Canada Gazette
Welcome to the official newspaper of the Government of Canada published since 1841

Vol. 139, No. 47 — November 19, 2005

Regulations Amending Certain Regulations Made under the Food and Drugs Act

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Description

This regulatory amendment proposes to amend the *Food and Drug Regulations* and the *Natural Health Products Regulations* to exempt drugs not listed on Schedule F to the *Food and Drug Regulations* from the preventative and treatment prohibitions in subsections 3(1) and 3(2) of the *Food and Drugs Act*. Drugs not listed on Schedule F include non-prescription drugs under the *Food and Drug Regulations* and natural health products (NHPs) under the *Natural Health Products Regulations*.

Prescription drugs, those with ingredients listed on Schedule F, would still be required to comply with section C.01.044 of the *Food and Drug Regulations* which restricts the advertising of prescription drugs, as well as subsections 3(1) and 3(2) of the *Food and Drugs Act*. Non-prescription drugs and NHPs that have been granted market authorization by Health Canada will be permitted to carry claims regarding prevention and treatment for Schedule A diseases, disorders or abnormal physical states. As is the case now, if any of the criteria used to place a drug on Schedule F is met during the course of

the review by Health Canada of any drug or NHP submission, then the submission would be reviewed as a potential Schedule F drug.

Schedule A and section 3 of the *Food and Drugs Act*

Schedule A of the *Food and Drugs Act* is a list of diseases, disorders or abnormal physical states. There are two components to the current section 3 prohibition on Schedule A claims. First, section 3 of the *Food and Drugs Act* prohibits the advertising of any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A. Second, it prohibits the sale to the general public of any food, drug, cosmetic or device that is labelled as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Schedule A and section 3 were added to the *Food and Drugs Act* in 1934 to prevent fraud in advertising and labelling, to prohibit the advertisement and sale of treatments for conditions where no treatment is known to medical science, to prohibit the advertisement and sale of treatments where self-treatment is not considered safe (such as sexually transmitted diseases), and to encourage people to seek medical attention for serious conditions (such as cancer, epilepsy, or heart disease).

The amendment reflects the fact that while the original objectives of Schedule A and section 3 are still valid (i.e. preventing fraudulent or misleading health claims in advertising or labelling, and ensuring that patients seek medical attention for serious diseases), they are addressed through other provisions of the *Food and Drugs Act* and Regulations.

The proposed amendment is consistent with evolving scientific knowledge and the overall health and safety protection provided to Canadians through the *Food and Drugs Act* and Regulations, while supporting informed choice for non-prescription drugs and NHPs. Advertising of Schedule F drugs will continue to not be permitted through the general prohibition in the *Food and Drug Regulations* as well as through subsections 3(1) and 3(2) of the *Food and Drugs Act*.

Some of the original health protection afforded by Schedule A and subsections 3(1) and 3(2) is also addressed in legislation and regulations. For example,

- section 9 of the *Food and Drugs Act* addresses the issue of fraud in advertising and labelling by prohibiting the fraudulent promotion of drugs; and
- section C.01.044 of the *Food and Drug Regulations* helps address the issue of patients not seeking medical attention for serious diseases. Section C.01.044 of the *Food and Drug Regulations* prohibits Direct to Consumer Advertising (DTCA) of prescription drugs, i.e. drugs listed on Schedule F. The determination for prescription status of drugs is made by the Health Canada's Drug Schedule Status Committee. This assessment is made on the basis of established and publicly available criteria. These criteria include, but are not limited to, concerns related to toxicity, pharmacological properties and therapeutic uses of the ingredients. By prohibiting labelling and advertising of these drugs to the general public, patients would more likely obtain information about prescription drugs from their medical practitioner.

In addition, the following have been introduced.

Pre-market review

To help protect the Canadian public from unsafe and ineffective health products, the *Food and Drug Regulations* and the *Natural Health Products Regulations* require that all drugs, including non-prescription drugs and NHPs, undergo a review by Health Canada prior to being granted market authorization. The review is based on scientific data in the form of safety data, efficacy data and quality data in an application to Health Canada for market authorization. Furthermore, claims or indications made on the label must be in keeping with the scientific evidence provided in the application. As further protection, marketed products carrying any claims that are contrary to those for which a market authorization was granted are in violation of the *Food and Drugs Act* and Regulations and therefore would come under the compliance and enforcement authority of the Regulations as exercised by the Health Products and Food Branch Inspectorate.

