UNIVERSITY OF CALGARY

RESEARCH SERVICES

Health Sciences Centre, Room G380
Telephone: (403) 220-2590
Fax: (403) 270-9497
Email: lmcrae@ucalgary.ca

May 8, 2001

VIA COURIER

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

Attention: Miles E. Brosseau, Inspector

Re: Dr. Bonnie Kaplan

As Legal Counsel for the University of Calgary, I have been asked to respond to your letter to Dr. Bonnie Kaplan dated 27 April 2001.

Firstly, it should be clarified that Dr. Kaplan is engaged in research projects which have been approved on scientific and ethical bases by her peers at the University of Calgary and funded by the Alberta Science and Research Authority. Subsequently, her work has been lauded by colleagues at other academic institutions including Harvard University. In general, her research seeks to examine the role of nutrition in mental disorders. Dr. Kaplan is conducting research, she is independent of commercial interests in such products.

Throughout the course of the research she has communicated with regualtors. At the outset, Sharon Chard was consulted, in her capacity as a Regional Director with the Therapeutic Products Directorate and member of the Transition Team for the Natural Health Products Directorate. Ms. Chard advised that it was unnecessary to pursue a D.I.N., an I.N.D. or any other regulatory review because the regulatory framework for the nutritional supplements does not yet exist. This is confirmed by the Interim Management Strategy for Natural Health Products approved by the Minister in March 2000 that states "While these amendments are being designed, products that will be regulated as NHP's are still governed by the current regulations and guidelines".

In October 2000, Dr. Kaplan participated in the public hearings, as part of the nationwide consultation process undertaken by HPB. She has also consulted with Dr. Saddika Mithani of the Therapeutic Products Directorate and Dr. Phil Waddington of the Natural Health Products Directorate. Both are aware of her research, and have not ever suggested that her research should cease. Further, both acknowledge the dilemna that arises from the fact that the product in use is not within the TPD's mandate, but that NHPD does not yet have the legislated regulatory authority to deal with these products.

With that background in mind, I will now address each of the allegations contained in your letter:

1. In general, most of the alleged violations are unfounded as the product in question is not a drug within the definition of the Food and Drugs Act because Dr. Kaplan is not involved in the manufacture, sale or representation of the product for use in any diagnosis, treatment or restoratioon of organic function. She is simply engaged in research in which she is testing certain

2500 University Drive N.W., Calgary, Alberta, Canada T2N 1N4 • www.ucalgary.ca

hypotheses. No representations are made regarding the product; rather she is simply asking and attempting to answer questions about such products.

2. She is not in violation of Article 3(2) of the Act because 1) she is not selling anything as selling is defined in the Act, 2) the labels of the product make no claim- they are labelled for research puposes only, and 3) she is not advertising any treatment or cure to the general public.
3. There is no violation of Article 9(1) because communications with participating physicians and patients advise that there is no scientific data to prove that value of nutraceuticals in treatment of mental disorders, hence the study.
4. There is no violation of Article 9(2) since Dr. Kaplan is not involved in labelling or packaging of the product. The product is provided by the manufacturer, labelled For Research Purposes.
5. As stated above, Dr. Kaplan is not selling the product as that term is defined in the Act. Accordingly, if she is not selling, she is not in breach of Reguations C.01.003, C.01.004.1, C.01.005, C.01.014, or C.08.002.
6. Further, because she is not manufacturing the product, she cannot be in breach of Reguations C.01.014, or C.08.005.

In light of the foregoing, we hereby request that you immediately release the products currently held and rescind your order calling for the cessation of the research being conducted by Dr. Kaplan.

Please do not hesitate to contact me to discuss this further.

Sincerely,

Lynn McRae
Legal Counsel
University of Calgary

154C

Canada

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

fla -> Synergy

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

June 20, 2001

Lynn McRae
Legal Counsel
University of Calgary
Research Services
Health Sciences Centre, Room G380
2500 University Drive N.W.,
Calgary, Alberta, Canada
T2N 1 N4

Dear Ms McRae:

Thank-you for the letter of May 8th , 2001 that you sent to the Health Products and Food Branch on behalf of Dr. Bonnie Kaplan.

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 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

Canada