

Minister of Health,
Minister of Intergovernmental Affairs
and Minister responsible for Official Languages



Ministre de la Santé,
ministre des Affaires intergouvernementales
et ministre responsable des langues officielles

Ottawa, Canada K1A 0K9

JUN 16 2004

Ms. Anne Rochon Ford
Women and Health Protection
P.O. Box 291, Station Q
Toronto, Ontario M4V 2M1

Dear Ms. Rochon Ford:

Thank you for your correspondence of January 22, 2004, concerning an advertising campaign on the promotion of cholesterol testing. I regret the delay in responding.

The campaign in question is a help-seeking message. *The Distinction Between Advertising and Other Activities* policy, on Health Canada's Web site at www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/advsactv_e.html, outlines the requirements to develop help-seeking messages of a non-promotional nature. The *Food and Drugs Act* and Regulations do not apply to non-promotional material. Under the Act, advertising is defined as including "any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device." In this case, neither a specific drug product nor a drug manufacturer's name is mentioned. Also, the message does not recommend the use of a specific cholesterol-lowering prescription drug or of any drug at all. Therefore, it cannot be determined that this message is a drug advertisement, will lead to unnecessary drug use or cause direct harm to a consumer. However, the message should lead to a medical consultation, where an appropriate treatment will be recommended to the patient.

Developing and financing such campaigns is not problematic when policy requirements are met. The use of a generic statement "Sponsored by one of Canada's research-based pharmaceutical companies" instead of naming a specific pharmaceutical company, which would lead to the indirect identification of a specific drug product, is acceptable if manufacturers provide information on a disease or medical condition rather than promote the sale of their drug products. The inclusion of such a statement is not

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misleading. Rather, it identifies to consumers that the message is sponsored by a pharmaceutical company. Nevertheless, Health Canada will be reviewing this issue, especially the alleged concerns about potential misleading claims on cardiovascular risks and exaggeration of cholesterol's risks among those without previous heart or vascular disease. A violation to the *Food and Drugs Act* and Regulations has not been determined. Should you agree to refer your complaint to the manufacturer, please submit your written consent to:

Manager, Regulatory Advertising and Risk Communications
Marketed Health Products Directorate
Tunney's Pasture
Ottawa, Ontario K1A 0K9

Facsimile: (613) 948-7996

I note that you provided a copy of your correspondence to the Advertising Standards Canada who administers the *Canadian Code of Advertising Standards*. Should you wish to appeal its decision, you may contact:

Ms. Janet Feasby
Director, Communications and Public Affairs
Standards Division
1801-175 Bloor Street East, South Tower
Toronto, Ontario M4W 3R8

Telephone: (416) 961-6311, extension 243
Facsimile: (416) 961-7904

Health Canada is reviewing its health protection legislation to replace outdated statutes with a new health protection legislative regime, better adapted to modern technology and society. The public consultations on the renewal of the health protection legislation included consultations on direct-to-consumer advertising. Providing balanced, objective information to consumers is important so that they may make informed decisions about their health. The health and safety of Canadians are the primary considerations in assessing the various options in this area. More information on Health Protection Legislative Renewal is available on the following Web site at: www.hc-sc.gc.ca.

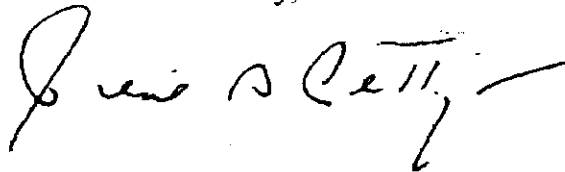
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My department strives to ensure that health risk factors to Canadians are minimized while the safety provided by the regulatory system is maximized. This necessarily encompasses ensuring that messages disseminated to Canadians are accurate, truthful, and not misleading.

Thank you for bringing this matter to my attention.

Sincerely,

A handwritten signature in dark ink, appearing to read "Pierre S. Pettigrew", with a long horizontal stroke extending to the right.

Pierre S. Pettigrew