

BRIEFING NOTE

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

ISSUE: This memorandum reports on recent enforcement activity undertaken by the Inspectorate HPFB to effect the recommended regulatory action that was proposed in the Briefing Note 00-100521-582rev_Briefing.wpd and the subsequent action taken on behalf of 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 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

Violations Under the current legislation, 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 an unauthorized product. No DIN has been issued for E.M Power

Bonnie Kaplan is in violation of the FDA in that she is conducting a clinical trial without having submitted an IND and therefore is not in receipt of a "No Objection" letter issued by Health Canada. For the purposes of her clinical trial, she is importing product which she distributes/sells to her patients. Without an IND, this distribution would be considered sale.

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On October 20, 2000, a letter signed by Dr. Peterson 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 is submitted and a "No Objection" letter is issued.; that the importing of the unapproved drug for further distribution/sale is in violation to the Food and Drugs Act and Regulations. The Inspectorate also sent a Warning letter to Synergy Group citing violations under the Food and Drugs Act regarding the promotion/ sale /advertising of the unapproved drug product, "E.M. Power", through Synergy's website at www.truehope.com . The website solicits participation in clinical trial research

On May 8, 2001, University of Calgary , Research Services, responds 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 does not address the fact that these clinical trials have not been approved by Health Canada. The letter indicates that B. Kaplan was in contact with BPA/TPD, NHPD, and a member of the Transition Team for the Natural Health Product Directorate where information disseminated may not have been consistent with the current requirements under the Food and Drugs Act. Natural Health Product legislative framework is not yet in place. While it is recognized that there may be changes to the requirements for natural health products in the future, these regulatory requirements do not currently exist.

On May 15, 2001 DIU was requested to provide a briefing to Minister Office who was contacted by Anthony Stephan. It was later discovered that the Minister's office was not requesting a Briefing but was requesting that Dr. Peterson contact Anthony Stephan directly. Dr. Peterson then stated that Anthony Stephan's request was as a result of two letters sent out by the Inspectorate and has now requested that the Inspectorate respond directly to Anthony Stephan.

A teleconference took place at 12:00 PM , May 15, 2001, between Jean Lambert, Dennis Shelley, Daniele Dionne, Bruce Wozny, Patricia Maynard, Phil Waddington, Peter Chan, Joan Korol to discuss a course of action and current status of Synergy issue. It was decided in the course of this teleconference, that the Inspectorate will move forward respecting issues related to the sale and promotion of Synergy product through the website,

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www.truehope.com. Also the Inspectorate will pursue the issue of the importation of product by Bonnie Kaplan. It was also recognized that a meeting has been arranged and will take place on Friday May 18, 2001 between BPA, NHPD and the Inspectorate to discuss the response to the letter from Legal Counsel on behalf of Bonnie Kaplan, as well as to reach a resolution regarding INDS as they relate to Natural Health Products.

The goal of the meeting is to look into the feasibility of developing a policy 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. This approach would need to be reviewed by Legal Counsel for Health Canada. Also, it was suggested at this meeting, that advice can be made available to Bonnie Kaplan and Anthony Stephan from the Inspectorate (Western Operational Centre) in regards to the requirements of Food and Drugs Act, should they request it.