



Health  
Canada

Santé  
Canada

Health Products  
and Food Branch

Direction générale des produits  
de santé et des aliments

Therapeutic Products Directorate  
Holland Cross, Tower "B"  
6<sup>th</sup> Floor, 1600 Scott Street  
Address Locator # 3106B  
OTTAWA, Ontario  
K1A 1B6

SEP 10 2001

01-112823-133

Dr. Bonnie J. Kaplan, Ph.D.  
Professor, Department of Paediatrics  
University of Calgary, and  
Director, Behavioural Research Unit  
Alberta Children's Hospital  
1820 Richmond Road, South West  
CALGARY, Alberta  
T2T 5C7

Dear Dr. Kaplan:

Re: Clinical Trial Application for E.M.Power +

In response to the discussion on August 27, 2001, involving representatives of the Health Products and Food Branch, University of Calgary and Synergy Inc., this is to advise you that ongoing clinical trials with E.M.Power + are in violation of Division 5 of the Food and Drug Regulations. To correct this, you are required to file a Clinical Trial Application (CTA) with the Therapeutic Products Directorate within four weeks of receipt of this letter.

The information regarding the current requirements for filing a CTA has been forwarded to you by e-mail. In addition to submitting all the required information, please ensure that the CTA also includes the following:

1. Safety data with respect to the high doses of vitamins and minerals contained in E.M.Power +. This should specifically address the issue of potential cumulative toxicity.
2. Detailed information on the safety monitoring of clinical trial participants for potential toxicity. This should also include stopping rules, rescue medications that will be used as part of the protocol, as well as premature withdrawal criteria.

Canada

....2/  
000380

- 2 -

3. Information on how you propose to assess the efficacy of the product.

Please also provide us with the membership and contact information of the Research Ethics Board that approved the ongoing trials so that we may forward our recommendations to them for immediate consideration.

Should you decide not to file a CTA with the Therapeutic Products Directorate, you are required to notify all your study subjects regarding the termination of the trial and ensure that these subjects are assessed and their care is transferred to an appropriate professional who can place them on standard therapy in a manner that will take the individual's health and well-being into account.

Yours sincerely,



Robert G. Peterson, MD, PhD, MPH  
Director General

c.c.: Dr. Philip Waddington  
Mr. Jean Lambert  
Dr. Siddika Mithani

000381

\*\* TOTAL PAGE.03 \*\*

\*\* TOTAL PAGE.03 \*\*