

# Tracking Federal Regulatory Initiatives

# Regulatory Affairs

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May 20, 1998

Circulate to:	<b>HIGHLIGHTS</b>
1.	<b>Proposed Regulations</b>
2.	Elimination of need to obtain a registered certificate number for general public (GP or proprietary medicines proposed) . . . . . 2
3.	<b>Exempt from Prepublication and Approved</b>
4.	Canada Student Loans Regulations changed to allow electronic filing of claims for loan losses . . . . . 3
5.	Prescription status set for 44 new drugs . . . . . 6 Certain nicotine patches to be available without prescription . . . . . 7

<b>Proposed Regulations for Pre-Publication in Part I, Canada Gazette</b>	<b>Statutory Authority</b>
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<p><b>Northwest Territories Fishery Regulations, amendment</b></p> <p>This amendment proposes to remove from the regulations the minimum 133 mm gill net mesh size for fishing in the Great Slave Lake management areas.</p> <p>In future, the Department of Fisheries and Ocean will specify gill net mesh sizes in these areas as a condition of licence.</p> <p>The commercial fishery, which focuses predominantly on harvesting whitefish and trout, has used 133 mm gill nets since 1977. In the spring of 1997, the Great Slave Lake Advisory Committee recommended to DFO that a new management strategy be implemented. Included in that strategy is the change to the minimum gill net mesh size as well as a stock status study that began in July 1997.</p> <p>Contact: Grant Pryznyk, Acting Director, Conservation and Protection and Legislation, Department of Fisheries and Oceans, P.O. Box 2310, Yellowknife, Northwest Territories, X1A 2P7. Tel: 867-920-6635; Fax: 867-873-8871.</p>	<p><i>Fisheries Act</i>, section 43</p> <p>Published in Canada Gazette May 16, 1998</p>
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# Proposed Regulations

for Pre-Publication in Part I, Canada Gazette

Statutory Authority

## Food and Drug Regulations, amendment

This proposal will revoke Division 10 of the Food and Drug Regulations, thereby eliminating the assignment of a numbered certificate of registration for some 1,300 general public (GP) or proprietary medical products.

Drugs regulated by Division 10 are intended for self-medication to relieve the symptoms of minor self-limiting ailments. These are considered to be low risk products.

Division 10 of the Regulations was introduced in the mid 1970s to regulate the sale of general public or proprietary medicines for sale to the public outside of pharmacies. At that time, it was determined that special attention should be given to the safety of the ingredients in these products.

Under these regulations, an application for a GP number must be accompanied by additional information which may include: details of the plant and equipment used in manufacturing; reports of investigations conducted to determine the toxicity of the drug; and substantial evidence of the effectiveness of the drug under the conditions of use recommended by the manufacturer. Based on the established low risk associated with GP products, the need for manufacturers to submit this additional information is no longer supportable and Division 10 of the Food and Drug Regulations is now considered unnecessarily restrictive.

The revocation of Division 10 would provide uniform premarket evaluation for all low risk drug products, including these proprietary medicines. This would result in a reduced regulatory and administrative burden for manufacturers of GP products. The manufacturers of over 1,300 marketed products registered under GP numbers would be directly affected by this deregulatory initiative.

Based on consultations on an earlier version of the proposal, several changes have been made to this proposal, including an amendment to permit drug products to be labelled with GP numbers until October 1, 1999, reducing the financial impact on the manufacturer, and enabling industry to deplete current label supplies.

Provincial authorities have agreed to amend provincial legislation to accommodate the revocation of Division 10 and hence the GP numbering system at the federal level; some provinces use the GP numbering system to establish where particular medicinal preparations can be sold in retail outlets.

