



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?

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