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Regulations Amending Certain Regulations Made under the Food and Drugs Act (Project 1539)

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

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

Description

Overview of the regulatory proposal

This regulatory Amendment proposes to amend the *Food and Drug Regulations* (FDR) and the *Natural Health Products Regulations* (NHPR)

(1) to revise the list of Schedule A diseases; and

(2) to exempt natural health products (NHPs) and certain drugs from the prohibition on preventative claims for the remaining diseases listed in Schedule A.

All other provisions of the *Food and Drugs Act* (FDA), the *Controlled Drugs and Substances Act* (CDSA), and their regulations would continue to apply.

(1) Revising the list of Schedule A diseases

Schedule A to the FDA is a list of diseases, disorders or abnormal physical states (hereafter referred to as diseases) for which preventative, treatment, and cure claims are prohibited by subsections 3(1) and 3(2) of the FDA (hereafter referred to as section 3) in the labelling and advertising to the general public of any food, drug, cosmetic, or medical device.

The broad terms "preventative" and "treatment" that are used in the FDA have been interpreted by Health Canada to include "risk reduction" and "symptomatic treatment," respectively. Therefore, preventative, risk reduction, treatment, symptomatic treatment, and cure claims are currently prohibited in labelling and advertising any food, drug, cosmetic, or medical device to the general public for diseases listed in Schedule A.

Examples of Schedule A diseases are cancer, appendicitis, gout, and heart disease. So far there has been no comprehensive list of criteria by which diseases can be added to or removed from the Schedule A list, as there is for the Schedule F list, in the FDR, of ingredients that are required by section C.01.041(1.1) of the latter regulations to be sold under prescription (the "Factors for listing drugs in Schedule F" are posted on Health Canada's Web site).

The regulatory proposal would revise Schedule A to list diseases which meet one or more criteria identified by a scientific advisory panel of experts. More details on this scientific advisory panel is provided under the next heading in this statement. The criteria used to populate the Schedule A list with diseases would be outlined in policy as it is done with the criteria used to populate the Schedule F list in the FDR. Criteria are a transparent mechanism to help ensure consistency in decisions with respect to inclusion and exclusion of diseases in Schedule A. If a disease does not meet any of the criteria, it will be removed from the Schedule A list. When a disease is removed from Schedule A, all products covered by section 3 (food, drugs, cosmetics, and medical devices) would no longer be subject to the preventative, treatment, and cure prohibitions for that disease. All these products would continue to be subject to all other provisions in the FDA, the CDSA, and their regulations; therefore, any other restrictions on the labelling and advertising of claims or any conditions for market authorization of these products remain in place.

(2) Exempting NHPs and certain drugs from the prohibition on preventative claims for the diseases remaining in Schedule A

Section 3 of the FDA contains the labelling and advertising prohibitions for Schedule A diseases. Section 3 prohibits the advertising of any food, drug, cosmetic, or medical device to the general public as a preventative, treatment, or cure for any of the diseases referred to in Schedule A. Section 3 also prohibits the sale of any food, drug, cosmetic, or medical device that is labelled or advertised to the general public as a preventative, treatment, or cure for any of the diseases referred to in Schedule A.

The regulatory proposal would exempt NHPs and certain drugs from the preventative components of the section 3 prohibition for diseases remaining in Schedule A (preventative prohibition).

Drugs not included in the exemption proposed by this regulatory amendment are

- those listed or described in Part I or II of Schedule F to the FDR, with the exception of veterinary-use drugs listed in Part II to Schedule F, so long as the drug is in a form not suitable for human use or is labelled for veterinary use only; and
- drugs included in any of Schedules I through V to the *Controlled Drugs and Substances Act* (CDSA).

Both categories of drugs exempted from the scope of this regulatory proposal are already subject to a high degree of regulatory rigour, including extensive restrictions on sale and advertising to the general public. Section C.01.044 of the FDR restricts the advertising to the general public of Schedule F drugs (with the exception of veterinary-use drugs listed in Part II to Schedule F, so long as the drug is in a form not suitable for human use or is labelled for veterinary use only) to only brand name, proper name, common name, price, and quantity of the drug. The advertising to the general public of controlled drugs is prohibited by section 70 of the *Narcotic Control Regulations*, section G.01.007 of the FDR, and section 3 of the *Benzodiazepines and Other Targeted Substances Regulations*.

There is also already a high level of practitioner oversight required in the sale and distribution of both categories of drugs exempted from the scope of this proposed regulatory amendment. Schedule F drugs (with the exception of veterinary-use drugs listed in Part II to Schedule F, so long as the drug is in a form not suitable for human use or is labelled for veterinary use only) generally must be sold pursuant to a prescription. Likewise, controlled substances must only be administered, sold, or provided to a patient under prescription from a practitioner according to the CDSA and its regulations. A controlled substance is a substance that can alter mental processes and that may produce harm to health and to society when distributed or used without supervision.

Accordingly, it is not appropriate to exempt drugs from either of the two categories described above from the preventive prohibition in section 3 of the FDA; thus, drugs from these two categories are not included in the exemption proposed by this regulatory amendment.

NHPs and drugs that are subject to this regulatory proposal would be permitted to carry preventative claims in labelling and advertising to the general public for diseases that remain in Schedule A. These products continue to be subject to all other provisions in the FDA, the CDSA, and their regulations; therefore, any other restrictions on the labelling and advertising of claims or any conditions for market authorization of these products remain in place.

The rationale for proposing that NHPs and those drugs that are subject to this regulatory proposal be permitted to carry preventative claims is that these NHPs and drugs are subject to a much lower level of regulatory rigour, and prevention claims with respect to these products do not require the same level of regulatory rigour as treatment or cure claims. For these NHPs and drugs, the prevention of a Schedule A disease generally does not require practitioner intervention, but the treatment or cure of a Schedule A disease would. "Practitioner" is defined in section C.01.001(1) of the FDR, an example of such being a physician.

Reason for the regulatory proposal

Schedule A and its accompanying prohibition section 6A, the predecessor of section 3,

were added to the FDA in 1934. Section 6A stated that

"No person shall import, offer for sale, or sell any remedy represented by label or by advertisement to the general public as a treatment for any of the diseases, disorders or abnormal physical states named or included in Schedule A to this Act or in any amendment to such Schedule."