As part of the transition to a single Drug Identification Number (DIN) system, the following provisions would apply if this regulatory proposal becomes law:

- (1) No new assignments of GP numbers will be issued as of July 1, 1998;
- (2) Persons holding valid GP numbers will be issued DIN numbers for their products if a request to the Therapeutic Products Programme of Health Canada is made prior to September 1, 1998;
- (3) Persons marketing drugs differing only in flavour, fragrance and colour and bearing distinct GP numbers will be requested to identify which identification number has been chosen for the DIN assignment;
- (4) Current GP holders will be asked to identify the premarketed GP products for which a DIN is requested;
- (5) No additional fees would be charged for the conversion of a GP to a DIN if an application for the conversion is made prior to September 1, 1998;

*Food and Drugs Act, section 30*

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## Proposed Regulations

### for Pre-Publication in Part I, Canada Gazette

#### Statutory Authority

(6) Failure on the part of the manufacturer to request the conversion of a GP to a corresponding DIN would result in the cancellation on September 30, 1998, of the certificate of registration assigned to that GP product. This will provide the TPP with a minimum of 30 days to assign DINs, as all products on the market after October 1, 1998, must have a DIN assigned to them;

(7) DIN holders will be permitted to label and package products up to October 1, 1999, with previously approved labels carrying the GP symbol. This will provide industry with an additional year to convert to DIN numbers on their labels, and hence reduce label conversion costs as this could be accomplished within the normal label life cycle;

(8) The current advertising restriction would be removed and hence provide persons marketing these products the same opportunities as those granted to persons who market drugs with a DIN; and

(9) Provide flexibility respecting limits of variability under the newly proposed section C.01.062(5), hence creating a level playing field for all products.

The target date for implementing the federal and provincial regulatory changes is July 1, 1998.

Contact: Joan Korol or Lauraine Bégin, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Directorate, Health Protection Building, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-952-3602; Fax: 613-941-6458; E-mail: joan-korol@hc-sc.gc.ca or laurainebegin@hc-sc.gc.ca.

## Exempt from Pre-Publication and Approved

#### Statutory Authority

### Canada Student Loan Regulations, amendment (SOR/98-287, OIC 1998-834)

*Canada Student Loan Act, section 17*

These amendments to Sections 23 and 28 improve procedures under student loans for transferring loans between lenders and for electronically submitting claims for loss.

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More specifically, the changes to Section 23 outline the procedures required in cases of missing and lost documents relating to student loans.

The changes to section 28 outline a new optional procedure for submitting claims for loss electronically through requisitioning, the handling of documents which supports and substantiates claim for loss. This section also adds an indemnification clause to ensure that the Minister does not bear any losses when the lenders are unable to provide original documents.

The amendments simplify the procedures for handling documents and benefit from the use of technology in transferring information.

Contact: Kalpana Prasad, Policy Analyst, Canada Student Loans Program, Policy Learning and Literacy Directorate, Human Resources Development Canada, 25 Eddy Street, 10th Floor, Hull, Quebec, K1A 0M5. Tel: 819-953-9733; Fax: 819-953-8147.

## Exempt from Pre-Publication and Approved

### Statutory Authority

#### **Order Designating the Province of Manitoba for the Purposes of the Definition “applicable guidelines” in subsection 2(1) of the Divorce Act (SOR/98-288, OIC 1998-835)**

The Order designates the Province of Manitoba for the purposes of the definition “applicable guidelines” in subsection 2(1) of the *Divorce Act*.

The province of Manitoba passed Bill 56 *The Family Maintenance Amendment Act* on June 28, 1997, which introduced provincial child support guidelines. The Bill and the *Child Support Guidelines Regulation* were proclaimed on April 8, 1998 to come into force on June 1, 1998. The *Child Support Guidelines Regulation* essentially mirrors the *Federal Child Support Guidelines*.

The provincial guidelines adopt the Federal Child Support Guidelines except for the following:

- the *Child Support Guidelines Regulation* makes reference to provisions and concepts found in both the *Divorce Act* and the *Family Maintenance Act*, to enable its application under both Acts.
- a non-custodial parent cannot apply for special expenses under the *Child Support Guidelines Regulation*. Therefore, paragraph 7(1)(b) of the *Federal Guidelines*, which refers to the portion of the medical and dental insurance premiums attributable to a child, is not listed as a special expense in Manitoba’s Guidelines as this is an expense that would normally be claimed by the non-custodial parent. Instead, subsection 7(4) of the *Child Support Guidelines Regulation* provides that this amount be taken into account when calculating the amount under paragraph 7(1)(b), which deals with health-related expenses. In addition, the health-related expenses are amounts that exceed \$100 “annually”, not “annually per illness or event” as stated in the *Federal Guidelines*.
- subsection 7(1) of the *Child Support Guidelines Regulation* has been drafted to allow the court to estimate the amount of special expenses.
- subsection 7(2) of the *Child Support Guidelines Regulation* states that the expenses will be shared only if a parent has an income over the threshold level of income below which no amount of child support is payable under the appropriate table.