Non-prescription drugs and NHPs are regulated as self-care products. If, in reviewing an application for either a Drug Identification Number (DIN) or a Natural Product Number (NPN), there is evidence that the product is not suitable for self-care, i.e. it appears that any of the factors for Schedule F designation could apply, then the product would be reviewed as a potential Schedule F drug, and if added to Schedule F, would be subject to subsections 3(1) and 3(2) of the *Food and Drugs Act*.

The pre-market review requirements are found in sections C.01.014 and C.08.003 of the *Food and Drug Regulations* for drugs, and section 4 of the *Natural Health Products Regulations* for NHPs.

Natural Health Products Regulations

Although NHPs fall within the definition of drug in the *Food and Drugs Act*, it was recognized that these products would benefit from a regulatory framework more suitable to the relatively low risk associated with these types of products. In 2004, the *Natural Health Products Regulations* were promulgated. These Regulations are a comprehensive framework which includes site licensing, good manufacturing practices, and product licensing (i.e. an NPN is issued) based on safety, efficacy and quality data. It also includes provisions for clinical trials, and labelling and packaging.

Advertising

Health Canada develops policies and guidances for the interpretation of section 9 of the *Food and Drugs Act* and its regulations. Health Canada oversees advertising activities in collaboration with accredited organizations which monitor advertising.

Advertising Standards Canada (ASC) administers the *Canadian Code of Advertising Standards* (the Code). ASC reviews advertising material for non-prescription drugs and NHPs. This voluntary system of pre-clearance is carried out in conjunction with the compliance and enforcement powers of Health Canada. The Code sets the criteria for acceptable advertising and forms the basis for evaluation when addressing complaints.

In the case of drugs, advertising must always be consistent with the terms of market

authorization or the authorized labelling material. Any changes in labelling will have an impact on advertising, and consequently, permissible claims must be the same for labelling and advertising.

Why the proposed amendment does not include foods

Food is not addressed through the proposed regulatory amendment for two reasons. First, there is already an exemption from section 3 of the *Food and Drugs Act* for food product labels or advertising pertaining to three specific health claims prescribed in the *Food and Drug Regulations*. Second, in order to inform Canadians about research demonstrating the role that certain foods play in reducing the risk of occurrence of certain diseases or disorders, Health Canada has announced in the fall 2005 *Smart Regulation Report on Actions and Plans* (RAP) that it intends to develop a new regulatory framework for the use of food labels and advertising as a means of delivering this important health information to the public, in consultation with stakeholders and the public. As outlined in the RAP, the proposed new regulatory framework for product-specific health claims for foods will set out the conditions for permitting, on a product-by-product basis, certain types of claims and disease risk reduction claims currently considered drug claims. Health Canada has targeted 2007 for the completion of this regulatory framework.

Health protection legislative renewal

Health Canada is currently reviewing all of its health protection legislation—with a view to preparing new legislation, and subsequently regulations—that will address the needs of Canadians today and in the future. This includes consideration of how best to achieve the objectives of Schedule A and section 3 of the current *Food and Drugs Act*.

Alternatives

1. Status quo

Description

- With few exceptions, subsections 3(1) and 3(2) prohibit certain claims for about 40 diseases, disorders or abnormal physical states that are listed on Schedule A.

Pros

- The original intent of Schedule A and section 3 would be retained as a health protection mechanism.

Cons

- Manufacturers that have provided Health Canada with adequate evidence of the safety, quality and efficacy of their self-care products are prohibited from labelling and advertising for a Schedule A disease, disorder or abnormal physical state.
- The status quo limits the ability of Canadians to make informed decisions about their health because they may not be aware of the benefits of self-care products.

2. To amend the Regulations to exempt from subsections 3(1) and 3(2) risk reduction and symptomatic treatment claims for all drugs

Description

- This would permit risk reduction and symptomatic treatment claims to be made for all drugs and all NHPs that have been granted DINs and NPNs unless otherwise prohibited elsewhere in regulation.

