

May/2001

FOR INFORMATION

BRIEFING NOTE

SUBJECT: Marketing of an unauthorized drug by The Synergy Group of Canada Inc.

ISSUE: This briefing note reports on compliance activity undertaken by the HPFB Inspectorate to carry out the recommended regulatory action that was proposed in the Briefing Note 00-100521-582rev_Briefing.wpd and the subsequent letter received from Bonnie Kaplan's Legal Counsel from the University of Calgary.

EXECUTIVE SUMMARY

Synergy Group of Canada in their website, www.truehope.com, claims to be a "research partner and consultant to the largest university research consortia utilizing a nutrient protocol for CNS research purposes". Bonnie Kaplan is the researcher affiliated with the University of Calgary who is believed to be conducting the research. The product, E.M.POWER, is being promoted by the Synergy Group for the treatment of CNS Disorders, such as Schizophrenia, Bipolar Disorder, Depression, ADHD, Panic / Anxiety Disorders, OCD, Tourette's Syndrome, Autism and the disorders of Fibromyalgia / Chronic Fatigue Syndrome. This product is the subject of two of Bonnie Kaplan's clinical studies being undertaken at the University of Calgary.

Violations under the current legislation: the Food and Drugs Act and Regulations.

Synergy Group is violating the Food and Drugs Act (FDA) and Regulations in that they are promoting the sale of E.M POWER, a vitamin-mineral herbal product for treatment of a disease without having obtained a Drug Identification Number (DIN).

Under the current regulatory framework, E.M. POWER is considered a drug. Therefore, Bonnie Kaplan is in violation of the FDA in that she is conducting a clinical trial without having submitted an IND. For the purposes of this clinical trial, Ms. Kaplan is importing product which she distributes to her patients. Without

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an approved IND, this distribution would be considered sale.

On October 20, 2000, a letter signed by Dr. Peterson, D.G. of the Therapeutic Products Directorate, was sent to Anthony Stephan of Synergy Group of Canada, identifying violations to the Food and Drugs Act and Regulations regarding the promotion/sale/distribution of product without an approved IND.

On November 7, 2000, a response from Anthony Stephan was received in Dr. Peterson's office stating that the Synergy Group of Canada was not the sponsor of the clinical research.

On April 27, 2001, the Inspectorate (Western Operational Centre) sent a Warning letter to Bonnie Kaplan to cease research activity until such time that an IND was submitted and a "No Objection" letter was issued and to notify her that the importation of the unapproved drug for further distribution/sale is in violation to the Food and Drugs Act and Regulations. On the same date, the Inspectorate also sent a Warning letter to Synergy Group citing violations under the Food and Drugs Act and Regulations regarding the promotion/sale/advertising of the unapproved drug product "E.M. Power" through Synergy's website, www.truehope.com. The website solicits participation in clinical trial research.

On May 8, 2001, Legal Counsel for the University of Calgary Research Services, responded to the Inspectorate (Western Operational Centre) that the research has been approved by the University of Calgary and funded by the Alberta Science and Research Authority but their response did not address the fact that these clinical trials have not been approved by Health Canada. The letter indicated that B. Kaplan was in contact with BPA/TPD, NHPD and a member of the Transition Team for the former Office of Natural Health Products. It was claimed by Anthony Stephan that the information received by Ms. Kaplan from the former Transition Team member may not have been consistent with the current requirements under the Food and Drugs Act. While it is recognized that there may be changes to the requirements for natural health products in the future, the Natural Health Product legislative framework is not yet in place.

On May 15, 2001 the Inspectorate was requested to provide a briefing to the Minister's Office who was contacted by Anthony Stephan. Subsequently, the Inspectorate has been requested to respond directly to Anthony Stephan.

A teleconference took place at 12:00 PM, May 15, 2001, with Dennis Shelley, Daniele Dionne, Bruce Wozny, Patricia Maynard, Phil Waddington, Peter Chan, and Joan Korol to discuss the current status of this file. It was determined that the Inspectorate will seek compliance regarding the sale and promotion of E.M.POWER through the Synergy website, www.truehope.com. As well the Inspectorate will monitor the

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importation of this product for sale eg. by Bonnie Kaplan.

A meeting has been arranged for Friday May 18, with BPA, NHPD and the Inspectorate to discuss the response to the letter from Ms. Kaplan's Legal Counsel. We will be looking also into the feasibility of developing a policy along with Legal Counsel representation that might address a transitional approach for the review of these types of product which will eventually fall under the mandate of the NHP regulatory framework.

The Western Operational Centre for the Inspectorate will be calling Mr. Anthony Stephan of Synergy on the morning of May 16, 2001 as a follow-up to Mr. Stephan's telephone call to the Minister's Office.

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