In 1946, section 6A was revised to state that

"No person shall import, offer for sale, or sell any food or drug represented by label or by advertisement to the general public as a treatment for any of the diseases, disorders or abnormal physical states named or included in Schedule A to this Act or in any amendment to such Schedule."

In 1952, section 6A was renumbered to section 7. In 1953, section 7 was replaced by section 3, which stated that

"3.(1) No person shall advertise 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 mentioned in Schedule A.

3.(2) No person shall sell any food, drug, cosmetic or device

(*a*) that is represented by label, or

(*b*) that he advertises to the general public

as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states mentioned in Schedule A."

In 1934, the Canadian public needed the health protection provisions of Schedule A and section 6A. The purposes of section 6A were (1) to discourage self-treatment by the general public, which would delay or replace medical treatment for diseases listed in Schedule A; (2) to encourage the general public to seek the advice of a doctor, or some other qualified health professional, prior to obtaining treatment and medication for serious diseases and/or conditions; and (3) to make unnecessary the proof in each case that a food or a drug is either unsafe or valueless for the treatment of one of the serious diseases or conditions listed in Schedule A.

In 1953, section 7 was replaced by section 3 because, while section 7 had been useful and effective, it had been subject to arguments as to whether or not certain practices were clearly within its intent and were within its current language. One of the practices considered to have been within the intent of the 1953 FDA was the prohibition against the advertising of a food or a drug to the general public as a treatment for any of the Schedule A diseases. Subsection 3(1) was therefore added as a separate prohibition that did not tie the advertising of a product to its sale. The prohibitions against sale to the general public were strengthened by further restricting the kinds of representations that could be made regarding efficacy. Whereas previously only the labelling and advertising of a specific product as a treatment was prohibited, the labelling and advertising of a specific product as a preventative or cure was also prohibited. Section 3 clarified the type

of products that could neither be advertised to the general public nor sold to the general public if so labelled or advertised. Whereas previously the FDA had referred to remedies and then to food and drugs, section 3 referred to "any food, drug, cosmetic, or device" represented by label or advertised to the general public as a treatment, preventative or cure for one of the Schedule A diseases.

In 2007, the health care environment has changed substantially from when Schedule A and section 3 were added to the FDA. Medical science has advanced, pre-market review of drugs and NHPs is required, a prescription drug regime exists, and publicly funded health care is available. In addition, and as will be discussed in greater detail below, some of the original health protections afforded by Schedule A and section 3 are now addressed in regulations. As well, information about diseases for which self-help is appropriate is increasingly available to the Canadian public who thus have the opportunity to make more informed decisions about their health. The public's desire for this approach is reflected in an increasing emphasis on alternative health care and a greater involvement of patients in their choice of treatment.

While some stakeholders oppose the restrictions of Schedule A and section 3, others feel that they serve a useful purpose but need to be modernized to reflect scientific and medical advances and to reflect the contemporary health care environment. From 2003 to 2004, Health Canada convened a Schedule A External Working Group (EWG) composed of external stakeholders to examine Schedule A and section 3. In 2004, the EWG completed a Majority Report and Minority Report. In February 2005, Health Canada made two commitments to the EWG.

Health Canada's first commitment to the EWG was to propose a regulatory amendment to remove some section 3 prohibitions for Schedule A diseases. Health Canada fulfilled this commitment in November 2005 by prepublishing in the *Canada Gazette*, Part I (CG I), Project 1474, the proposed regulatory amendment to exempt nonprescription drugs and NHPs from the preventative and treatment prohibitions of section 3. Because both Majority and Minority Reports recommended that experts review the diseases listed in Schedule A, Health Canada's second commitment to the EWG was to convene an expert scientific panel to develop criteria and review Schedule A diseases in order to reflect current scientific and medical knowledge. Health Canada fulfilled this commitment by convening a Scientific Advisory Panel (SAP) in September 2005. The SAP was tasked (1) to recommend criteria by which diseases could be added to or removed from Schedule A, and (2) to recommend revisions of Schedule A using those criteria. The final recommendations of the SAP were completed and posted on the Health Canada Web site in March 2006.

In considering the recommendations made by the SAP to revise Schedule A, it became evident that such revisions should take place before or at the same time that any section 3 prohibitions were lifted. Therefore, Health Canada modified its approach by proposing this new regulatory amendment, Project 1539, which achieves the original intent of Project 1474 by revising the list of Schedule A diseases and by removing the preventative prohibitions with respect to NHPs and certain drugs for diseases remaining in Schedule A.

Project 1474 is being withdrawn in CG I at the same time that Project 1539 is being prepublished in CG I.

Project 1539, a one-step regulatory approach, maintains Health Canada's long-held

policy position that direct-to-consumer advertising should not be allowed for prescription drugs, nor drugs that treat or cure serious diseases, as prohibited by section 3.

Details about the regulatory proposal

A. The proposed criteria to revise Schedule A

The SAP was composed of experts from a range of health care specialities, including homeopathy, naturopathy, medicine, pharmacy, nutrition, advertising, and patient advocacy. The SAP recommended the following six criteria by which diseases should be added to or retained in Schedule A; it is their criteria which underlie the revisions to Schedule A that are proposed in this regulatory amendment:

1. The condition or disease results in serious risks to individual or public health, and generally requires diagnosis, treatment and management by a health professional.

2. The disease is likely to be spread within the population without appropriate treatment.

3. There is an emergency situation during which self-care is inappropriate.

4. The severity of the disease limits the person's ability to make health decisions.

5. The disease state is recent (i.e. the disease state has only recently been recognized by medical science) and it is unclear whether or not self-treatment is appropriate.

6. The disease or condition is one which renders individuals especially vulnerable to harm (e.g. dementia, pregnancy, malnourishment).

