



pa. Synergy Group of Canada.

# STRINGAM DENECKY

BARRISTERS & SOLICITORS

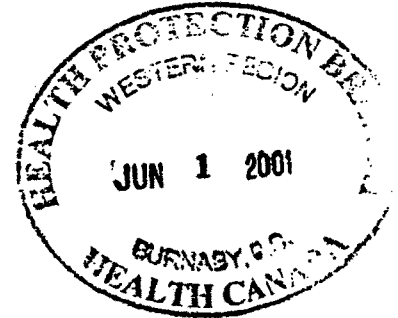
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SHARON M. SPROULE NEIL DOBSON



Your File:

Our File: 75108-1/RGB

May 29, 2001

Health Products and  
Food Branch Inspectorate  
3155 Willingdon Green  
Burnaby, BC V5G 4P2

Attention: Dennis Shelley

Dear Sir:

Re: Synergy Group of Canada Inc.

*Handwritten notes:*  
DMS  
1-26-01  
re: to  
ack

Further to my discussion of last week with you and with Miles Brousseau, and the warnings provided with regard to alleged violations under the Food and Drug Act and regulations, we confirm that our client is desirous of complying with the law.

To that end, our client, Synergy Group of Canada Inc., no longer maintains the website at [www.truehope.com](http://www.truehope.com). Further, there have been some modifications to the website which is now owned by a US corporation.

This whole area appears to me to be problematic. I have been provided with a copy of a letter to the Honorable Alan Rock, Minister of Health, provided by the transition team.

It is my understanding that the interim management policy is in place, and includes those items set out on page 2 of the enclosed letter.

It is further my understanding that our client's vitamin and mineral supplement has been deemed, or should be deemed as a NHP for the purpose of NHP's working definition.

It states, that among other things, that this matter, in our view, should have been dealt with by the office of Natural Health Products and not through TPP.

While my discussion with you was most enlightening as to the difficulties you are experiencing in this transition and your kind assistance has been appreciated, it strikes me that this matter should not be handled through your department. This is exactly the problem which we are experiencing which precipitated the commitment by the Government of Canada to move these matters to a department which naturally reflects the product being considered. In our opinion, the application for a DIN number flies in the face of the interim policies as described, and admits that my client indeed comes under the jurisdiction of the Food and Drug Act, which we do not believe.

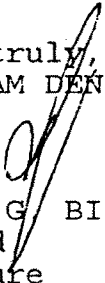
While I have advised my client to be patient with the transition announced by the Federal Government in this area, it appears that we need to make a firm stand in connection with this matter. Your suggestion with regard to having a meeting in Ottawa between the Health Products and Food Branch Inspectorate and the transition team for the NHP branch be held as soon as possible in combination with Dr. Bonnie Kaplan. Hopefully they can clear the air as to which department ought to be handling this matter, and proceed.

In any event, we have complied with your request in terms of the website and we request your confirmation that no further action will be taken until this matter can be resolved inter-departmentally.

In the interim, we would request that you release to Dr. Bonnie Kaplan, the nutritional product to allow Dr. Kaplan to complete the research which she is conducting in relation thereto, so that the results of this research may be provided to the proper department in due course. Please advise on those two matters as soon as possible.

Yours truly,  
STRINGAM DENECKY

Per:

  
ROBERT G. BISSETT  
RGB/drd  
Enclosure

cc: Synergy Group of Canada Inc.

Writer's e-mail: [rgbissett@lethlaw.com](mailto:rgbissett@lethlaw.com)

000251

*for - synergy*

**Health Products and Food Branch Inspectorate  
#282, 220 4th Avenue S.E.  
Calgary, Alberta  
T2G 4X3**

**June 20, 2001**

**Robert G. Bissett  
Legal Counsel  
Stringam Denecky  
P.O. Box 757  
314-3rd St. S.  
Lethbridge, AB.  
T1J 3Z6**

**Dear Mr. Bissett:**

Thank-you for the letter of May 29 , 2001 that you sent to the Health Products and Food Branch Inspectorate on behalf of Synergy Group of Canada Inc.

The requirement for the approval of clinical trials is a federal regulatory responsibility. The Therapeutic Products Directorate in collaboration with the Natural Health Products Directorate will propose a pre-IND meeting with Dr. Kaplan and the Synergy Group of Canada to more formally facilitate the compliance process in this regard.

The status of the commercial importation of the product E.M.Power+ will be maintained and discussion regarding further steps will be pursued following this meeting.

As you may be are aware, the Health Products and Food Branch is moving towards a new regulatory framework that will eventually define the regulatory requirements for products falling under the term natural health product. This transition will be taken into consideration during the proposed pre-IND meeting.

Yours truly,



**Miles Brosseau**