Background

Title	Synergy Update

Issue	Synergy Group of Canada Inc. has been advertising and selling the unapproved drug product, "E.M. Power", through your website at www.truehope.com . Bonnie Kaplan of the University of Calgary has imported the Synergy Group of Canada's unapproved drug product "E.M. Power" for distribution and research purposes, what appears to be unapproved clinical trials. The website www.truehope.com solicits participation in clinical trial research and seeks to attract parents of children with mental illness with statements such as "finding true hope in despair". The product is being promoted for the study and treatment of serious disorders such as anxiety and panic disorder, bipolar affective disorder, fibro myalgia, schizophrenia, attention deficit hyperactive disorder, clinical depression, Tourett's Syndrome, etc. which are not amenable to self-diagnosis or self-monitoring.
Background Information	Miles Brosseau, an inspector with the Inspectorate has provided 2 reports of his finding to date. 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.

Background Situation	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.. 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, and natural health products which are considered to fall under the definition of a drug must adhere to the requirements under the Food and Drugs . May 16, 2001 teleconference (9:00 am until 10:45 am) Mr. Tony Stephan and David Hardy, representing the Synergy Group of Canada and Dennis Shelley and Rod Neske, representing Health Canada (HPFB Inspectorate) OUTCOMES: SGC agreed to make a DIN application. A meeting was proposed for SGC , Bonnie Kaplan and HPFBI WOC in Calgary on May 29th to discuss clinical trial requirements. SGC has agreed to review its website and would consider a reorientation of it to tone down the promotional emphasis on the product E.M. Power+. General points: • SGC want to ensure that there is continued public access to E. M. Power+. • They want a 'win-win' ultimate outcome for all parties. I advised that for a win-win opportunity to exist it would imply a willingness on their part to make an adjustment. • They will consider looking at corporate procedural changes. • Synergy does not own E.M. Power+. (Their statement to me). • No product in Canada. Everything imported under PUED.(Personal Use Enforcement Directive) On June 20, Miles sent out H.C response to letters received from lawyers.

Background:	Dr. Peterson on **July 24, 2001** sent a warning letter to Synergy citing the firm's involvement in unauthorized clinical studies and violative promotion of the product . The response back from Synergy was that they were not the sponsor of the trials. **August 27, 2001** Pre-Ind meeting via video conference took place between Bonnie Kaplan, the Synergy Group BPA, NHPD and the Inspectorate. Bonnie is to submit an IND for BPA review. **Sept. 10, 2001** Letter signed by Bob Peterson to Bonnie Kaplan requiring an IND to be filed by October 10, 2001 or termination of the trial would be mandated and patients would need to be transferred to appropriate professionals for conventional treatment .

20(1)(b)(c)

Prepared by: Joan Korol
Jean Saint-Pierre **Date:** **February 14, 2002**

C:\temp\synegy_1.wpd