B. The proposed revision of the Schedule A list using the criteria

The SAP used the above criteria to recommend the following revisions to Schedule A; it is their revised Schedule A list which is proposed in this regulatory amendment:

1. Delete the following 17 diseases, disorders and abnormal physical states:

- Alopecia (except hereditary androgenetic alopecia)
- Bladder disease
- Disease of the prostate
- Disorder of menstrual flow
- Dysentery
- Edematous state
- Epilepsy
- Gall bladder disease
- Gout
- Hypotension
- Impetigo
- Kidney disease
- Leukemia
- Liver disease (except hepatitis)

- Pleurisy
- Sexual impotence
- Tumor

2. Add the following 6 diseases, disorders and abnormal physical states:

- Acute infectious respiratory syndromes
- Acute psychotic conditions
- Addiction
- Dementia
- Haematologic bleeding disorders
- Hepatitis

3. Make the following 6 replacements:

Replace the reference to

- Alcoholism

with

- Acute alcoholism

Replace the reference to

- Anxiety state

with

- Acute anxiety state

Replace the reference to

- Arthritis

with

- Acute, inflammatory and debilitating arthritis

Replace the reference to

- Heart disease

with

- Congestive heart failure

Replace the reference to

- Hernia

with

- Strangulated hernia

Replace the reference to

- Venereal disease

with

- Sexually transmitted diseases

The revised Schedule A list, as recommended by the SAP, would therefore be the following 29 entries (the current Schedule A list has 40 entries). Each criterion used by the SAP to rationalize each disease listing is indicated after the disease name (the numbers 1–6 refer to the six criteria listed earlier under section "A. The proposed criteria to revise Schedule A"). This information is posted on Health Canada's Web site:

Acute alcoholism (1, 3)

Acute anxiety state (3)

Acute infectious respiratory syndromes (2, 5)

Acute psychotic conditions (3, 4)

Acute, inflammatory and debilitating arthritis (1)

Addiction (1)

Appendicitis (3)

Arteriosclerosis (1)

Asthma (1, 3)

Cancer (1, 3)

Congestive heart failure (1, 3)

Convulsions (3)

Dementia (4)

Depression (1)

Diabetes (1)

Gangrene (3)

Glaucoma (1)

Haematologic bleeding disorders (1)

Hepatitis (1, 2, 3)

Hypertension (1)

Nausea and vomiting of pregnancy (6)

Obesity (1)

Rheumatic fever (3)

Septicaemia (3)

Sexually transmitted diseases (2)

Strangulated hernia (3)

Thrombotic and embolic disorders (1, 3)

Thyroid disease (1)

Ulcer of the gastro-intestinal tract (1, 3)

C. The effect of the Schedule A revision on all products referred to in section 3 of the FDA

1. For a disease removed from Schedule A, the prohibitions in section 3 for labelling and advertising to the general public would no longer apply to food, drugs, cosmetics, and medical devices. However, all other provisions of the FDA, the CDSA, and their regulations that already apply to these products continue to apply. For example, as explained earlier, section C.01.044 of the FDR would continue to place advertising restrictions on Schedule F prescription drugs regardless of the disease which the drug is claimed to prevent, treat, or cure.

2. For a disease added to Schedule A, the prohibitions in section 3 for labelling and

advertising to the general public apply to food, drugs, cosmetics, and medical devices. As well, all other relevant labelling and advertising provisions of the FDA, the CDSA, and their regulations continue to apply.

D. Food, medical devices, and cosmetics also continue to be prohibited from carrying preventative claims in labelling and advertising to the general public for diseases remaining in Schedule A (unless otherwise permitted in other provisions in the FDA or its regulations)

1. Food

Food is not included in the preventative exemption for several reasons. First, the representation of a food for the "prevention, treatment or cure" of a disease, disorder, or abnormal physical state brings it into the definition of a drug; this would then make it subject to the drug regulations. Second, section B.01.601 of the FDR already provides that a food with a label or advertisement that carries a statement or claim set out in the table following section B.01.603 is exempt from the provisions of the FDA, including section 3, and the FDR with respect to drugs. Finally, in order to help inform the Canadian public about the role that certain foods may play in reducing the risk of certain diseases, Health Canada announced in the fall 2005 *Smart Regulation Report on Actions and Plans* (RAP) that it intends to develop new regulations for the use of food labels and advertising as a means of delivering this health information to the public. It is anticipated that Health Canada will engage in stakeholder consultation regarding these new regulations in 2007.

2. Medical devices

Medical devices are not included in the preventative exemption since Class I and II medical devices do not undergo pre-market review, nor are their claims approved by Health Canada. Class I medical devices do not have a licence requirement and are not subject to pre-market review. Class II medical devices do have a licence requirement, but are licensed by attestation of safety and effectiveness by the manufacturer. Class III and IV medical devices undergo pre-market review, but generally require the intervention of a practitioner. Some *in vitro* diagnostic devices are designated Class III for home use but, since their use is as a diagnostic (not as a preventative, treatment, nor cure), they were never subject to the section 3 prohibition.

Presently, condoms are exempt from section 3 pursuant to subsection 24(1) of the *Medical Devices Regulations* (MDR) and may be advertised and sold to the general public for the purpose of preventing the transmission of venereal disease if the advertisement and the label of the condom claim only that the condom reduces the risk of transmitting venereal diseases. Because the regulatory amendment proposes to replace the current Schedule A listing of "venereal disease" with the listing of "sexually transmitted diseases," a consequential amendment to subsection 24(1) of the MDR is required to also replace "venereal disease" with "sexually transmitted diseases."

3. Cosmetics

Cosmetics are defined in the FDA as "any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes." Cosmetics are

not permitted to carry drug claims; therefore, cosmetics are not included in the preventative exemption. If it carries drug claims, the product is either regulated as a drug or an NHP, as explained in sections 2.1 and 2.2 of the *Guidelines for Cosmetic Advertising and Labelling Claims* posted on Health Canada's Web site, and as explained in the *Guidelines for Cosmetics Manufacturers, Importers and Distributors* also posted on Health Canada's Web site.

Important components to the health protection afforded by legislation other than Schedule A and section 3

1. Section 9 of the FDA

Section 9 of the FDA prohibits false, misleading, or deceptive labelling and advertising of drugs. Furthermore, this section mandates that a drug be labelled as required by the Regulations.

2. Section C.01.044 of the FDR

Section C.01.044 of the FDR restricts advertising to the general public of Schedule F prescription drugs to only brand name, proper name, common name, price, and quantity of the drug. The provision is in part intended to encourage patients to seek medical attention for serious diseases.