This Order comes into force on May 1, 1998. The *Manitoba Child Support Guidelines Regulation* will apply to all child support orders made where both parents reside in Manitoba as of June 1, 1998.

Contact: Lise Lafrenière Henrie, Counsel, Coordinator, Policy Development, Child Support Team, Department of Justice, 284 Wellington, Ottawa, Ontario, K1A 0H8: Tel: 613-957-0059; Fax: 613-952-9600.

#### **Order Prohibiting Entry on Certain Lands in the Yukon Territories (1983 - No. 3, Little Salmon/Carmacks First Nation, Y.T.) (SOR/98-289, OIC 1998-857); Order Respecting the Withdrawal of Certain Lands in the Yukon Territories (Little Salmon/Carmacks First Nation, Y.T.) (SI/98-60, OIC 1998-858)**

The purpose of this Order is to withdraw certain lands from disposal and to prohibit entry onto these lands pursuant to a final land claim agreement with the Little Salmon/Carmacks First Nation.

*Divorce Act*, subsection 2(5)

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*Yukon Placer Mining Act*, section 98; *Yukon Quartz Mining Act*, section 14.1; *Territorial Lands Act*, paragraph 23(a)

To be published in Canada Gazette May 27, 1998

## Exempt from Pre-Publication and Approved

Statutory Authority

Pursuant to negotiations of the Umbrella Final Agreement for the Yukon First Nations, the Government of Canada has agreed that certain lands be prohibited from entry to ensure that no new third-party interests are created.

An existing Prohibition of Entry Order (OIC 1997-1419) which protects the sub-surface rights for this Yukon First Nation and which terminates December 1, 2001 is being repealed and substituted with a new Order.

The Withdrawal Order withdraws both designated lands and mines, minerals and hydrocarbon rights, except certain existing rights.

Both Orders will be effective on the date of registration (May 14, 1998) and will end on the earlier of February 1, 2003, or upon registration of the survey plan of the Site Specific Settlement Land parcels with the Registrar of Land Titles, in the Yukon Territory.

Contact: Chris Cuddy, Chief, Land & Water Management Division, Department of Indian Affairs and Northern Development, Les Terrasses de la Chaudière, 10 Wellington Street, Ottawa, Ontario, K1A 0H4. Tel: 819-994-7483; Fax: 819-953-2590.

### **Order Prohibiting Entry on Certain Lands in the Yukon Territories (1983 - No. 4, Selkirk First Nation) (SOR/98-290, OIC 1998-859); Order Respecting the Withdrawal of Certain Lands in the Yukon Territories (Selkirk First Nation, Y.T.) (SI/98-61, OIC 1998-860)**

The purpose of this Order is to withdraw certain lands from disposal and to prohibit entry onto these lands pursuant to a final land claim agreement with the Selkirk First Nation.

Pursuant to negotiations of the Umbrella Final Agreement for the Selkirk First Nation, the Government of Canada has agreed that certain lands be prohibited from entry to ensure that no new third-party interests are created.

An existing Prohibition of Entry Order (OIC 1997-1369) which protects the sub-surface rights for this Yukon First Nation and which terminates December 1, 2001 is being repealed and substituted with a new Order.

The Withdrawal Order withdraws both designated lands and mines, minerals and hydrocarbon rights, except certain existing rights.

Both Orders will be effective on the date of registration (May 14, 1998) and will end on the earlier of February 1, 2003, or upon registration of the survey plan of the Site Specific Settlement Land parcels with the Registrar of Land Titles, in the Yukon Territory.

Contact: Chris Cuddy, Chief, Land & Water Management Division, Department of Indian Affairs and Northern Development, Les Terrasses de la Chaudière, 10 Wellington Street, Ottawa, Ontario, K1A 0H4. Tel: 819-994-7483; Fax: 819-953-2590.

