measures to allow the use of amylase derived from *Aspergillus oryzae var.* The amendments are supported by the safety assessment and would have low impact on the economy and the environment. Consequently, the regulatory amendments may proceed directly to final approval and publication in the *Canada Gazette*, Part II.

Interested persons may make representations with respect to Health Canada's intention to amend the 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 the contact person identified below.

Contact

Marie-Claude Tardif, Associate Director, Bureau of Food Regulatory, International and Interagency Affairs, Health Canada, 200 Tunney's Pasture Driveway, Address Locator 0702C1, Ottawa, Ontario K1A 0K9, 613-957-1750 (telephone), 613-941-3537 (fax), sche-ann@hc-sc.gc.ca (email).

February 20, 2008

MEENA BALLANTYNE
Assistant Deputy Minister
Health Products and Food Branch

[9-1-o]

DEPARTMENT OF HEALTH

FOOD AND DRUGS ACT

Notice of Intent — Food and Drug Regulations —*Project No. 1584 — 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 naproxen and its salts to allow non-prescription status when sold for oral use with a daily dose of 440 mg.

"Naproxen and its salts" is currently listed in Part I of Schedule F

without any qualifying phrases or exceptions. This means that all strengths of naproxen and its salts currently require a prescription in order to be sold 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 do not require a prescription for veterinary use if so labelled or if in a form unsuitable for human use.

Description

Naproxen and its salts is a non-steroidal anti-inflammatory drug (NSAID) that is used to treat inflammation and pain. Naproxen and naproxen sodium, a naproxen salt, have been available as prescription drugs in Canada since 1975 and 1980, respectively.

Naproxen and its salts as a non-prescription drug would have indications for use that are amenable to self-diagnosis, self-treatment and self-monitoring. These indications for use include symptomatic treatment of headache, toothache, muscular ache, backache, pain or stiffness of arthritic conditions, menstrual pain, minor aches and pain associated with the common cold and pain due to minor surgery, dental extractions and muscle sprains as well as for fever reduction. The recommended non-prescription daily dose is 440 mg. The duration of use should not exceed five days of continuous treatment without consulting a practitioner.

Naproxen sodium was approved for non-prescription use in the United States in 1994 and, subsequently, in 33 other countries. Non-prescription status is currently under review in four additional countries, including Canada. Naproxen sodium has a wide margin of safety. Postmarketing experience has shown that a 440-mg daily dose is not 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 daily 440-mg dose are minor and transient in nature, with incidence and severity being equivalent to that observed in placebo-treated groups.

Alternatives

The alternative option would be to leave naproxen and its salts in Schedule F for all dosages and conditions of use. As measured against the factors for listing drugs in Schedule F, it has been determined that maintaining naproxen and its salts in Schedule F for all strengths and conditions of use is not appropriate.

The availability of a non-prescription naproxen and its salts with a 440-mg daily dose would provide consumers with another option for self-treatment of mild to moderate pain.

Benefits and costs

The proposed amendment would impact on the following sectors:

- Public

The availability of naproxen and its salts with a 440-mg daily dose as a non-prescription product would provide consumers with more convenient access to treatment for pain.

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. 1584, 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.

MEENA BALLANTYNE
Assistant Deputy Minister

[9-1-o]

DEPARTMENT OF INDUSTRY