:31 AM

To: Robert Peterson@HWC
cc: philip_waddington@hc-sc.gc.ca

Subject: Re: Clinical Trial In Alberta

Bob:

Further to my e-mail of yesterday, I got a follow-up call this morning from Dr. Bonnie Kaplan? (Fac. of Med., University of Calgary) who has been trying to contact Siddika regarding conducting a clinical trial with what could be an nhp in future but a "drug" or a food nutrition formula?? under the current system. The product name is EM Power Plus. She has been frustrated for not being able to get a hold of someone from TPD. My advice to her at the first phone call was to contact Siddika as we were not in the position to regulate clinical trials as yet. I indicated to her that she would likely have to follow the current requirements for conducting clinical trials. I gave her a brief update on where NHPD was and that we would explore the ideas of having clinical trails for nhps in our regulatory framework once we get our reg. in place. This is a heads up as she may call you if she still cannot reach Siddika.

Peter.

----- Forwarded by Peter Chan on 2001/04/05 10:17 AM -----

Peter Chan
2001/04/04 04:36 PM

To: Robert Peterson@HWC
cc: philip_waddington@hc-sc.gc.ca, Diane Gorman
Subject: Re: Herbal study in B.C. (Document link: Peter Chan)

Bob:

I am not aware of this study and as you know that we are not set up to review IND yet and we are still exploring the options for IND on nhps. I have touched base with Siddika regarding the general approach and am aware of the proposed new framework for IND.

*following
3 pages
N/R*

000119



Peter_Chan@hc-sc.gc.ca on 2001/04/10 12:31:56 PM

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To:
cc: Philip Waddington@HWC
Subject: re: query

I would like to further clarify a few points with regard to the conversation with the Group at the University of Calgary. Although, I do not usually discuss conversations I have had with a company, such as Synergy, with someone outside of that company, since I know that you commonly communicate with them on issues, and because I believe they would want me to reply to your questions, I am making an exception.

As you are aware, under the current Food and Drug Regulations, an Investigational New Drug submission is required to be filed with Health Canada for any investigator who wishes to conduct a clinical trial in Canada using a product for the purpose to treat, mitigate or prevent a disease. Currently, the Therapeutic Products Directorate is the Programme responsible for reviewing these IND submissions. I had suggested that The Synergy Group contact Dr. Siddika Mithany to explore further the current requirements.

However, notwithstanding the above, I had also drew the attention of this Group to the fact that the Natural Health Products Directorate is currently in the process of developing its regulatory framework (regulations) and is also in the process of exploring the options regarding clinical trials/experimental studies involving NHPs. Thus, I am puzzled by your understanding of the apparent conclusion of the person with whom you spoke, i.e., that clinical trails with NHPs will continue to fall under TPP (now the TPD). This was not what I stated, nor is it what I thought was understood by the Synergy Group representative with whom I spoke.

I hope this clarifies the situation for you. I will also follow up with The Synergy Group to ensure that they also fully understand our position.

Thank you for allowing me the opportunity to clarify our position on this matter.

Peter

on 2001/04/07 04:51:06 PM

To: Peter_Chan@HWC
cc:
Subject: re: query

Peter,

I've been told by the Synergy Group of Canada, that in response to their speaking to you regarding the recent seizure of research products destined for the University of Calgary, you said, "clinical trials with nutrients will still fall under TPP".

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If these are your words, can you please explain this?

 - att1.htm

19 (1)

DENNIS SHELLEY

2001/04/20 12:13

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

Subject: Synergy

FYI.

----- Forwarded by Dennis Shelley/HC-SC/GC/CA on 2001/04/20 12:14 -----

Joan Korol on 2001/04/20 11:01:54



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

Subject: Synergy

Hi Miles,

I believe you have the letter to Anthony Stephan from Dr. Peterson and the response form Synergy to Dr. Peterson. We request that you follow up with Anthony Stephan respecting his violations under the Food and drug Act regarding the sale and promotion of his product . This product has not been approved as an IND, therefore any kind of distribution would constitute sale.