The determination of drug status is made by Health Canada's Drug Schedule Status Committee subsequent to the filing of an appropriate submission and at the recommendation of the clinical review bureau. This assessment is made on the basis of established and publicly available factors which include, but are not limited to, concerns related to the pharmacodynamic, pharmacokinetic and/or toxicological profile of the drug and the nature of the proposed therapeutic use(s).

The following are the factors used by Health Canada to determine the drug schedule status for a particular drug. Drugs will be listed in Schedule F if any of the following apply (posted on Health Canada's Web site):

(*a*) individualized instructions and/or direct practitioner supervision, adjunctive therapy with scheduled drugs or routine laboratory monitoring are required;

(*b*) there is a narrow margin of safety between the therapeutic and toxic doses, especially in populations such as geriatrics, children and pregnant or nursing mothers;

(*c*) there are potential or known undesirable or severe side effects at normal therapeutic dosage levels;

(*d*) they are known by experimental data to induce toxicity in animals but have not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans;

(*e*) they are used in the treatment of a serious disease easily misdiagnosed by the public;

(*f*) their use may mask other ailments;

(*g*) they have contributed to, or are likely to contribute to, the development of resistant strains of micro-organisms in humans;

(*h*) they possess a dependence or abuse potential that is likely to lead to harmful non-medical use;

(*i*) they possess a high level of risk relative to expected benefits; or

(*j*) they have a therapeutic effect based on recently elucidated pharmacological concepts, the consequences of which have not been established.

Exceptions will be considered for drugs if any of the following apply:

(*a*) are required to be readily available under emergency circumstances where it is not practical to obtain a prescription (such as adrenalin in insect bite kits);

(*b*) are rarely used without a practitioner's supervision, and where the need for free availability outweighs the need for protection under Schedule F (such as insulin and nitroglycerin); or

(*c*) have potential to produce dangerous interactions with other drugs or food constituents but effective labelling can minimize the risk.

In its review of veterinary-use drugs, the Department also considers if any one of the above-mentioned factors or any one of the following factors are present. If so, drugs used in animals will be listed on Part I of Schedule F:

- there exists a narrow margin of safety between the therapeutic and toxic dosages when used in animals;
- they are known by experimental data to induce toxicity in animals but have not been in clinical use for a sufficient period of time to establish the pattern or the frequency of long-term toxic effects in humans;
- they are known to be liable to be diverted to humans;
- it is not possible to write directions for use that could be easily followed by a layperson;
- they may be hazardous to the handler or administrator;
- they have contributed to or may contribute to the development of resistant strains of micro-organisms in humans and to dissemination of antimicrobial resistance genes;
- they are new antibiotics for veterinary use that may be used in human medicine or that may lead to cross-resistance to antibiotics used in human medicine;
- they possess the potential for an adverse impact on the environment as it relates to public health at therapeutic dosage rates; or
- their misuse may lead to potential "moderate to high levels" of risk from residues in food of animal origin.

3. *Controlled Drugs and Substances Act*

Section 70 of the *Narcotic Control Regulations*, section G.01.007 of the FDR, and section 3 of the *Benzodiazepines and Other Targeted Substances Regulations* prohibit the advertising of controlled drugs to the general public.

A substance that can alter mental processes and that may produce harm to health and to society when distributed or used without supervision may be added to a schedule to the CDSA. When determining in which schedule to the CDSA a substance should be listed, Health Canada considers several factors, including international requirements, the dependence potential and likelihood of abuse of the substance, the extent of its abuse in Canada, the danger it represents to the safety of the public, and the usefulness of the substance as a therapeutic agent.

4. Pre-market review

To help protect the Canadian public from unsafe and/or ineffective health products, the FDR and the NHPR require that all drugs and NHPs undergo a submission review by Health Canada prior to being granted market authorization. The review is based on all the scientific data available to Health Canada on the safety of the product, its efficacy according to scientific and other types of evidence, as appropriate for the recommended use (e.g. evidence from references to traditional use or homeopathic pharmacopoeias, as permitted by the NHPR and guidance documents), and evidence that the product is of high quality. This evidence for safety, efficacy, and quality must be included in a submission to Health Canada for market authorization. Furthermore, claims or indications made on the label must be supported by the scientific evidence provided in the submission. The pre-market review requirements are found in sections C.01.014, C.08.002, C.08.002.1, and C.08.003 of the FDR, for drugs, and in sections 4 and 5 of the NHPR, for NHPs.

With respect to pre-market review of submissions with Schedule A claims, the standard of evidence applied will depend upon the level of risk associated with the inherent safety of the product and the nature of the Schedule A claim being made. As Schedule A is generally characterized as a list of serious diseases, Health Canada will expect evidence beyond references to "traditional use" for NHPs, meaning the use of a medicinal ingredient within a cultural belief system or healing paradigm for at least 50 consecutive years, or evidence beyond references to claims from other healing paradigms not based on conventional pharmacology (such as homeopathy). These on their own are not a sufficient standard of evidence for Schedule A or other serious disease preventative claims; thus, supporting human clinical evidence of efficacy and safety would be required.

If, in the review of a submission for either a Drug Identification Number (DIN), a Natural Product Number (NPN), or a Homeopathic Medicine Number (DIN-HM), it appears that any of the factors for Schedule F designation could apply and that any health risk thus identified cannot be mitigated (e.g. through appropriate cautionary labelling), then the product would be reviewed as a potential Schedule F prescription drug under Division 8 of the FDR or the applicant could withdraw the submission. In the case of the former, where the drug is added to Schedule F but is not a veterinary-use drug listed in Part II of Schedule F, the advertising restrictions of section C.01.044 of the FDR apply.

However, if there is conclusive scientific evidence to support a preventative claim for a Schedule A disease, then Health Canada may issue a market authorization for the product. Only after the issuance of a DIN, an NPN, or a DIN-HM are manufacturers then

permitted to label for and advertise to the general public the authorized preventative claims about Schedule A diseases for NHPs and drugs subject to this regulatory proposal.

5*. Natural Health Products Regulations*

Although NHPs fall within the definition of drug in the FDA, it was recognized that these products would benefit from a regulatory framework more suitable to their generally relatively low risk. On January 1, 2004, the NHPR came into force. The NHPR are a comprehensive framework and include site licensing, good manufacturing practices, and product licensing (i.e. the issuance of an NPN or a DIN-HM). Provisions for clinical trials, adverse reaction reporting, labelling, and packaging are also included.

