



Français	Contact us	Help	Search	Canada Site
Home	About us	History	FAQ	Site Map

[Notice](#)

Vol. 142, No 8. — April 16, 2008

Registration

SOR/2008-101 April 3, 2008

FOOD AND DRUGS ACT

Regulations Amending the Food and Drug Regulations (1528 — Schedule F)

P.C. 2008-614 April 3, 2008

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) [\(see footnote a\)](#) of the *Food and Drugs Act* [\(see footnote b\)](#), hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1528 — Schedule F)*.

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1528 — SCHEDULE F)**AMENDMENTS****1. The reference to**

Botulinum Toxin Type A
Antitoxine botulinique, Type A

in Part I of Schedule F to the *Food and Drug*

Regulations

(see footnote 1) is replaced by the following:

Botulinum toxin Type A
Toxine botulinique, type A

2. Part I of Schedule F to the Regulations is amended by adding the following in alphabetical order:

Alglucosidase alfa
Alglucosidase alfa

Darunavir
Darunavir

Natalizumab
Natalizumab

Rasagiline and its salts
Rasagiline et ses sels

Sorafenib and its salts
Sorafénib et ses sels

Tigecycline
Tigécycline

COMING INTO FORCE

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

**REGULATORY IMPACT
ANALYSIS STATEMENT**

(This statement is not part of the Regulations.)

Description

This amendment makes a correction to one current listing

on Schedule F, Part I to the *Food and Drug Regulations* and adds six medicinal ingredients to Part I of Schedule F to the *Food and Drug Regulations*.

Schedule F is a list of medicinal ingredients, the sale of which is controlled under sections C.01.041 to C.01.049 of the *Food and Drug Regulations*. Part I of Schedule F lists ingredients that require a prescription for human use and for veterinary use. Part II of Schedule F lists ingredients that require a prescription for human use, but do not require a prescription for veterinary use if so labelled or if in a form unsuitable for human use.

The Drug Schedule Status Committee determines the necessity for prescription status for medicinal ingredients 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.

Correction of one current Schedule F, Part I listing

The current listing in Schedule F, Part I:

Botulinum Toxin Type A
Antitoxine botulinique, Type A

is revised to:

Botulinum toxin Type A
Toxine botulinique, type A

Rationale:

Botulinum toxin Type A was added to Schedule F on September 5, 1991. An error in the French version of the listing has been noted and requires correction. The medicinal ingredient is a toxin, not an antitoxin.

Additions to Schedule F, Part I

Description of the medicinal ingredients:

1. Alglucosidase alfa is a synthetic protein produced by recombinant DNA technology that is used to treat individuals with Pompe disease. Pompe disease is a rare, but serious, genetic disorder in which a person's muscle and respiratory function are drastically reduced. Individualized instructions or direct supervision by a practitioner are required. Alglucosidase alfa may cause undesirable or severe side effects at normal therapeutic dosage levels.

2. Darunavir is a protease inhibitor that is used to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults. Darunavir is administered in combination with another anti-HIV medication. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Darunavir may cause undesirable or severe side effects at normal therapeutic dosage levels.

3. Natalizumab is a monoclonal antibody used to treat patients with the relapsing-remitting form of multiple sclerosis (MS), a disease of the central nervous system. Natalizumab is generally recommended in MS patients who have had an inadequate response to, or are unable to tolerate, other therapies for multiple sclerosis. Natalizumab should not be administered in combination with other immune system modifying drugs. Individualized instructions or direct supervision by a practitioner are required. Natalizumab may cause undesirable or severe side effects at normal therapeutic dosage levels.

4. Rasagiline and its salts is a monamine oxidase inhibitor (MAOI) used to treat the signs and symptoms of Parkinson's disease, a disorder of the central nervous system. Individualized instructions or direct supervision by a practitioner are required. The patient may also

require treatment with other drugs and routine laboratory monitoring. Rasagiline and its salts may cause undesirable or severe side effects at normal therapeutic dosage levels.

5. Sorafenib and its salts is used to treat advanced kidney cancer in adults for whom other anti-cancer therapies have failed or are considered unsuitable. Sorafenib and its salts acts by slowing down the rate of tumor growth and cutting off the blood supply that keeps tumors growing. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Sorafenib and its salts may cause undesirable or severe side effects at normal therapeutic dosage levels.

6. Tigecycline is an antibiotic that is administered intravenously to treat complicated infections of the skin and abdominal organs. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Tigecycline may cause undesirable or severe side effects at normal therapeutic dosage levels.

The degree of regulatory control afforded by Schedule F (prescription drug) status coincides with the risk factors associated with these medicinal ingredients. Oversight by a practitioner is necessary to ensure that appropriate risk/benefit information is considered before the drug containing the medicinal ingredient is administered and that the drug therapy is properly monitored.

Alternatives

Any alternatives to the degree of regulatory control provided by this amendment would have to be established through additional scientific information and clinical experience.

No other alternatives were considered.

Benefits and costs

The amendment impacts on the following sectors:

Public

Prescription access to drug products containing these medicinal ingredients will benefit Canadians by decreasing the opportunities for improper use and by ensuring the guidance and care of a practitioner.

Another benefit is that drug products for human use containing medicinal ingredients listed on Schedule F may be covered by both provincial and private health care plans.

Health insurance plans

Drug products for human use containing medicinal ingredients listed on Schedule F may be a cost covered by both provincial and private health care plans.

Provincial health care services

The provinces may incur costs to cover practitioners' fees for services. However, the guidance and care provided by the practitioners would reduce the need for health care services that may result from improper use of drug products for human use that contain medicinal ingredients listed on Schedule F. The overall additional costs for health care services should therefore be minimal.

Consultation

The manufacturers affected by this amendment were made aware of the intent to recommend these medicinal ingredients for inclusion on Schedule F during the review of the drug submission.

Direct notice of the regulatory proposal was provided to provincial and territorial Ministries of Health, medical and pharmacy licensing bodies, and industry, consumer and professional associations on July 6, 2007 with a 75-day comment period. This initiative was also posted on the Health Canada Web site and the *“Consulting With Canadians”* Web site. No comments were received.

The medicinal ingredient, ciclesonide, was mistakenly included in the regulatory proposal provided for consultation on July 6, 2007 and has subsequently been removed from this amendment. Ciclesonide is already included in Schedule F in the group listing in Part II for *Adrenocortical hormones and their salts and derivatives*.

The process for this consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F. The MOU, signed by Health Canada, the Privy Council Office and the Department of International Trade on February 22, 2005, is posted on the Health Canada Web site.

Compliance and enforcement

This amendment does not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act* and the *Food and Drug Regulations* enforced by the Health Products and Food Branch Inspectorate.

Contact

Refer to Project No. 1528
Policy Division
Bureau of Policy, Sciences and International Programs
Therapeutic Products Directorate
1600 Scott Street, Holland Cross
Tower B, 2nd Floor
Address Locator: 3102C5
Ottawa, Ontario
K1A 0K9

Telephone: 613-948-4623
Fax: 613-941-6458
Email: regaff-affreg@hc-sc.gc.ca

[Footnote a](#)

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

[Footnote b](#)


R.S., c. F-27

[Footnote 1](#)

C.R.C., c. 870

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](#)

[Important notices](#)

Updated: 2008-04-16