

P.A. Synergy



Jennifer Osterholm
2001/05/22 11:19

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

Subject: telephone message recv'd today at 10:38a.m.

Please call Mr. Bissett, he is the lawyer representing Synergy. He can be reached at 403-328-5576.
Thank you

*A combination product of net, mins, + helix
is NOT subject to special measures + must
have a DIN.*

000214

947-1-1



Joan Korol on 2001/05/24 02:50:00 PM

To: Michelle L Boudreau@HWC
 cc: Dennis Shelley/HC-SC/GC/CA@HWC, Miles Brosseau/HC-SC/GC/CA@HWC, Rod
 Neske/HC-SC/GC/CA@HWC, Sharon Chard/HC-SC/GC/CA@HWC, Daniele Dionne@HWC, Philip
 Waddington@HWC, David K Edwards@HWC, Jean Saint Pierre@HWC, France Dansereau@HWC,
 Patricia Maynard@HWC, Bruce Wozny@HWC, Peter Chan@HWC, Jean Lambert/HC-SC/GC/CA@HWC,
 Robert Peterson@HWC, Allison Ready/HC-SC/GC/CA@HWC

Subject: Re: Synergy : Draft Response

Thank you Michelle
Once I have received all comments this will go back to you and David for final review.

Michelle L Boudreau



Michelle L Boudreau
2001/05/24 12:52 PM

To: Joan Korol@HWC
 cc: Dennis Shelley/HC-SC/GC/CA@HWC, Miles Brosseau/HC-SC/GC/CA@HWC, Rod
 Neske/HC-SC/GC/CA@HWC, Sharon Chard/HC-SC/GC/CA@HWC, Daniele Dionne@HWC, Philip
 Waddington@HWC, David K Edwards@HWC, Jean Saint Pierre@HWC, France Dansereau@HWC,
 Patricia Maynard@HWC, Bruce Wozny@HWC, Peter Chan@HWC, Jean Lambert/HC-SC/GC/CA@HWC,
 Robert Peterson@HWC, Allison Ready/HC-SC/GC/CA@HWC

Subject: Re: Synergy : Draft Response

Joan,

David,

Anything to add?

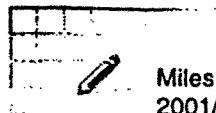
Merci.

MLB

MLB
27/05/01

21(1)(a)(b)

000222



Miles Brosseau
2001/05/25 09:23

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

cc:

Subject: BONNIE KAPLAN

Have you contacted her yet about cancelling the meeting on Tuesday? I got a call from her about a response letter and the Tuesday meeting but, not wanting to muddle things up, didn't say anything about the plan to have the meeting here in Calgary cancelled and have her make a presentation to the folks in Ottawa. I understood from our conference call of last Friday that Ottawa wanted Calgary cancelled to be replaced by an Ottawa presentation.

000224



Health Canada
Santé Canada

Health Products and Food Branch Inspectorate
Inspectorat de la Direction générale des produits de santé et des aliments

Fax / Télécopie

Date : 2001-May-25

From / De : Dennis Shelley
Operational Manager
Tel: (604) 666-3704

Fax: (604) 666-3149

To / À : Joan Korol

Fax : (613) 952-9805

CC : N/A

Number of page(s) / Nombre de page(s): 10

Subject / Sujet: Synergy Group of Canada

Message : I will be telephoning you. I need to discuss the strategy re the still uncanceled meeting on the 29th in Calgary.

To Chris Turner
Phil Wobderg
David K. EDWARDS
Michelle Boudi
cc - Siddika Mathan
Michelle Ho.
Conne Diatta
Allison Ready.

000226



UNIVERSITY OF
CALGARY

Faculty of Medicine

Department of Paediatric
Alberta Children's Hospital
Telephone: (403) 229-736
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Email: kaplan@ucalgary.c

May 23, 2001

Mr. Dennis Shelley
Health Products and Food Inspectorate
3155 Willingdon Green
Burnaby, B.C. V5G 4P2
Via FAX 604-666-3149 *v. 2001*

*13(1)(c)
19(1)
20(1)(c)(b)*

Dear Mr. Shelly:

Re: Research involving E.M.Powert

It was a pleasure talking to you on May 16 and finding out that you will be helping us sort out this "situation." At the end of our conversation, you suggested that I might be able to facilitate matters if I were to put into writing some background information. That is the purpose of this letter.

History

In 1995-96 Mr. David Hardy of Raymond, Alberta, had the amazing insight that since trace minerals are used by western Canadian farmers to treat irritable and aggressive behaviour in farm animals, perhaps there was potential for treating *human* irritability and aggression in the same way. This simple insight seems never to have occurred to anyone prior to that time. Mr. Hardy had owned an animal feed company for two decades, and routinely provided mineral and electrolyte mixtures to farmers with pigs exhibiting such behaviours. As an expert in animal nutrition (a field that is far more advanced than human nutrition), he discussed with Mr. Tony Stephan of Cardston, Alberta, the possibility of giving Mr. Stephan's mentally ill children a supplement consisting primarily of dietary minerals. Two of Mr. Stephan's children had bipolar disorder. In spite of optimal psychiatric treatment, their lives were in a shambles; they both experienced severe mood swings and explosive rage. Mr. Hardy and Mr. Stephan experimented with a variety of mineral supplements bought from pharmacies (i.e., for human consumption), and by March 1996 both children were symptom-free and medication-free. They remain well to this day.

Mr. Hardy and Mr. Stephan continued their development work the supplement, helping other relatives and friends.

During that time, they discovered that the medical community in Alberta was not ready to believe their discovery, and they quickly concluded that they needed university scientists to provide scientific validation of their observations. In approximately May 1997 they approached Dr. [redacted] at the University of [redacted]. Because I had done some research in the 1980s on additive-free diets in children with ADHD, Dr. [redacted] emailed me and asked if I would be able to help these two gentlemen. It is a now-amusing story (and a true one) that I refused, saying "better you than me" because I was tired of dealing with true believers and fanatics in the nutrition world. In 1997 I still firmly believed that it was impossible to significantly influence mental health with dietary supplements. But I FAXed Dr. [redacted] some questionnaires that I thought these two fellows might find useful. On August 11, 1997, long after I had forgotten the matter, Dr. [redacted] FAXed me an analysis of variance of some data Mr. Hardy and Mr. Stephan collected over the summer: it was significant. As I explained to you on the phone, Mr. Shelley, I am trained to pay attention to statistical significance, even when it contradicts my belief system.

20(1)(b)(c) 13(1)(c)

In the interests of solving the conundrum of regulatory approval, I would very much like the opportunity to present our research in Ottawa to individuals in the three relevant directorates (Therapeutic Products Directorate, Natural Health Products Directorate, and Health Products and Food Inspectorate). If this can be arranged, I would be most grateful. I believe that the well-meaning individuals from these directorates with whom I have spoken will understand the importance of facilitating our research, if they are shown the significance of this work.

Sincerely,

Bonnie J. Kaplan
Bonnie J. Kaplan, Ph.D.

Professor, Department of Paediatrics, University of Calgary, and
Director, Behavioural Research Unit, Alberta Children's Hospital

following 4 pages
13(1)(c) - 19(1)
20(1)(b)(c)