Although the NHPR came into force in 2004, transition provisions were developed in consultation with stakeholders to provide for the staged implementation of these NHPR. This allows time for training, education, and public awareness to help stakeholders comply with the NHPR.

The provisions set out a two-year transition period for site licensing, from January 1, 2004, to December 31, 2005, for manufacturers, packagers, labellers, and importers of NHPs conducting activities in Canada under the FDR.

There is a six-year transition period for product licensing, from January 1, 2004, to December 31, 2009, for NHPs with DINs issued under the FDR. The applicable provisions of the FDR continue to apply for products with a DIN until they are licensed under the NHPR, or until the application is withdrawn. From January 1, 2004, all products not previously on the market that fit the NHP definition must comply with the NHPR immediately and must be subject to the full licence application process in order to be sold in Canada.

The *Compliance Policy for Natural Health Products*, posted on the Health Canada Web site, explains the compliance approach with respect to NHPs which have not received market authorization by way of a DIN, an NPN, or a DIN-HM.

6. Advertising and terms of market authorization

Health Canada is the national regulatory authority for health product advertisement and bears the responsibility for enforcing the FDA, the FDR, the NHPR, and the CDSA and its regulations. More specifically, Health Canada

- develops guidance documents and policies for the interpretation of the regulatory framework for marketed health products; and
- oversees regulated advertising activities.

When permitted, advertising for drugs, including those subject to this regulatory proposal, and NHPs should always be consistent with the terms of the product's market authorization or the authorized labelling material. Any changes in the terms of market authorization may have an impact on what is permitted to be advertised. Section A.5 of the *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*, which is posted on the Health Canada Web

site, states that advertising must respect subsection 9(1) of the FDA and that advertising should clearly communicate the intended use of the product in a manner that is consistent with the terms of market authorization. Section 1.1 of this guideline further states that therapeutic claims for NHPs must be consistent with their terms of market authorization, which is the Product Licence, and that therapeutic claims for nonprescription drugs must be consistent with their terms of market authorization, which are the Labelling Standards, Category IV Monographs, Product Monographs or Authorized Labelling. Furthermore, section 1.4.1 of the *Guidance for Industry: Product Monograph*, also posted on the Health Canada Web site, states that the product monograph serves as a standard against which all promotional material, or advertising distributed or sponsored by the sponsor about a nonprescription drug which falls under Division 8 of the FDR, can be compared. The product monograph establishes the parameters for all advertising, representations, and promotional or information material distributed or otherwise sponsored by the sponsor. It contains all the representations to be made in respect of the new drug, as set out in paragraphs C.08.002(2)(*k*) and C.08.003(2)(*h*) of the FDR.

With respect to drugs for human use, advertising preclearance agencies review and preclear advertising material in order to help industry ensure compliance with the regulatory provisions of the FDA, the FDR, the NHPR, and the CDSA and its regulations, and ensure consistency with the various Health Canada guidance documents and codes of advertising. The agencies also offer independent mechanisms to resolve complaints on advertising for authorized health products. This voluntary system of pre-clearance is carried out in conjunction with the compliance and enforcement powers of Health Canada.

7. Post-market surveillance

Finally, post-market surveillance is another mechanism to protect the health of the Canadian public by monitoring the safety, efficacy, and quality of health products after they have reached the marketplace. Health Canada undertakes compliance and enforcement activities to ensure that claims carried by marketed products are consistent with the market authorization granted under the FDA, the FDR, and the NHPR. Health Canada is prepared to implement this regulatory proposal by increasing the number of inspectors and by providing the inspectors with access to databases that carry the exact wording of authorized Schedule A claims for use in compliance and enforcement activities. NHPs and drugs subject to this regulatory proposal carrying claims which have not been reviewed by Health Canada, and NHPs and drugs subject to this regulatory proposal carrying claims which differ from those which were approved are in violation of the FDA and the FDR or the NHPR, respectively.

The future of Schedule A and section 3 — Health Protection Legislative Renewal

Health Canada is currently reviewing its health protection legisation, with a view to preparing new legislation and regulations, that will address the needs of the Canadian public today and in the future.

Alternatives

Six options were considered in the development of this regulatory proposal. The following summary table (Table A) indicates the mechanism(s) used in each option to permit claims

currently prohibited by the FDA. Both mechanisms are described after the table. Option 6 is the recommended option.

Table A

		Mechanism to permit claims	
	Option — General description	**Revision to Schedule A**	**Exemption from section 3**
1	Maintain the status quo	**no**	**no**
2	Permit risk reduction and symptomatic treatment claims	**no**	**yes**
3	Permit preventative and treatment claims	**no**	**yes**
4	Revise Schedule A with criteria in regulations	**yes**	**no**
5	Revise Schedule A with criteria in policy	**yes**	**no**
6	Revise Schedule A with criteria in policy and permit preventative claims	**yes**	**yes**

In reference to Table A — Explanation for how claims are permitted using the mechanism "Revision to Schedule A"

When the criteria are applied to Schedule A and a disease does not meet any of the criteria, that disease is removed from the list. The labelling and advertising prohibitions in section 3 no longer apply to the claims for that disease. This means that preventative, treatment, or cure claims are permitted in labelling and advertising to the general public. Products continue to be subject to all other provisions in the FDA, the CDSA, and their regulations, therefore any other restrictions on labelling and advertising of claims or any conditions for market authorization remain in place.

In reference to Table A — Explanation for how claims are permitted using the mechanism "Exemption from section 3"

NHPs and drugs subject to this regulatory proposal are exempt from the preventative prohibition, which means that they are permitted to carry preventative claims in labelling and advertising to the general public. These products continue to be subject to all other provisions in the FDA, the CDSA, and their regulations, therefore any other restrictions on labelling and advertising of claims or any conditions for market authorization of these products remain in place.

Option 1: Maintain the status quo

Mechanism used to permit claims: none

With the exception of section B.01.601 of the FDR, as explained earlier in the RIAS, section 3 of the FDA continues to prohibit preventative, treatment, and cure claims in labelling and advertising to the general public for the diseases currently listed in Schedule A.

