FOOD AND DRUGS ACT

Notice of Intent — Food and Drug Regulations — *Project No. 1496 — 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 famotidine and its salts to "Famotidine and its salts, except when sold in preparations for oral use containing 20 mg or less of famotidine per dosage unit and indicated for the treatment of heartburn". All strengths of famotidine 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.

Famotidine is currently listed on Part I of Schedule F as "Famotidine and its salts (except in preparations for oral use containing 10 mg or less of famotidine per dosage unit)". The wording of the current listing means that all strengths of famotidine greater than 10 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

Famotidine belongs to a class of drugs known as H_2-receptor antagonists. Famotidine in 20 mg and 40 mg strengths has been available in Canada since 1986 as a prescription drug for the treatment of gastrointestinal conditions requiring diagnosis and treatment by a practitioner, such as peptic or duodenal ulcer, gastro esophageal reflux and hiatus hernia. The 10 mg strength of famotidine has been available for non-prescription use since 1996 for the treatment of heartburn, also referred to as acid indigestion or sour or upset stomach. Treatment of heartburn may involve taking famotidine after symptoms have occurred or before consumption of food or beverage to prevent the anticipated symptoms of heartburn. Both the 10 mg and the 20 mg dosage units of famotidine have shown to be effective in the treatment and prevention of heartburn, acid indigestion and sour or upset stomach.

The non-prescription 20 mg strength of famotidine would have the same indications for use as the currently marketed 10 mg strength, namely, for the treatment of heartburn, acid indigestion, sour or upset stomach and for the prevention of these symptoms when associated with the consumption of food and/or beverage, including night-time symptoms associated with the evening meal and expected to cause sleep disturbance. The recommended dose is one 20 mg tablet. Not more than one 20 mg tablet should be taken at a time and not more than two tablets in 24 hours. The duration of use should not exceed two weeks of continuous treatment without consulting a practitioner.

Postmarketing experience has also shown that neither the 10 mg nor 20 mg dosage strength is associated with significant adverse effects. There are no dose-related or age-related adverse effects, no special populations at risk and no clinically significant drug or

food interactions. In addition to its large safety margin, side effects associated with the use of a single 10 mg or 20 mg dose of famotidine (not exceeding 20 mg or 40 mg daily, respectively) are minor and transient in nature, with incidence and severity being equivalent to that observed in placebo-treated groups.

Monitoring of non-prescription use has shown no appreciable increase in consumption of these drugs, and the pattern of admissions to hospital for complications of ulcer disease has not changed. The risk of masking a more serious disease such as stomach cancer is the same as that associated with antacids and pain medications that are available as non-prescription drugs. In addition, there is no evidence that non-prescription use of famotidine 20 mg will delay diagnosis and treatment any more than the use of conventional antacids.

Alternatives

The alternative option would be to leave famotidine 20 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 famotidine 20 mg on Schedule F for all conditions of use is not appropriate.

Data from two clinical trials demonstrated that a 20 mg dose of famotidine provided a statistically significant increase in the proportion of subjects who do not experience heartburn following ingestion of a provocative meal, compared to a 10 mg dose of famotidine under these conditions. The availability of a non-prescription 20 mg strength of famotidine will provide an option to those heartburn sufferers who find that a 10 mg dose of famotidine is not sufficiently effective.

Benefits and costs

The proposed amendment would impact on the following sectors:

- Public

The availability of famotidine 20 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. 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

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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