There would be no anticipated cost to provincial drug benefit plans since most do not cover the costs of non-prescription drugs.

Compliance and enforcement

This amendment would 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.

Consultation

The process for this consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F, which came into effect on February 22, 2005. The MOU is posted on the Health Canada Web site.

This NOI is being sent by email to stakeholders and is also being posted on the Health Canada Web site and the "Consulting with Canadians" Web site.

Any comments regarding this proposed amendment should be sent within 75 days following the date of publication in the *Canada Gazette*, Part I. The policy analyst for this project, Karen Ash, may be contacted at the following address: Refer to Project No. 1496, Policy Division, Bureau of Policy, Science and International Programs, Therapeutic Products Directorate, Holland Cross, Tower B, 2nd Floor, 1600 Scott Street, Address Locator 3102C5, Ottawa, Ontario K1A 0K9, 613-948-4623 (telephone), 613-941-6458 (fax), regaff_access@hc-sc.gc.ca (email).

Final approval

In accordance with the MOU process, it is anticipated that this amendment will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately six to eight months from the date of publication of this NOI in the *Canada Gazette*, Part I. If the amendment is approved by the Governor in Council, publication in the *Canada Gazette*, Part II, would follow. The amendment will come into force on the date of registration.

NEIL YEATES
Assistant Deputy Minister

[30-1-o]

DEPARTMENT OF HEALTH

FOOD AND DRUGS ACT

Notice of Intent — Food and Drug Regulations — *Project No. 1510 — Schedule F*

This Notice of Intent (NOI) is to provide an opportunity to comment on the proposal to

amend Part I of Schedule F to the *Food and Drug Regulations* to revise the listing for ranitidine and its salts to "Ranitidine and its salts, except when sold in concentrations of 150 mg or less per oral dosage unit and indicated for the treatment of heartburn". All strengths of ranitidine and its salts would have prescription status when sold for conditions of use that require the intervention of a practitioner, such as treatment of ulcers and gastro esophageal reflux disease.

Ranitidine is currently listed on Part I of Schedule F as "Ranitidine and its salts (except when sold in a dosage form containing not more than the equivalent of 75 mg of ranitidine)". The wording of the current listing means that all strengths of ranitidine greater than 75 mg require a prescription in order to be sold for any condition of use in Canada.

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 that do not require a prescription for veterinary use if so labelled or if in a form unsuitable for human use.

Description

Ranitidine belongs to a class of drugs known as H_2-receptor antagonists. The 75 mg strength of ranitidine has been available for non-prescription use since 1997 for the treatment of heartburn, also referred to as acid indigestion and sour or upset stomach. Treatment of heartburn may involve taking ranitidine after symptoms have occurred or before consumption of food or beverage to prevent the anticipated symptoms of heartburn.

The non-prescription 150 mg strength of ranitidine would have the same therapeutic indications for use as the currently marketed 75 mg strength. To prevent symptoms of heartburn, one 150 mg tablet should be taken 30–60 minutes before a meal. The consumer should not take more than one 150 mg tablet at a time and not more than two tablets in 24 hours (i.e. 300 mg maximum in 24 hours). The duration of use should not exceed two weeks of continuous treatment without consulting a practitioner.

Ranitidine has an established high margin of safety. No evidence exists that the use of ranitidine or other non-prescription H_2-receptor antagonists delays diagnosis and treatment of serious underlying conditions of the gastrointestinal tract. No safety concerns associated with non-prescription use have arisen during either the eight-plus years of market history of the 75 mg non-prescription strength in Canada or since the launch of the 150 mg strength as a non-prescription drug in the United States in January 2005.

Alternatives

The alternative option would be to leave ranitidine 150 mg on Schedule F for all conditions of use. As measured against the factors for listing drugs on Schedule F, it has been determined that maintaining ranitidine 150 mg on Schedule F for all conditions of use is not appropriate.

The data from five trials that had been submitted in support of market authorization, in

addition to data previously submitted for the 75 mg product, provided adequate information to grant non-prescription status for a 150 mg strength of ranitidine, with prevention and treatment claims identical to those that have been approved for the 75 mg strength. An increase in the 24-hour maximum daily dose from 150 mg to 300 mg does not pose any safety concerns.

The non-prescription availability of a 150 mg strength of ranitidine provides a dose option to those heartburn sufferers who find that a 75 mg dose is not sufficiently effective.

Benefits and costs

The proposed amendment would impact on the following sectors:

- Public

The availability of ranitidine 150 mg as a non-prescription product would provide consumers with more convenient access to treatment for heartburn.

Product labels would be required to include directions for use and applicable cautionary statements. This would help to provide information to the public about the product's safe and proper use.

The public would be required to pay directly for the product, as products which do not require a prescription are not usually covered by drug insurance plans.

- Health insurance plans

There would be no anticipated cost for privately funded drug benefit plans since most do not cover the cost of non-prescription drugs.

- Provincial health care services

There would be no anticipated cost to provincial drug benefit plans since most do not cover the costs of non-prescription drugs.

Compliance and enforcement

This amendment would 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.

Consultation

The process for this consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F, which came into effect on February 22, 2005. The MOU is posted on the Health Canada Web site.

This NOI is being sent by email to stakeholders and is also being posted on the Health

Canada Web site and the "Consulting with Canadians" Web site.

Any comments regarding this proposed amendment should be sent within 75 days following the date of publication in the *Canada Gazette*, Part I. The policy analyst for this project, Karen Ash, may be contacted at the following address: Refer to Project No. 1510, Policy Division, Bureau of Policy, Science and International Program, Therapeutic Products Directorate, Holland Cross, Tower B, 2nd Floor, 1600 Scott Street, Address Locator 3102C5, Ottawa, Ontario K1A 0K9, 613-948-4623 (telephone), 613-941-6458 (fax), regaff_access@hc-sc.gc.ca (email).

Final approval

In accordance with the MOU process, it is anticipated that this amendment will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately six to eight months from the date of publication of this NOI in the *Canada Gazette*, Part I. If the amendment is approved by the Governor in Council, publication in the *Canada Gazette*, Part II, would follow. The amendment will come into force on the date of registration.

NEIL YEATES
Assistant Deputy Minister

[30-1-o]

DEPARTMENT OF INDUSTRY

OFFICE OF THE REGISTRAR GENERAL

Appointments

Name and position	*Order in Council*
Adam, Dyane Commissioner of Official Languages for Canada	2006-711
Foster, Julia E. National Arts Centre Corporation Chairperson of the Board of Trustees	2006-706
Gonthier, The Hon. Charles Doherty Communications Security Establishment Commissioner	2006-707
Government of Manitoba Administrators Huband, The Hon. Charles R.	2006-703