*Yukon Placer Mining Act*, section 98; *Yukon Quartz Mining Act*, section 14.1; *Territorial Lands Act*, paragraph 23(a)

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## Exempt from Pre-Publication and Approved

### Statutory Authority

#### **Food and Drug Regulations, amendment (Schedule 1045, Schedule F) (SOR/98-291, OIC 1998-867)**

*Food and Drugs Act, section 30(1)*

This amendment updates Schedule F to require prescription status for forty-four new drugs being added to Part I, and for two new drugs being added to Part II. In addition, the amendments were made to reflect the prescription status of pilocarpine in an oral form and all derivatives of etoposide. Amendments are made to correct the English spelling of the drugs methoxsalen and dimethyl sulfoxide.

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The drugs being given prescription status include:

Abciximab; Amifostine and its salts; Anastrozole; Atorvastatin and its salts; Atracurium besilate; Cisatracurium besilate; Desflurane; Dexfenfluramine and its salts; Dolasetron and its salts; Donepezil and its salts; Dorzolamide and its salts; Epoprostenol and its salts; Fleroxacin and its salts and derivatives; Florfenicol and its derivatives; Folicle stimulating hormone; Fosphenytoin and its salts; Gemcitabine and its salts; Glatiramer and its salts; Imiglucerase; Indinavir and its salts; Irinotecan and its salts; Latanoprost; Letrozole; Meropenem and its salts and derivatives; Molgramostim; Olopatadine and its salts; Pantoprazole and its salts; Pinaverium bromide; Potassium gluconate, when sold or recommended for administration to cats; Quinagolide and its salts; Raltitrexed and its salts and derivatives; Reviparin and its salts; Ritonavir; Ropinirole and its salts; Saquinavir and its salts and derivatives; Stavudine; Tazarotene; Tiludronic acid and its salts; Topiramate; Topotecan and its salts; Trandolaprilat and its salts and derivatives; Troglitazone; Tubocurarine chloride; and Valaciclovir and its salts.

The Regulations also amend Part II of Schedule F by adding the following in alphabetical order: Dirithromycin; and Praziquantel.

These Regulations come into force on May 14, 1998.

Contact: Karolyn Lui, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Directorate, Health Protection Building, Address Locator 0702B1, Tunney's Pasture Ottawa, Ontario K1A 0L2. Tel: 613-941-3693; Fax: 613-941-6458; E-mail: karolyn\_lui@hc-sc.gc.ca.

#### **Food and Drug Regulations, amendment (Schedule 1069) (SOR/98-292, OIC 1998-868)**

*Food and Drugs Act, section 30(1)*

This amendment permits sodium cromoglicate 2% nasal solution to be made available without a prescription. Sodium cromoglicate 2% nasal solution is indicated to prevent and relieve seasonal allergy symptoms.

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There are no known drug interactions between sodium cromoglicate and other medications commonly used in the nose. There have also been no reported cases of an overdose in humans. Seventeen years of Canadian clinical experience have confirmed both the efficacy and safety of sodium cromoglicate 2% nasal solution. The nonprescription labelling of sodium cromoglicate 2% nasal solution includes warnings and ensures that medical attention is sought when appropriate.

These Regulations come into force on June 15, 1998.

Contact: Karolyn Lui, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Directorate, Health Protection Building, Address Locator 0702B1, Tunney's Pasture Ottawa, Ontario K1A 0L2. Tel: 613-941-3693; Fax: 613-941-6458; E-mail: karolyn\_lui@hc-sc.gc.ca.

## Exempt from Pre-Publication and Approved

### Statutory Authority

#### **Food and Drug Regulations, amendment (Schedule 1080) (SOR/98-293, OIC 1998-869)**

*Food and Drugs Act, section 30(1)*

This amendment permits nizatidine to be made available without a prescription for concentrations equivalent to 75 mg of nizatidine or less per dosage unit.

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The indications on the label will be limited to symptomatic treatment of heartburn and acid indigestion. The maximum daily dose of nizatidine is limited to 150 mg. The recommended duration of treatment without medical supervision is 2 weeks.

