Contact
Regulatory Affairs

This document is also available in PDF format [project_projet_1478_e.pdf]
Pages: 03, Size: 16 K, Date: 2006-08-22

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

05-117132-496

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 # 1478 - Schedule F

The purpose of this letter is to provide an opportunity to comment on the proposed addition of resocortol and its derivatives to Part I of

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

- **Emergencies & asters**
- **Environmental & rkplace Health**
- **First Nations & it Health**
- **Food & Nutrition**
- **Health Care stem**
- **Healthy Living**
- **Science & search**

- **Government alth Partners**
- **Need ger xt?**

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.

Description of the medicinal ingredient:

Resocortol and its derivatives - is a corticosteroid that is used topically in veterinary medicine for the treatment of pyotraumatic dermatitis ("Hot Spots") in dogs. Resocortol butyrate should be used only under the supervision of a veterinarian since professional veterinary expertise is required to diagnose and treat pyotraumatic dermatitis. This medicinal ingredient also possesses the potential for undesirable side effects at normal therapeutic dosage levels, further reinforcing the need for veterinary supervision.

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 adequate 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 the 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, Karen Ash, may be contacted at:

Refer to Project No. 1478
Policy Division
Bureau of Policy, Science and International Programs

Therapeutic Products Directorate
1600 Scott Street, Holland Cross Building
Tower 'B', 2nd Floor
A. L. 3102C5
Ottawa ON K1A 0K9
Telephone: 613-948-4623
Facsimile: 613-941-6458
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 six to eight 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