Pros

- No regulatory changes are required, therefore no resources would be spent in implementing a regulatory amendment.

Cons

- The Schedule A list currently contains some diseases which no longer require the high level of regulatory rigour provided by section 3.
- Manufacturers who provide Health Canada with adequate evidence of the safety, quality and efficacy of their products are prohibited from labelling and advertising that their products prevent, treat, or cure a Schedule A disease, even if they receive market authorization for such.
- The ability of the Canadian public to make informed decisions about their health is limited because products available to the general public are not permitted to be labelled as a preventative, treatment, or cure for any Schedule A disease when there is evidence for such.

Conclusion: Option 1 is rejected.

Option 2: Exempt drugs from the section 3 prohibitions on risk reduction and symptomatic treatment claims for Schedule A diseases

Mechanism used to permit claims: Exemption from section 3

Option 2 would permit risk reduction and symptomatic treatment claims to be made about Schedule A diseases in labelling and advertising to the general public for all drugs and all NHPs that have undergone pre-market review and have been granted market authorization for those claims, unless otherwise restricted in regulation, such as in the case of Schedule F prescription drugs and controlled substances scheduled under the CDSA.

Pros

- Manufacturers would no longer be prohibited from labelling and advertising to the general public when there is evidence for risk reduction and symptomatic treatment claims about Schedule A diseases for NHPs and certain drugs.
- The ability of the Canadian public to make informed decisions about their health is increased because products available to the general public are permitted to be labelled for risk reduction or symptomatic treatment for any Schedule A disease when there is evidence for such.

Cons

- The terms "risk reduction" and "symptomatic treatment" are not defined in the FDA, the FDR, nor the NHPR. They are difficult to define in regulation.
- The Schedule A list contains some diseases which no longer require the high level of regulatory rigour provided by section 3. It limits the Canadian public's access to labelling information that could serve to maintain or improve their health.

Conclusion: Option 2 is rejected.

Option 3: Exempt nonprescription drugs and NHPs from the section 3 prohibitions on preventative and treatment claims for Schedule A diseases

Mechanism used to permit claims: Exemption from section 3

Option 3 would permit preventative, risk reduction, treatment, and symptomatic treatment claims to be made for Schedule A diseases in labelling and advertising to the general public for nonprescription drugs and NHPs that have undergone pre-market review and have been granted market authorization for those claims.

Pros

- The broad terms "preventative" and "treatment" are terms used in the FDA and have been interpreted by Health Canada to encompass "risk reduction" and "symptomatic treatment," respectively.
- The broad exemptions of preventative and treatment would permit the labelling and advertising to the general public of preventative, risk reduction, treatment, or symptomatic treatment claims for nonprescription drugs and NHPs.
- The ability of the Canadian public to make informed decisions about their health is increased because NHPs and certain drugs would be permitted to be labelled to the general public for preventative, risk reduction, treatment, or symptomatic treatment for any Schedule A disease when there is evidence for such because the claims would no longer be prohibited in labelling and advertising to the general public.

Cons

- The Schedule A list contains some diseases which no longer require the high level of regulatory rigour provided by section 3. It limits the Canadian public's access to labelling information that could serve to maintain or improve their health.

Conclusion: Option 3 is rejected.

Option 4: Amend Schedule A and include Schedule A criteria in regulation

Mechanism used to permit claims: Revision to Schedule A

Pros

- The revised Schedule A list contains diseases which require the high level of regulatory rigour provided by section 3.
- Criteria will improve predictability and consistency in Schedule A listings and enhance Health Canada's accountability, openness, and transparency to stakeholders and the public.

Cons

- With Schedule A criteria in regulation, it is more difficult to keep the criteria responsive to current medical needs in the ever-changing health products and food environment because amending regulations in order to modify criteria takes a relatively longer time than revising a policy in order to modify criteria.
- There are preventative claims for diseases remaining in Schedule A which are appropriate for NHPs and certain drugs to carry in labelling and advertising, but which are prohibited by section 3.

Conclusion: Option 4 is rejected.

Option 5: Amend Schedule A and include Schedule A criteria in policy

Mechanism used to permit claims: Revision to Schedule A

Pros

- The revised Schedule A list contains diseases which require the high level of regulatory rigour provided by section 3.
- With Schedule A criteria in policy, it is easier to keep the criteria responsive to current medical needs in the ever-changing health products and food environment. Revising a policy in order to modify criteria takes less time than amending regulations in order to modify criteria.
- Criteria will improve predictability and consistency in Schedule A listings and enhance Health Canada's accountability, openness, and transparency to stakeholders and the public.

Cons

- There are preventative claims for diseases remaining in Schedule A which are appropriate for NHPs and certain drugs to carry in labelling and advertising, but which are prohibited by section 3.

Conclusion: Option 5 is rejected.

Option 6: Amend Schedule A by including criteria in policy and exempt NHPs and certain drugs from the preventative prohibition for Schedule A diseases

Mechanism used to permit claims: Revision to Schedule A and exemption to section 3

Option 6 was chosen because

- The revised Schedule A list contains diseases which require the high level of regulatory rigour provided by section 3.
- With Schedule A criteria in policy, it is easier to keep the criteria responsive to current medical needs in the ever-changing health products and food environment. Revising a policy in order to modify criteria takes less time than amending regulations in order to modify criteria.
- Criteria will improve predictability and consistency in Schedule A listings and enhance Health Canada's accountability, openness, and transparency to stakeholders and the public.
- There are preventative claims for diseases remaining in Schedule A which are appropriate for NHPs and certain drugs to carry in labelling and advertising, and which are no longer prohibited by the preventative exemption to section 3.

Option 6 reflects the current health care context of a comprehensive regulatory system and a publicly funded health care system and allows consumers to be made aware of substantiated, evidence-based labelling that previously was inaccessible due to the section 3 prohibition.

Benefits and costs

The following benefits and costs are associated with this regulatory proposal.