Nizatidine is an uncomplicated drug with a short half life. This makes it unlikely that any accumulation would occur with low dose use.

Nizatidine has been marketed, in Canada, since 1988 and worldwide, since 1987. With nizatidine now available in 67 countries, there is a large body of postmarketing surveillance data to support the safety of nizatidine during "real world" use, cumulative worldwide prescriptions is approximately 57 million. This represents approximately 32 million patient exposures. Such broad safety experience has led to the availability of nizatidine 75 mg, without a prescription, in the United States.

A Notice of Intent to deregulate nizatidine 75 mg or less was published in Canada Gazette, Part I on June 28, 1997 with a forty five day comment period as well as being posted on the Therapeutic Products Programme electronic bulletin board.

These Regulations come into force on May 14, 1998.

Contact: Karolyn Lui, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Directorate, Health Protection Building, Address Locator 0702B1, Tunney's Pasture Ottawa, Ontario K1A 0L2. Tel: 613-941-3693; Fax: 613-941-6458; E-mail: karolyn\_lui@hc-sc.gc.ca.

#### **Food and Drug Regulations, amendment (Schedule 1084) (SOR/98-294, OIC 1998-870)**

*Food and Drugs Act, section 30(1)*

This amendment updates Schedule F to permit nicotine when contained in transdermal patches to be made available without a prescription for delivery rates of 22 mg per day or less.

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Nicotine in a dosage form has been marketed in Canada as a temporary aid to smoking cessation since 1984. Nicotine 2 mg and 4 mg gums received nonprescription drug status in 1993 and 1997, respectively.

These Regulations come into force on June 1, 1998; no retail sale or consumer advertising of nicotine transdermal patches will be allowed until this date.

Contact: Eric Ormsby, Bureau of Policy and Coordination, Therapeutic Products Directorate, Health Protection Building, Address Locator 0702B1, Tunney's Pasture, Ottawa, Ontario, K1A 0L2. Tel: 613-941-3694; Fax: 613-941-6458; E-mail: eric\_ormsby@hc-sc.gc.ca.

#### **Honeywell Remission Order (SI/98-59, OIC 1998-833)**

*Financial Administration Act, subsection 23(2)*

This Order remits the goods and services tax (GST) of approximately \$363,000 as well as any related interest and penalties payable by Honeywell, for an aircraft and testing equipment temporarily imported into Canada in 1998 to satisfy Transport Canada's commissioning specifications relating to the air navigation system. It is the only aircraft in the world appropriately certified and equipped to conduct the required tests.

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Without the remission, GST would apply to the full value of the aircraft and testing equipment temporarily imported by Honeywell.

# Ministerial Orders Approved

## Statutory Authority

### Public Service Superannuation Regulations (SOR/98-286)

The amendments correct minor discrepancies between the French and English versions of the Regulations and deal with other concerns regarding the application of the erroneous advice provisions to part-time employment which were identified by the Standing Joint Committee on Regulations.

Changes are made to subsection 6.3(2), section 6.4, and subsection 18(1).

The amendments come into force May 11, 1998.

Contact: Joan M. Arnold, Acting Director, Pensions Legislation Development Group, Pensions Division, Treasury Board Secretariat, Ottawa, Ontario, K1A 0R5. Tel: 613-952-3119.

*Public Service Superannuation Act*, paragraphs 42.1(1) and 42.1(1)(d);  
*Financial Administration Act*, paragraph 7(2)(a)

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### St. John's Harbour Due By-law, amendment (SOR/98-295)

This order approves of St. John's Port Corporation making minor changes to the wording of the *St. Johns Harbour Dues By-law*, as recommended by the Department of Justice.

The amendment changes section 1 of the French version, substitutes a new definition for "harbour dues" in section 2 of the English version, and replaces in the French version the words "règlement" with "règlement administratif" in a number of places, including in the long title, part of section 2, section 3, subsection 4(1), paragraph 4(2)(b) and subsections 6(1) and (2).

The Order comes into force May 15, 1998.

*Canada Ports Corporation Act*, sections 13

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