



Health
Canada

Santé
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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

Bonnie J. Kaplan, PhD
University of Calgary
Alberta Children's Hospital
1820 Richmond Dr. S.W.,
Calgary, Alberta
T2T 5C7

Attention: Dr. Kaplan

**RE: WARNING: VIOLATION OF SECTIONS 3(2), 9(1), 9(2), A.01.040,
C.01.003, C.01.004.1, C.01.005, C.01.014(1),
C.01A.004.(1), C.08.002, AND C.08.005 of the
FOOD AND DRUGS ACT AND REGULATIONS.**

It has come to our attention that you are importing the Synergy Group of Canada's unapproved drug product "E.M. Power" for distribution and research purposes.

Apparently, the sale and clinical trial use of the product is for the treatment of mental disorders in Adults and other specific disorders such as Bipolar Disorder.

The sale 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 indication and is not properly labelled. Consequently, the selling 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.

Please be advised that selling E.M. Power for diseases that are listed in Schedule A is a violation of section 3(2).

Also, there is no record you have submitted an application for an establishment license. As per section C.01A.04.(1), no person shall import and distribute a drug product in Canada without an establishment licence.

The importation of E.M. Power or any other unapproved drug for the purposes of sale and distribution is in violation of section A.01.040 of the Food and Drug Regulations.

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 imperative that the sale, distribution, and clinical trail 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 any similar activity in future will be undertaken in 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