

BRIEFING NOTE

SUBJECT: Marketing of an unauthorized drug by The Synergy Group of Canada Inc.

ISSUE: The purpose of this memorandum is to inform you of a proposed regulatory action in relation to the company named above.

EXECUTIVE SUMMARY

It has come to the attention of the Therapeutic Products Programme (TPP) through a patient enquiry, that the above-named firm is conducting clinical trials without the required prior filing of an Investigation New Drug Submission (IND) and receipts of a "No Objection Letter". In addition, it has been determined that the firm's website promotes the use of the product for medicinal purposes, prior to obtaining marketing authorization, in violation of the *Food and Drugs Act and Regulations*.

It is the intention of the TPP to send a letter to The Synergy Group of Canada Inc. informing them of the violations, and requesting that the proper authorization be obtained.

The Synergy Group of Canada may be under the mistaken impression that no authorization is required prior to investigating or promoting the product or products (a combination of products under the name Synergy may be used) as they believe the products to be classed as "natural health products".

Under the Interim (DIN) Drug Identification Number Enforcement Directive where drug products, as defined under the current Food and Drugs Act and Regulation, that meet certain requirements are not subject to enforcement measures other than the marketer being made known of the legislative requirements. The activities of The Synergy Group of Canada Inc. would not meet

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these requirements. The products are being studied and promoted on the Internet for serious conditions, including autism, fibromyalgia, attention deficit and panic disorders, conditions which are not amenable to self-diagnosis or self-monitoring.

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The Website solicits participation in the research, and seeks to attract parents of children with mental illness with statements such as "finding true hope in despair", asking them to assist with the research, listing several Canadian universities as being involved in the research project.

Note that a similar approach was used on a comparable case, a few months ago.

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