



Health Canada  
Santé Canada

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

Your file    Votre référence

October 11, 2001

Our file    Notre référence  
01-112823-133

Dr. Ian Mitchell  
Director, Office of Medical Bioethics  
Conjoint Health Research Ethics Board  
Office of Medical Bioethics  
University of Calgary  
3330 Hospital Drive, N.W.  
Calgary, Alberta  
T2N 4N1

Dear Dr. Mitchell:

Re: Ongoing clinical trials at the University of  
Calgary with EM Power +.


It has been brought to our attention by Dr. Bonnie Kaplan that the Conjoint Research Ethics Board of the University of Calgary has approved clinical trials with EM Power + in patients with bipolar depression and in patients with fibromyalgia. Please be advised that these ongoing trials are in violation of Division 5 of the Food and Drug Regulations. Prior to initiating a clinical trial, an application must be filed with the Health Products and Food Branch for authorization to sell or import a drug for the purposes of a clinical trial.

In correspondence dated September 10, 2001 to Dr. Kaplan, Health Canada has indicated that a Clinical Trial Application must be filed within four weeks of receipt of the letter (attached). We are currently awaiting Dr. Kaplan's response. If a Clinical Trial Application is filed, a response will be provided within 30 days of receipt of the Application, and we will advise you accordingly.

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In the event that a Clinical Trial Application is not filed, the trial must be terminated. Dr. Kaplan is required to notify all study subjects regarding the termination of the trial and ensure that the 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

cc: Dr. Bonnie Kaplan  
Dr. Philip Waddington  
Ms. Daniele Dionne  
Dr. Brian Gillespie  
Ms. Lynn Bernard  
Dr. Siddika Mithani