Pros

- Manufacturers would be permitted to advertise nonprescription drugs and NHPs to the general public for risk reduction and symptomatic treatment claims.
- The Canadian public would be able to make informed choices about self-care products.

Cons

- The phrases "risk reduction" and "symptomatic treatment" are not commonly understood nor easily defined. In addition, in contrast to the proposed amendment, this narrow exemption would only permit consumers to obtain information about a very select type of claim.
- This proposed amendment would remove one of the barriers to DTCA for high-risk drugs listed on Schedule F to the *Food and Drug Regulations*.

3. Recommendation: Proposed regulatory amendment

The recommended option is to exempt drugs, including NHPs, not listed on Schedule F of the *Food and Drug Regulations* from the preventative and treatment prohibitions in subsections 3(1) and 3(2) of the *Food and Drugs Act*.

This recommendation would allow the Canadian public to be informed through advertising and labelling about benefits associated with all self-care products that have been granted market authorization by Health Canada.

Benefits and costs

Public

Benefits

- Claims associated with products for which manufacturers have been granted market authorization by Health Canada would be shared with the Canadian public through advertising and labelling. Therefore, consumers would have increased access to science-based information through advertising and labelling regarding the self-care products they use. This would provide consumers with an increased ability to make informed choices about their health.
- This proposed amendment is in keeping with the following guiding principles outlined in the External Working Group's Majority Report on Schedule A and

section 3, as posted on the Health Canada Web site: optimize health outcomes, improve access to validated health information, and facilitate responsible self-care.
- This amendment reflects the Canadian public's desire to participate in and make informed decisions about their health care. It permits consumers to have greater awareness of potentially beneficial health products.
- A Canadian public better informed about self-care products may have less need to use the health care system.

Costs

- Advertising is not the ideal way for the public to obtain complete and unbiased information because manufacturers will provide only enough information to sell the product. However, this cost must be weighed against the benefit of the public obtaining, through advertising and labelling, evidence-based information as reviewed by Health Canada**.**

Government

Benefits

- This amendment may result in less strain being put on provincial health care plans because the Canadian public may be more aware of the benefits of self-care.

Costs

- Schedule A has been a straightforward way for government inspectors to gauge regulatory compliance: if a Schedule A claim appears on a product, its manufacturer would be subject to investigation. This amendment would remove that standard, forcing in some cases a more complex investigation to determine if the claims on the label are in keeping with those for which market authorization was granted.
- Currently, Health Canada policies use any reference to Schedule A diseases, disorders or abnormal physical states in advertising or on labels as one criterion for compliance and enforcement actions. Therefore, compliance and enforcement policies and consumer advertising guidances would need to be amended.

Industry

Benefits

- Industry could benefit from a potential increase in sales of compliant self-care products for diseases, disorders or abnormal physical states listed on Schedule A.

Costs

- There is no additional cost to industry.

Consultation

- 2002-2003: In 2002, Health Canada convened an Internal Working Group on Schedule A. In February 2003, the group produced *Schedule A and Section 3: Guidance Document* in order to clarify to stakeholders the intent and Health Canada's interpretation of the statute. This Guidance Document was posted on the Health Canada Web site.
- 2002-2004: In 2002, Health Canada convened an External Working Group (EWG) on Schedule A, comprised of representatives from government and regulatory groups, professional associations, consumer/advocacy groups, advertising, media, foods, and health products and medical devices. The EWG was mandated (1) to develop criteria for determining Schedule A diseases, (2) to review Schedule A diseases, and (3) to recommend modifications to or elimination of Schedule A and section 3. The EWG submitted a Majority Report and a Minority Report in January 2004, and both EWG Reports were posted on the Health Canada Web site. Both reports were considered in this proposed regulatory amendment.
- In February 2005, Health Canada met with the EWG and committed to convening a Scientific Advisory Panel (SAP) to develop criteria to be used to revise Schedule A and to propose revisions to Schedule A using these criteria. At the same time, Health Canada committed to proposing a regulatory amendment to permit risk reduction and symptomatic treatment claims for diseases, disorders or abnormal physical states listed on Schedule A.
- The SAP was convened on September 21, 2005. It was composed of experts from a range of health care specialities, including homeopathy, naturopathy, medicine, pharmacy, nutrition, advertising, and patient advocacy. In addition to the work outlined above, it was also tasked with examining the intent of subsections 3(1) and 3(2) and Schedule A to determine what other options were now available in regulations to fulfill the intent of the legislation.
- The Record of Proceedings of the September meeting of the SAP will be posted on the Health Canada Web site in early November 2005.

