Health Canada executes search warrant related to Empowerplus


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Proactive Disclosure
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Information
July 15, 2003
Ottawa, Ontario

Health Canada is aware that some individuals who are taking Empowerplus and suffer from serious central nervous system disorders may be concerned about recent actions taken by Health Canada concerning the drug. Health Canada however believes that individuals using Empowerplus could be putting their health at risk. For this reason, we issued a health advisory on June 6, 2003.

Truehope Nutritional Support Limited and Synergy, despite repeated requests by Health Canada, is still refusing to comply with the Food and Drugs Act and Regulations, and continues to sell its unapproved drug, Empowerplus, in Canada. Health Canada inspectors, with the assistance of the RCMP, are therefore executing a search warrant to seize records related to the advertising, importation for sale and sale of Empowerplus by Truehope and Synergy.

Our main concern deals with the unproven health claims being made about Empowerplus, and the recommendation that patients decrease the dose of, or eliminate altogether, medications prescribed by their doctors. This can result in serious adverse health consequences. The drug is being promoted and sold to treat serious disorders, such as bipolar disorder, anxiety disorder, panic attacks, attention deficit disorder, schizophrenia, autism, Tourette's syndrome, fibromyalgia and obsessive compulsive disorder. Serious central nervous system disorders such as these should not be self-medicated or self-diagnosed. Individuals who suffer from those disorders are best treated under the supervision of a health care provider.

Why a search warrant?

Health Canada's responsibility is to monitor drugs sold in Canada for safety and effectiveness. We require that drug manufacturers provide us with scientific evidence that demonstrates the drug is safe, effective and of acceptable quality. We have indicated to Truehope and Synergy on more than one occasion that we would evaluate any health benefits that may be offered by Empowerplus through a new drug submission. A new drug submission has never been filed and Truehope and Synergy continue to illegally sell the drug in Canada. Health Canada has informed Synergy and Truehope that the advertising and sale of Empowerplus contravenes the Food and Drugs Act and Regulations and that Empowerplus poses potential risks to public health.

Because Synergy and Truehope have not complied with requests to stop selling Empowerplus without first demonstrating its safety and effectiveness in a new drug submission, Health Canada is now increasing compliance and enforcement activities and taking steps to mitigate the risk to the Canadian public from the sale of this unapproved drug.

Under the Criminal Code, an inspector may be authorized by a search warrant issued by a Justice of the Peace or a Judge to conduct a search of premises where it is believed evidence of an offence may be located. It is Health Canada’s belief that evidence of offences under the Food and Drugs Act and Regulations will be found at this Raymond, Alberta address.

In this case, Health Canada inspectors and members of the RCMP have entered the premises to conduct a search for various business records, both paper and electronic, related to the sale of Empowerplus. Inspectors are also searching for media, electronic and printed promotional materials related to the advertising and sale of Empowerplus.

As required by the Criminal Code, Health Canada will return to a Justice of the Peace or Judge to report back on any articles that may be seized under this warrant.

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Health Canada recognizes the difficult circumstances faced by people with serious central nervous system conditions, and understands that some may have been using Empowerplus. In recognition of the seriousness of this issue, we have been working to provide those individuals with appropriate referral options to health care professionals and services through a toll-free health assistance referral line.

The Health Canada toll-free telephone line is 1-800 504-4156.

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Date Modified: 2003-07-15