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Graham Spry Building
250 Lanark Avenue
A.L. 2005D
Ottawa, Ontario
K1A 0K9

05-125672-719

Provincial and Territorial Deputy Ministers of Health
Canadian Veterinary Medical Association
Association des vétérinaires en industrie animale du Québec
Canadian Council on Animal Care
College of Veterinarians of Ontario
Provincial and Territorial Drug Program Managers
Deans of Pharmacy
Registrars of Provincial Medical and Pharmacy Associations
Industry and Consumer Associations
Regulatory and Health Professional Associations
Other Interested Parties

Dear Sir/Madam:

Re: ***Food and Drug Regulations*** **- Project # 1491 - Schedule F**

- Public Involvement & Consultations
- Regulatory Requirements for Advertising
- Special Access to Drugs & Health Products
- Substances: Problematic Use
- Veterinary Drugs
- Legislation & Guidelines
- Reports & Publications

Emergencies & Disasters

Environmental & Workplace Health

First Nations & Inuit Health

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Health Care System

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This letter is to provide an opportunity for comment on the proposed addition of deracoxib 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 determined the necessity for prescription status for the medicinal ingredient in this proposed amendment 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 applications.

Description of the medicinal ingredient:

Deracoxib is a cox-2 inhibitor belonging to the NSAID (non-steroidal anti-inflammatory) class of drugs. Deracoxib is indicated for the relief of pain and inflammation associated with orthopedic surgery and osteoarthritis in dogs. Deracoxib is the first coxib class NSAID for use in animals. The human NSAID drugs are not very useful for dogs as metabolism of the drugs is not predictable in individual dogs. Deracoxib has a predictable duration of action and dose response in dogs. Deracoxib must be administered under the supervision of a veterinarian because the dosage has a narrow margin of safety, especially in older dogs, and there may be 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 this medicinal ingredient. Oversight by a veterinarian 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 recommended in this amendment would need to be established through additional scientific information and clinical experience.

No other alternatives were considered.

Benefits and Costs

The amendment would have the following impact on the public sector:

Prescription access to drug products containing this medicinal ingredient would benefit Canadians by decreasing opportunities for improper use. The products would be used under the supervision of a veterinarian.

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 manufacturer affected by this proposed amendment was made aware of the intent to recommend this medicinal ingredient for inclusion on Schedule F during the review of the drug submission.

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 website.

This letter is being sent by email to stakeholders and is also being posted on the Health Canada website and the *Consulting With Canadians* website.

Any comments regarding this proposed amendment should be addressed as follows within **75** days following the date of posting of this letter on the Health Canada website. The policy analyst for this project, Ginette Chalifoux, may be contacted at:

Project No. 1491
Policy Division
Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
1600 Scott Street, Holland Cross
Tower 'B', 2nd Floor
A. L. 3102C5
Ottawa ON K1A 0K9
telephone: 613-948-4623 (refer to Project No. 1491)
facsimile: 613-941-6458 (refer to Project No. 1491)
email: regaff_access@hc-sc.gc.ca

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 6 to 8 months from the date of posting of this letter on the Health Canada website. If approved by the Governor in Council, publication in the *Canada Gazette*, Part II, would follow. The amendment would come into force on the date of registration.

Yours sincerely,

Original signed by

Neil Yeates
Assistant Deputy Minister