Public

Benefits

- Consumers would have greater access to evidence-based information in labelling for NHPs and drugs subject to this regulatory proposal. Authorized claims for marketed products would be shared with the Canadian public through labelling. This would increase the ability of consumers to make informed choices about their health, which satisfies the Canadian public's desire to participate in their health care.
- This regulatory proposal is consistent with the following guiding principles outlined in the External Working Group's (EWG) 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 regulatory proposal is consistent with a position of the EWG's Minority Report on Schedule A and section 3, as posted on the Health Canada Web site. The report supported labelling of products that is consistent with authorized product information.
- This regulatory proposal is consistent with both Majority and Minority Reports, which recommend that experts review the diseases listed in Schedule A.
- A Canadian public, better informed about NHPs and drugs subject to this regulatory proposal, may have less need to use the health care system.

Costs

- There may be an increase in non-compliant labelling and advertising of Schedule A diseases for NHPs and drugs subject to this regulatory proposal, which is disadvantageous to the consumer.

Government

Benefits

- This regulatory proposal may result in less strain being placed on provincial health care plans because the Canadian public may be more aware of the benefits of NHPs and drugs subject to this regulatory proposal.

Costs

The start-up costs to Government for implementation of the regulatory proposal are anticipated to be approximately $500,000 (plus departmental overhead). Annual ongoing costs to Government for implementation of the regulatory proposal are anticipated to be $3,000,000 (plus departmental overhead). Government costs are anticipated to be

- an increase in the number of reviewers (6.5 people) at Health Canada to address the projected increase in submissions;
- an increase in the number of inspectors (9 people) at Health Canada to monitor compliance and adherence to guidelines, and to address the potential increase in investigations of whether manufacturers' claims exceed what is permitted by the terms of market authorization;
- an increase in the number of regulatory advertising officers (1.5 people) at Health Canada to deal with the potential increase in advertising complaints;
- the updating of databases holding authorized Schedule A claims, used by the inspectors and regulatory advertising officers;
- the revisions of existing consumer advertising guidance documents, revisions of standard operating procedures (SOPs), revisions of forms, and training required for inspectors to implement the change in regulations; and
- the evaluation of the impact of this regulatory proposal.

Industry

Benefits

- Industry may benefit from a potential increase in sales of authorized NHPs and drugs subject to this regulatory proposal due to an increase in claims in labelling and advertising.

Costs

- There may be a cost to manufacturers of promoting a product in a market environment which is made more competitive by the partial lifting of an advertising prohibition.

In summary, the benefits that would be derived from this regulatory proposal outweigh its costs.

Consultation

2002-2003: In 2002, Health Canada convened an internal working group on Schedule A. In February 2003, the group produced the *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.

2003-2004: In 2003, Health Canada convened an EWG on Schedule A, comprised of representatives from government and regulatory groups, professional associations, consumer/advocacy groups, advertising/media organizations, and foods, health products and medical devices industries. 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 were posted on the Health Canada Web site. The recommendations of the two EWG reports were considered when drafting this regulatory proposal.

In February 2005, Health Canada met with the EWG and committed to convening a scientific advisory panel (SAP) to develop criteria for revising 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 listed in Schedule A, as per Option 2 explained earlier.

On September 21, 2005, the SAP was convened. 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 reasons for subsections 3(1) and 3(2) and Schedule A to determine what other options were now available in regulations to fulfill the intent behind the legislation.

On November 19, 2005, Project 1474 was pre-published in the *Canada Gazette*, Part I (CG I), for a 75-day comment period. During this time, 25 representations were received. Sixteen representations were in support of the proposal, eight representations were against the proposal, and one representation was neutral, meaning that no position was taken when providing comments.

Those stakeholders in support of the proposal were drug manufacturers, NHP manufacturers, medical devices manufacturers, media organizations, consultants, and academics. Stakeholders against the proposal consisted of government ministries, health care associations, advocacy groups, and individuals.

Project 1474 and the current regulatory proposal, Project 1539, would both permit claims related to NHPs and certain drugs which are currently prohibited by section 3 in the labelling and advertising to the general public. However, the mechanism used in each regulatory proposal to achieve this objective is different. In Project 1474, exemptions to section 3 were used without any revisions to the list of Schedule A diseases. Project 1539 achieves the original intent of Project 1474 by revising the list of Schedule A diseases and by permitting preventative claims for diseases remaining in Schedule A.

The following relationships can be drawn between Project 1474's CG I comments and Project 1539.

The following is the same for projects 1474 and 1539:

Comments in support of Project 1474: Both projects 1474 and 1539 state that the Schedule A/section 3 provisions are out of date. Both acknowledge that there are NHPs and certain drugs which have scientific evidence for Schedule A claims. Both allow manufacturers to promote approved claims which would be currently prohibited in labelling and advertising to the general public.

Comments against Project 1474: The following stakeholder comments and the Department's responses would also be applicable to Project 1539.

— *Comment* - Stakeholders stated the risk for consumers to believe that there are different rules for labelling and advertising for prescription drugs versus NHPs/nonprescription drugs.

— *Response* - However, there are currently different rules for the labelling and advertising of prescription drugs and NHPs/ nonprescription drugs. This is due to the difference between the higher-risk profile of prescription drugs and the lower-risk profile of NHPs/nonprescription drugs, and due to the difference in how the consumer accesses these products — the former are mediated through a physician and a pharmacist, and the latter are not.

— *Comment* - Stakeholders stated that NHPs should not carry Schedule A claims because the standards of evidence for the review of NHPs are inferior to those used for nonprescription and prescription drugs, therefore, NHPs carrying Schedule A claims may increase the health risk to the Canadian public. Furthermore, stakeholders stated that the backlog of NHP submissions would result in non-compliant NHPs being on the market with Schedule A claims for years.

— *Response* - The standards of evidence for NHPs provide for a range of evidence appropriate to the safety risk inherent in the NHPs and the claim being made. Higher standards of evidence are required for higher-risk products; therefore, traditional references would not be considered a sufficient standard of evidence on their own for claims to prevent Schedule A or other serious diseases. Finally, products that present a significant risk to consumer health, including products that make unauthorized claims with respect to serious diseases, are targeted for compliance actions. Any backlog in assessment of NHP licence applications has no bearing on the application of the risk-based approach to compliance.

The following is different between projects 1474 and 1539:

— *Comment* - In the Project 1474 consultation period, stakeholders stated that the Record of Proceedings (RoP) from the Scientific Advisory Panel (SAP) should be available for consultation.

