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SUBJECT: Withdrawal of Project 1474 (Schedule A claims) and introduction of Project 1539 (Schedule A revision and claims)

Dear Madam/Sir:

This is to inform you of Health Canada's change in approach for allowing claims presently prohibited by the *Food and Drugs Act* in the labelling and advertising of non-prescription drugs and natural health products (NHPs).

Explanation of Schedule A and section 3

Subsections 3(1) and 3(2) (*section 3*) of the *Food and Drugs Act* prohibit the labelling and advertising to the general public of food, drugs, cosmetics, or medical devices for the prevention, treatment, or cure of any of the diseases, disorders, or abnormal physical states (*diseases*) listed in Schedule A to the *Food and Drugs Act*.

Change in approach

Health Canada will withdraw Project 1474, the regulatory proposal to permit non-prescription drugs and NHPs to carry prevention and treatment claims for Schedule A diseases, if the products have undergone pre-market review and have received market authorization for those claims. In its place, Health Canada will introduce Project 1539, a regulatory proposal that achieves the original intent of Project 1474 and, in addition, revises the list of diseases in Schedule A.

Project 1539

Project 1539 is a regulatory amendment that proposes to revise the list of diseases in Schedule A, and to exempt non-prescription drugs and NHPs from the prevention prohibitions in section 3. All claims must undergo pre-market review and receive market authorization.

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The first part of Project 1539 (Schedule A) would be revised to list only diseases which meet one or more criteria identified by a Scientific Advisory Panel. The results of the Scientific Advisory Panel are posted on Health Canada's web site at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/sci-consult/fda-lad-a/sapscha_rop_gcsaa_crd_2005-09-21_e.html. As a result, non-prescription drugs and NHPs would be permitted to carry approved prevention, treatment, or cure claims in labelling and advertising for diseases which are no longer listed in Schedule A.

The second part of Project 1539 (Approved prevention claims) would be permitted in labelling and advertising for non-prescription drugs and NHPs for the diseases that remain in Schedule A.

Reason for change from Project 1474 to Project 1539

In September 2005, Health Canada convened a Scientific Advisory Panel to examine Schedule A diseases. In November 2005, Health Canada pre-published Project 1474 in *Canada Gazette*, Part I. In March 2006, the Scientific Advisory Panel recommended revisions to Schedule A. When Health Canada considered the recommendations, it became evident that revisions to Schedule A should take place before or at the same time that any prohibitions for Schedule A diseases were lifted. Furthermore, this position is supported by comments received during the *Canada Gazette*, Part I, consultation period for Project 1474. Consequently, Health Canada will withdraw Project 1474 and, at the same time, will propose Project 1539, which revises the list of Schedule A diseases as recommended by the Scientific Advisory Panel, and permits prevention claims for the remaining Schedule A diseases.

This one-step regulatory approach continues to sustain Health Canada's long held policy position that direct-to-consumer advertising should not be allowed for prescription drugs and drugs that treat or cure serious diseases.

Timing of change in approach

The withdrawal of Project 1474 and the pre-publication of Project 1539 are planned to occur at the same time in *Canada Gazette*, Part I, targeted for Spring/Summer 2007. Project 1539 will allow for a 75-day comment period at that time on both parts of the project.

Yours sincerely,

Original signed by

Neil Yeates
Assistant Deputy Minister