



Philip
Waddington/HC-SC/GC/CA
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To Anthony Stephan
cc Helene Amyot/HC-SC/GC/CA@HWC, Jasmin
Eldib/HC-SC/GC/CA@HWC
Subject PLA for Truehope

Hi Anthony,

I know that you are trying to set up a teleconference with me to, as I understand, discuss progress on you PLA for "Truehope EMPowerPlus".

First, regarding your application, our work on this has been ongoing as usual. I appreciate you and your colleagues coming to speak with us on December 6th, and I believe the reviewers on the file also appreciated hearing your views and information. At that meeting, we discussed how, notwithstanding a few minor issues, the real area of concern appeared to be in the wording of the risk statements. In considering all the information that has now been presented, we are essentially ready to propose another draft of the risk statements that would need to appear on the product label as per the *NHP Regulations*. We believe that there is wording which would address the concerns you expressed to us, while still including statements that we feel are necessary. If you agree with this wording, then we will be able to proceed with completing your application. The draft of the risk statements will follow shortly through the usual routes of communication with product licence applications.

My second issue is with respect to your company's recent communications, which appear to be much more adversarial in your dealings with Health Canada. I must say that I am surprised and somewhat disappointed that you have chosen to pursue this approach. While we have worked together over the past years, I have always felt that we had the shared goal of getting high quality and effective natural health products to Canadians, so that they could use them to maintain and improve their health. Our dealings have always been open and, in my opinion, cooperative. This has led to the approval of a clinical trial studying the ingredients of your products, and to you receiving an NPN for your previous product licence application. Changing to now try to use pressure or accusations of wrongdoing does not help this process. We are ready to proceed with your application because our work has been ongoing, not because of recent letters from Truehope. I am not sure upon whose advice you have chosen this route, but it appears much less professional than your previous dealings. The other effect from this change of tactic is that now there is concern that Truehope may inadvertently misinterpret or misquote discussions, and then publicly state them as fact. Therefore, we now be communicating with you in writing only. This way, both parties can be assured that there is minimal room for misinterpretation, or inadvertent misunderstandings.

We will continue to deal with you professionally, and in an open, polite and cooperative manner.

Sincerely,
Phil Waddington.
NHPD, HC.