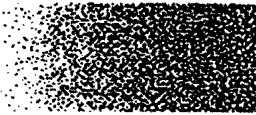


*Philip Waddington*  
1-403-292-5881



Philip Waddington

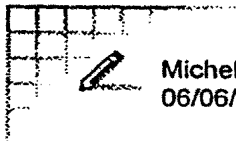
2000/06/06 08:03:18 PM

To: Micheline Ho@HWC  
cc: Marta Caris@HWC, Tony Halisky@HWC, Patricia Maynard@HWC, Heather Throop, Peter Chan  
Subject: Re: URGENT: Synergy Group of Canada/Synergy Nutrient

Micheline,  
thank you for forwarding these messages to my attention. Mr. Stephan called me today, and outlined what they are doing, much the same as is outlined below. I mentioned that our regulations will not be ready for about a year, and that I do not have the information available for answering questions about clinical trials. However, I did mention that we have had a lot of cooperation with TPP, and that I would try to find out if I could help him in getting any required information. At this point I don't even know what is in the product. Therefore, we would like to meet / phone / email to discuss what options they have, and how we can all proceed at this time. On Thursday, we have a meeting with our TAT, and I understand that a member is a friend of Mr. Stephan. If we could develop some ideas around an approach before that, it would be beneficial for us.

Thanks again for including our office,  
Phil

Micheline Ho



Micheline Ho  
06/06/2000 03:29 PM

To: Marta Caris@HWC  
cc: Philip Waddington@HWC, Tony Halisky@HWC, Patricia Maynard@HWC

Subject: URGENT: Synergy Group of Canada/Synergy Nutrient

Marta, the situation detailed below is similar to the one we dealt with recently where a herbal remedy was undergoing clinical investigation and we therefore indicated that an IND was required and

I have therefore copied BCE on it as a heads up and in view of the claims on Website.

I have also copied Phil Waddington as his office is mentioned in the background.

Perhaps Phil could have someone from his office contact us so that we may discuss how to follow-up on this case. Note that Siddika was copied on Joanne's message.

----- Forwarded by Micheline Ho on 06/06/2000 03:12 PM -----

Joanne Garrah

06/06/2000 02:35 PM

000002

To: Micheline Ho@HWC  
cc: Ian MacKay, Siddika Mithani@HWC

Subject: URGENT: Synergy Group of Canada/Synergy Nutrient

Micheline;

As discussed yesterday, I have provided below a summary of the conversations that I had with the Synergy Group of Canada regarding the use of 'synergy' nutrient product' in Canada, under what appears to be large scale clinical trials without approved INDs.

As we agreed, I will leave this with you for follow-up but if you could please cc me on your findings or actions, so that I can get back to the patient.

Thanks,  
Joanne

**Background:**

I received a call on Friday from a patient whose Dr. recommended that she use 'synergy nutrient' for the treatment of her depression, since she can not tolerate the alternative products on the market. She eventually contacted me because she was concerned about the lack of available product information from the company and the continually changing price of the product. She was also concerned about the general lack of awareness for this product in Canada, since she had been unsuccessful at obtaining any product information from her pharmacist or with her initial call to Health Canada.

I explained that the product was not listed in our database but that that didn't exclude the possibility that other groups within TPP were aware of the product and its availability in Canada. I agreed to check into the status of this product in Canada and to follow-up with her.

The patient referred me to the groups website ([www.truehope.com](http://www.truehope.com)) as a starting point.

**Current Situation:**

**1. Website:**

- The website describes the Synergy Group of Canada as a "research partner and consultant to the largest university research consortia ever to utilize a nutrient protocol for CNS research purposes" with researchers and scientists participating from The University of Calgary, the University of Alberta and the University of Alberta.
- The website also makes reference to an ongoing trial at the University of Calgary, with opportunity for enrollment in a variety of open case research studies in the clinical areas of Bipolar Affective disorder, Fibromyalgia, Clinical Depression, Schizophrenia, Tourette's syndrome and Anxiety-Panic disorder, ADHD and Obsessive Compulsive Disorder.
- It appears that participation in the study requires that individuals submit a personal information summary, a baseline symptom summary and commit to providing weekly symptom summary reports and in return, the synergy group will help the patient in obtaining a supply of nutrients for the disorder study.
- The website also makes reference to an ongoing double-blind, placebo controlled trial at the University of Calgary, where they hope to "enroll a total of 120 patients" in a protocol designed to evaluate this product as a treatment for chronic pain associated with fibromyalgia

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- There is a phone number listed on the site for individuals who wish to obtain more information (tel: 877-549-3777).

## 2. Contact with the company:

- As you know, I consulted with your group, after checking the website, to see if you were aware of the products or had any information on the group. When we weren't able to find anything in the database, I contacted the company for additional information on the status of the product in Canada.
- During my initial contact with the company, I spoke to a "research assistant" by the name of Dan. I introduced myself by name and indicated that I was calling from the Special Access Programme of Health Canada and that I was following up on a call that I had received from a concerned patient.
- Dan explained that the 'Synergy nutrient' or 'EM Power' (as it is also know?) is a multi-vitamin and trace mineral supplement that is not commercially available in Canada but is manufactured in Utah and shipped directly to patients homes under the provisions of personal importation. He confirmed that there are a number of open case trials and double-blind trials running in Canada and that the trials had been approved by the Alberta Heritage Foundation for Medical Research. Concerned with the mention of clinical trials, I asked for a copy of the product information so that I could confirm that status of the product in Canada, with hopes of confirming the legitimacy of the trials. Dan agreed to send a copy of the information by email.
- Shortly after my conversation with Dan, I was contacted by Anthony Stephan who is the president of Synergy Group of Canada. He was obviously concerned by my call and indicated that they would not send any product information until he received a written request from me outlining the type of information I was seeking and the reasons for my request.
- Apparently, Mr Stephan contacted the Office of Natural Health Products several months ago to discuss mechanisms for distributing this product in Canada for the purpose of clinical research. His understanding of the advice that he was given was that personal importation was both an appropriate and legitimate mechanism for bringing product into Canada.
- Mr Stephan obviously did not want this product labeled as a 'drug' and was uncomfortable with my distinction between personal importation and clinical research. Nevertheless he did confirm that approximately 300-400 Canadian patients were receiving/using this product as part of ongoing open-case studies or controlled trials through the participating University centres.
- I tried not to engage Mr Stephan by making any suggestion that their conduct was inappropriate but simply indicated that I was following up on a call from a concerned patient. I left the conversation by noting that I was not an expert in the area of compliance and enforcement and that I would be passing the information on to colleagues who were more knowledgeable in this area and that those individual would follow-up with the situation if there were any concerns that needed be addressed.
- I received a second call from Mr Stephan this morning, who indicated that there group had held an emergency board meeting last night to discuss my calls and the 'possible involvement of compliance and enforcement'. Apparently he also contacted Dr Phil Waddington, the Executive Director of the Office of Natural Health Products. I re-iterated my comment that I was not the best person to provide advice on compliance issues and that the information would be passed on to individuals with more knowledge in this area.

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