



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

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

April 27, 2001

DOUBLE REGISTERED

Mr. Anthony F. Stephan
Synergy Group of Canada Inc.
635 - 2nd Avenue West,
Cardston, Alberta
TOK OKO

Attention: Mr. Stephan

**RE: WARNING: VIOLATION OF SECTIONS 3(1), 3(2), 9(1), 9(2),
C.01.003, C.01.005, C.01.004.1, C.01.014(1),
C.01A.004.(1), C.08.002, AND C.08.005 of the
FOOD AND DRUGS ACT AND REGULATIONS.**

It is apparent that the Synergy Group of Canada Inc. is advertising and selling the unapproved drug product, "E.M. Power", through your website at www.truehope.com

The website 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, fibromyalgia, schizophrenia, attention deficit hyperactive disorder, clinical depression, Tourett's Syndrome, etc. which are not amenable to self-diagnosis or self-monitoring.

The activities of the Synergy Group of Canada Inc. are considered violative of the above noted sections and compliance with the regulatory requirements is necessary.

The sale and advertisement of a drug, and in this case a new drug, prior to receipt of a Notice of Compliance (NOC) and a Drug Identification number (DIN) is in violation of sections C.01.014(1) and C.08.002.

E.M. Power has not received a DIN or NOC for any of the indications for which it is being sold and advertised and is not properly labelled. Consequently, the false, misleading, and deceptive selling/advertising of this unapproved and improperly labelled drug product is in violation of sections 9(1), 9(2), C.01.003, C.01.004.1, and C.01.005.

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As well, marketing E.M. Power for diseases that are listed in Schedule A is a violation of sections 3(1) and 3(2).

As per section C.01A.04.(1), no person shall distribute a drug product in Canada without an establishment licence.

You were previously advised that the Food and Drugs Act and Regulations require that an Investigational New Drug Submission (IND) be filed for evaluation prior to initiating a clinical trial. A "No Objection Letter" would be issued, should review of the proposed clinical trial be considered satisfactory. Failure to submit an IND with respect to the research conducted with E.M. Power is in violation to section C.08.005.

A copy of definitions, Schedule A, and the violated sections is attached for your reference. It is my recommendation that you disseminate this information to the parties involved (ie. corporate directors, clinical trial investigators, the manufacturer, and Synergy research assistants).

It is imperative that the sale, distribution, any form of advertising, and research with the product E.M. Power be concluded immediately. I am requesting, by May 31, 2001, your written response confirming that the violative activities have ceased and that the Synergy Group of Canada Inc. will maintain compliance with the Food and Drugs Act and Regulations.

If you have further questions or wish discussion, please call (403) 292 - 5081.



Miles E. Brosseau
Inspector - HPFBI