— *Response* - The recommendations of the SAP, which are in the RoP, are open for consultation in Project 1539.

— *Comment* - In the Project 1474 consultation period, stakeholders stated that the principle behind Schedule A is relevant today, therefore, changes should be made to

Schedule A itself.

— *Response* - Revisions to Schedule A are proposed in Project 1539.

— *Comment* - In the Project 1474 consultation period, stakeholders stated that issues raised by the External Working Group (EWG) should be addressed.

— *Response* - The EWG recommended that revisions be made to Schedule A, and Project 1539 responds to this recommendation.

On March 29, 2006, the recommendations by the SAP were finalized in a record of proceedings and were posted on the Health Canada Web site.

Compliance and enforcement

This amendment does not alter existing compliance authorities under the *Food and Drugs Act* and its Regulations enforced by the Health Products and Food Branch Inspectorate (HPFBI). However, compliance and enforcement resources will be increased in the form of more inspectors, and enforcement tools will be enhanced in the form of databases which carry authorized Schedule A claims available to inspectors.

Contact

Project 1539
Policy Division
Bureau of Policy, Science, and International Programs
Therapeutic Products Directorate
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Ottawa, Ontario
K1A 0K9
Telephone: 613-948-4623 (please refer to Project 1539)
Fax: 613-941-6458 (please refer to Project 1539)
Email: regaff-affreg@hc-sc.gc.ca

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) (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 (Project 1539)*.

Interested persons may make representations concerning 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 #1539, Policy Division, Bureau of Policy, Science, and International Programs, 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-affreg@hc-sc.gc.ca), with a reference to Project #1539.

Ottawa, June 7, 2007

MARY O'NEILL
Assistant Clerk of the Privy Council

REGULATIONS AMENDING CERTAIN REGULATIONS MADE UNDER THE FOOD AND DRUGS ACT (PROJECT 1539)

FOOD AND DRUG REGULATIONS

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

EXEMPTIONS

Application

A.01.066. Sections A.01.067 and A.01.068 do not apply to

(*a*) a drug included in Schedule I, II, III, IV or V to the *Controlled Drugs and Substances Act*; or

(*b*) a drug that is listed or described in Schedule F, other than a drug that is listed or described in Part II of that Schedule and that is

(i) in a form not suitable for human use, or

(ii) labelled in the manner prescribed by paragraph C.01.046(*b*).

Advertising

A.01.067. A drug is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

Sale

A.01.068. A drug 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 preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

NATURAL HEALTH PRODUCTS REGULATIONS

2. The *Natural Health Products Regulations* (see footnote 2) **are amended by adding the following after section 103.1:**

EXEMPTIONS

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 preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

Sale

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 preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

COMING INTO FORCE

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

[24-1-o]

Footnote a

S.C. 1999, c. 33, s. 347

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.

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Important notices

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

Vol. 141, No. 24 — June 16, 2007

Regulations Amending Schedule A to the Food and Drugs Act and the Medical Devices Regulations (Project 1539)

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

For the Regulatory Impact Analysis Statement, see the Regulations Amending Certain Regulations Made under the Food and Drugs Act (Project 1539).

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) (see footnote a) of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending Schedule A to the Food and Drugs Act and the Medical Devices Regulations (Project 1539)*.

Interested persons may make representations concerning 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 #1539, Policy Division, Bureau of Policy, Science, and International Programs, 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-affreg@hc-sc.gc.ca), with a reference to Project #1539.

Ottawa, June 7, 2007

MARY O'NEILL
Assistant Clerk of the Privy Council

REGULATIONS AMENDING SCHEDULE A TO THE FOOD AND DRUGS ACT AND THE MEDICAL DEVICES REGULATIONS (PROJECT 1539)

FOOD AND DRUGS ACT

1. The references to

Alcoholism
Alcoolisme

Alopecia (except hereditary androgenetic alopecia)
Alopécie (sauf l'alopécie androgénogénétique)

Anxiety state
États d'angoisse

Arthritis
Arthrite

Bladder disease
Vessie (maladies)

Disease of the prostate
Prostate (maladies)

Disorder of menstrual flow
Troubles du flot menstruel

Dysentery
Dysenterie

Edematous state
Œdème

Epilepsy
Épilepsie

Gall bladder disease
Vésicule biliaire (maladies)

Gout

Goutte

Heart disease
Cœur (maladies)

Hernia
Hernie

Hypotension
Hypotension

Impetigo
Impétigo

Kidney disease
Reins (maladies)

Leukemia
Leucémie

Liver disease (except hepatitis)
Foie (maladies sauf l'hépatite)

Pleurisy
Pleurésie

Sexual impotence
Impuissance sexuelle

Tumor
Tumeurs

Venereal disease
Maladies vénériennes

in Schedule A to the *Food and Drugs Act* (see footnote 1) **are repealed.**

2. Schedule A to the Act is amended by adding the following in alphabetical order:

Acute alcoholism
Alcoolisme aigu

Acute anxiety state
État anxieux aigu

Acute infectious respiratory syndromes
Syndromes respiratoires infectieux aigus

Acute, inflammatory and debilitating arthritis
Arthrite aiguë, inflammatoire et débilitante

Acute psychotic conditions
Troubles psychotiques aigus

Addiction
Dépendance

Congestive heart failure
Insuffisance cardiaque congestive

Dementia
Démence

Haematologic bleeding disorders
Affections hématologiques hémorragiques

Hepatitis
Hépatite

Sexually transmitted diseases
Maladies transmises sexuellement

Strangulated hernia
Hernie étranglée

MEDICAL DEVICES REGULATIONS

3. Subsection 24(1) of the *Medical Devices Regulations* (see footnote 2) **is replaced by the following:**

24. (1) For the purposes of subsections 3(1) and (2) of the Act and subject to section 27, a condom may be advertised and sold to the general public for the purpose of preventing the transmission of sexually transmitted diseases if the advertisement and the label of the condom claim only that the condom reduces the risk of transmitting sexually transmitted diseases.

COMING INTO FORCE

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

[24-1-o]

Footnote a

S.C. 1999, c. 33, s. 347

Footnote 1

R.S., c. F-27

Footnote 2

SOR/98-282

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