Compliance and enforcement

This amendment does not alter existing compliance authorities under the provisions of the *Food and Drugs Act* and Regulations enforced by the Health Products and Food Branch Inspectorate. However, compliance and enforcement policies and guidances would need to be amended.

Contact

Project No. 1474, Policy Division, Policy Bureau, Therapeutic Products Directorate, Holland Cross, Tower B, 2nd Floor, 1600 Scott Street, Address Locator 3102C5, Ottawa, Ontario K1A 0K9, (613) 948-4623 (telephone) [Please refer to Project No. 1474.], (613) 941-6458 (fax) [Please refer to Project No. 1474.], regaff_access@hc-sc.gc.ca (email).

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to section 30 (see footnote a) of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending*

Certain Regulations Made under the Food and Drugs Act.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Project #1474, Policy Division, Policy Bureau, Therapeutic Products Directorate, 1600 Scott Street, Holland Cross, Tower B, 2nd floor, Address Locator 3102C5, Ottawa, Ontario K1A 0K9 (tel.: (613) 948-4623; fax: (613) 941-6458; e-mail: regaff_access@hc-sc.gc.ca), with a reference to Project #1474.

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, November 14, 2005

DIANE LABELLE
Acting Assistant Clerk of the Privy Council

REGULATIONS AMENDING CERTAIN REGULATIONS MADE UNDER THE FOOD AND DRUGS ACT

FOOD AND DRUG REGULATIONS

1. The *Food and Drug Regulations* (see footnote 1) **are amended by adding the following after section A.01.065:**

Prohibited Advertising

A.01.066. A drug, other than a drug that is listed or described in Schedule F to these Regulations, is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a treatment or preventative for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

Prohibited Label or Advertisement Where Sale Made

A.01.067. A drug, other than a drug that is listed or described in Schedule F to these Regulations, is exempt from subsection 3(2) of the Act with respect to its sale by a person where the drug is represented by label or is advertised by that person to the general public as a treatment or preventative for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

2. Section C.01.010 of the Regulations is replaced by the following:

C.01.010. Where it is necessary to provide adequate directions for the safe use of a drug that is listed or described in Schedule F to these Regulations and that is used in the treatment or prevention of any disease, disorder or abnormal physical state referred to in

Schedule A to the Act, those diseases, disorders or abnormal physical states may be mentioned on the labels and inserts accompanying that drug and, to that extent, that drug is exempt from the provisions of section 3 of the Act.

NATURAL HEALTH PRODUCTS REGULATIONS

3. The portion of subsection 93(1) of the *Natural Health Products Regulations* (see footnote 2) **before paragraph (*a*) is replaced by the following:**

93. (1) Subject to section 3 of the Act and sections 94, 103.2 and 103.3, the inner and outer labels shall show the following information in respect of a natural health product:

4. The portion of subsection 94(1) of the Regulations before paragraph (*a*) is replaced by the following:

94. (1) Subject to section 3 of the Act and sections 103.2 and 103.3, a natural health product shall be labelled as follows if the immediate container is not large enough to accommodate an inner label that complies with the requirements of section 93:

5. The Regulations are amended by adding the following after section 103.1:

Prohibited Advertising

103.2 A natural health product is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a treatment or preventative for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

Prohibited Label or Advertisement Where Sale Made

103.3 A natural health product is exempt from subsection 3(2) of the Act with respect to its sale by a person where the natural health product is represented by label or is advertised by that person to the general public as a treatment or preventative for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

COMING INTO FORCE

6. These Regulations come into force on the day on which they are registered.

[47-1-o]

Footnote a

S.C. 2004, c. 23, s. 2

Footnote 1

C.R.C., c. 870

Footnote 2

SOR/2003-196

NOTICE:
The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

Top of page

Maintained by the Canada Gazette Directorate
Important notices
Updated: 2005-11-18