

Office of the Minister
of Health



Cabinet de la ministre
de la Santé

Ottawa, Canada K1A 0K9

JUN - 8 2005

Ms. Anne Rochon Ford
Coordinator
Women and Health Protection
P.O. Box 291, Station Q
Toronto, Ontario M4T 2M1

Dear Ms. Ford:

Thank you for your correspondence of March 31, 2005, addressed to the Honourable Ujjal Dosanjh, Minister of Health, concerning advertising of the drug Xenical.

Health Canada is opposed to any advertising campaigns that pose a risk to public health and violate the *Food and Drugs Act*. The *Food and Drugs Act* defines advertising as “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.” The advertisements in question do not mention a specific product or manufacture and are thus within the boundaries of the *Food and Drugs Act*.

In the Therapeutic Products Programme policy titled, “The Distinction Between Advertising and Other Activities”, help-seeking announcements are defined as announcements that ask patients among the general public having a particular medical disorder, or that experience a given set of symptoms, to consult a physician for discussion of treatment, or to call a 1-800 telephone number for further information. These type of messages are considered non-promotional when there is no specific drug mentioned, no drug manufacturer named, and no implication that the drug is the sole treatment available for the specified disease or condition. These messages are not subject to the advertising provisions of the *Food and Drugs Act* and Regulations.

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From a regulatory perspective, a violation of the *Food and Drugs Act* has not been noted. However, Health Canada will bring this matter to the attention of the regulated party and invite them to re-consider this campaign from an ethical perspective. Although the ad does not mention a specific product, it is of poor taste and may offend the Canadian population, particularly women.

Health Canada's primary objective is to ensure that Canadians are not exposed to undue health risks. All therapeutic products have benefits and risks associated with their use. Health Canada has not, to date, been provided with evidence of health risks directly linked to the announcements. Health Canada's regulatory requirements state that drug manufacturers maintain the most up to date safety information on their health products, which is communicated to health professionals and consumers in the official Canadian Product Monograph for each product. Health Canada carefully weighs the benefits of a health product against its potential risk. This is reflected in the provision of adequate information for physicians and patients to make informed choices. The provision of general health product information or advice on an individual patient's therapy are part of the practise of medicine, pharmacy, or other health professions, which are regulated by provincial and territorial governments.

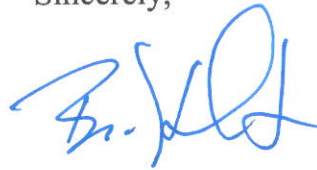
The current advertising regulatory provisions for prescription drugs do not allow any representation other than name, price and quantity when directed to consumers. This means that no information on the benefits of a prescription drug, as well as no representation of the risks can be presented in a help-seeking announcement directed at the general public.

Health Canada is reviewing and evaluating the current legislation to see whether the public is still adequately protected, and to ensure that Canadians have access to objective information on health products. In 2003 and 2004, Health Canada conducted national consultations on a proposal to renew its health protection legislation. Some of those consultations focussed specifically on the issue of health product promotion. The Department put forward several options on direct-to-consumer advertising, which generated valuable feedback from the public. Now that the consultations have completed, the Department is finalizing its analysis of issues of importance to Canadians with respect to the Health Protection Legislation Renewal proposal. It is key that a system is

developed whereby balanced and objective information is presented to the public in the delivery of direct-to-consumer advertising. Maintaining and improving the health of Canadians is always the priority of Health Canada.

I appreciate having had this opportunity to respond to your concerns.

Sincerely,

A handwritten signature in blue ink, appearing to read "Brian Klunder". The signature is stylized with a large initial "B" and "K".

Brian Klunder
Policy Advisor