

Changes to Schedule “A” to Canada’s Food and Drugs Act Come Into Force June 1, 2008

On December 26, 2007, Health Canada published amendments to the *Food and Drugs Act*, *Food and Drugs Regulations*, *Medical Device Regulations* and *Natural Health Product Regulations*, which have the effect of changing allowable claims for those health products that may be advertised in Canada. (As has always been the case, prescription drugs are not permitted to be advertised to the public in Canada.)

Schedule “A” to the *Food and Drugs Act* is a list of diseases, disorders and abnormal physical states which have been appended to the *Food and Drugs Act* since its initial passage in 1934. It is a list of diseases and conditions which are considered to serious for self-diagnosis and treatment. As a result, the *Food and Drugs Act* has always provided, at Section 3(2), that no one may advertise a food, drug, cosmetic or device to the general public for any of the items listed on Schedule “A”.

After many years of lobbying, the list has finally been modernized by the regulatory change appearing in *Canada Gazette Part II* (SOR/2007-288) of December 13, 2007. The most important change is that claim to the prevention of the diseases and conditions listed in Schedule “A” will now be permitted for OTC drugs and natural health products. Claims to prevent Schedule “A” diseases remain prohibited for medical devices, cosmetics and foods.

Simultaneously, by SOR/2007-289, certain amendments have been made to modernize Schedule “A” itself (the *Act* permits the modification of its schedules by regulation), removing conditions with antique names, adding and deleting certain other conditions, and restricting the prohibition to the acute form of certain other conditions.

The result of this is that OTC drug and natural health product manufacturers in Canada will now be permitted to make more preventative claims, and a broader range of claims, without running afoul of the prohibition in *Food and Drugs Act* Section 3(2) regarding Schedule “A”.

In a more recent development, on April 8, 2008, the government introduced a new Bill, C-51, which proposes to make extensive changes to the *Food and Drugs Act* itself and other corresponding legislation. The changes would include a complete repeal of all schedules to the *Food and Drugs Act* (including Schedule “A”), increased recall powers and higher penalties, a tremendous increase in regulation making authority, an apparent removal of the DTC advertising ban, and, less controversially, the wholesale modernization of the drug, device and food approval regime.

Given the minority status of the Conservative government, the fact that this bill has only received first reading and has not yet been studied by committees, it is difficult to know whether the changes proposed in Bill C-51 will become law.