Also Bonnie Kaplan and anybody else identified by Synergy should be notified to tell them they are in

contravention of the Regulations and that clinical studies require approval from Health Canada. IND.wpd

You mentioned that a shipment to Bonnie Kaplan was stopped at customs ... Have you placed a customs alert?

If you think a National Customs Alert would be helpful, please provide me with information you may have on brand names used for the product , where it's coming from etc. is it Synergy 3022 Bottom Road , Fallon Nevada 89406 .or Nvision International in Utah ... does this vary ? ...Do you have an electronic picture of the label? I suppose most of this is coming in as personal importation so not much can be done in this regard but maybe we can stop some of the larger shipments. What do you think?

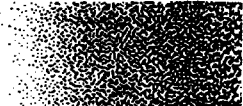
Call to discuss further.

...joan



IND.wpd

000125



Philip Waddington

2001/04/24 03:09:14 PM

To: Peter_Chan@hc-sc.gc.ca
cc:

Subject: Re: clinical trials

Peter,
when you get a few minutes, can we please talk about this again.
Thanks,
Phil

Peter_Chan@hc-sc.gc.ca on 04/18/2001 05:01:34 PM



Peter_Chan@hc-sc.gc.ca on 04/18/2001 05:01:34 PM

To: Philip Waddington@HWC
cc: Michael J Smith/HC-SC/GC/CA@HWC, Michelle L Boudreau@HWC, Eileen Quinn@HWC

Subject: Re: clinical trials

Phil:

I am not sure what else we can do at this point in time as in accordance with the current Regulations (C.08.005 and C.08.005.1) that the manufacturer has to file a preclinical submission (IND) with Health Canada for a "new drug". Since within Health Canada, TPD is the current regulator for this process, this group will have to meet the current requirements as outlined in the TPD guidelines. What I can suggest is that this group should contact Siddika and ask her about what specific information she needs to evaluate the submission in order to satisfy the requirements, such as, pre-clinical information, manufacturing process information, could this be published literature, etc., so that their product can get the no objection letter. This is what I told her during my telephone conversation back in January 15, 2001. As you mentioned, this product would not meet PSSM as outlined in the Interim DIN Enforcement Directive and that it would not be considered to be a Traditional Medicine and the DIN process under TM would not apply. Furthermore, TPD might have already contacted them back in June of last year.
Peter.

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file: Philip Waddington
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2001/04/18 03:08:38 PM
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000129

April 18/01

To: Peter Chan
cc: Michael J Smith/HC-SC/GC/CA@HWC, Michelle L Boudreau

Subject: clinical trials

Peter,
as you know, I took a call from Bonnie Caplan wrt a study they are doing, and some product that has been stopped at the US border. Bonnie, from the University of Calgary, wants to do a clinical trial on a nutritional supplement being used to treat depression and bi-polar disorder. Apparently they have started the study and the preliminary results look very promising. They have gone through the ethics review board of the university, are working with doctors and psychologists, are not financially involved with the product, etc. They are trying to do everything "by the book". She heard they have to inform TPD of any clinical trials, and so proceeded to do so.

I also spoke with Sedika who handles clinical trials, and she mentioned that they have done joint reviews with other regulators, where they looked at the drug portion of a procedure, and another body has looked at another portion, such as a medical device. We discussed whether or not we could do a joint review in this circumstance, but I do not know if it is possible, as the "drug" portion is what we would also be looking at for an NHP, so I'm not sure what would be accomplished. Perhaps we should look at what would be required (I realize this process has already started), and see if there would be anything we can do to assist in this process.

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Right now of her order of product was stopped at the border, and she is
Apparently it contains vitamins and minerals, an antioxidant (grape seed extract) and a botanical. I think that this mixing will not permit the product to fall under the Interim DIN, and would also not permit it to pass the normal DIN process b/c the herb is in the active dosage range.

Can you think of any next steps, and where can we go from here?
Thanks,
Phil

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