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FOOD AND DRUGS ACT

Regulations Amending the Food and Drug Regulations (1398 — Addition of Ferric Ferrocyanide to Paragraph C.01.040.2(4)(a))

P.C. 2005-501 April 5, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1398 - Addition of Ferric Ferrocyanide to Paragraph C.01.040.2(4)(a))*.

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1398 - ADDITION OF FERRIC FERROCYANIDE TO PARAGRAPH C.01.040.2(4)(a))

AMENDMENT

1. Paragraph C.01.040.2(4)(a) of the *Food and Drug Regulations* ([see footnote 1](#)) is amended by adding the following in alphabetical order:

FERRIC FERROCYANIDE (C.I. No. 77510),

COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

The Therapeutic Products Directorate adds Ferric Ferrocyanide (Colour Index 77510) to the *Food and Drug Regulations*, paragraph C.01.040.2(4)(a), the list of colouring agents permitted in drugs for external use.

Rationale

Colouring agents permitted for use in drugs are restricted to those listed in section C.01.040.2 of the *Food and Drug Regulations*. Subsection C.01.040.2(4) lists colours which are permitted in drugs only for external use.

Ferric Ferrocyanide refers to ferric hexacyanoferrate pigment characterized by the structural formula $\text{Fe}_4[\text{Fe}(\text{CN})_6]_3$, which functions as a colourant predominantly in cosmetics.

Names and description:

Colour Index Number: C.I. 77510

Chemical Abstract Service (CAS): 14038-43-8

EINECS Number: 237-875-5

Colour/Shade: Blue

Other Common Names: Prussian Blue (United States), Pigment Blue 27, Berlin Blue, Ferrihexacyanoferrate, Ferrotsin, Paris Blue.

The proposal to add Ferric Ferrocyanide to subsection C.01.040.2(4) is based on a review, by the Therapeutic Products Directorate, of relevant safety data and an assessment of the use of this colour in other products for external (including cosmetic use) and internal use.

Ferric Ferrocyanide has been approved for use in externally applied drugs and cosmetics in the United States and in cosmetics in Europe and Japan.

The Cosmetics Programme of the Product Safety Programme of Health Canada has not objected to the use of Ferric Ferrocyanide in cosmetics. Approximately 800 cosmetic products, including 627 deodorants, contain this substance identified as C.I. 77510.

In the United States, the use of Ferric Ferrocyanide is permitted to colour externally applied drugs, including those for use in the area of the eye. In addition, Ferric Ferrocyanide is recognized to be a safe and effective internal treatment for thallium poisoning. This recommendation provides further indication of the safety of this compound.

In arriving at its conclusion to add Ferric Ferrocyanide to subsection C.01.040.2(4), the Therapeutic Products Directorate took into account the widespread use of this colouring agent in both cosmetics and drugs. The

application of Ferric Ferrocyanide in both cosmetics and drugs worldwide, and the lack of significant adverse reactions lends itself to the conclusion that the agent is safe to use externally in drugs.

Alternatives

The alternative option was not to propose the addition of Ferric Ferrocyanide to the Regulations. This option was not considered to be acceptable as it would unduly restrict manufacturers' ability to market drug products for external use containing a colouring agent which is widely used in other products for external use.

Benefits and Costs

This amendment would permit an additional colourant for external use drug products and would impact on the following sectors.

1. Industry

The industry sector would benefit from being permitted to market in Canada drug products for external use that contain Ferric Ferrocyanide.

2. Government

This amendment is not expected to result in additional costs.

3. Public

Consumers would benefit from access to a wider selection of drug products for external use.

Consultation

The proposed amendment was pre-published in the *Canada Gazette*, Part I, on April 3, 2004 with a 75-day comment period. The proposal was posted on the Therapeutic Products Directorate web site.

One comment was received. The comment was supportive of the addition of ferric ferrocyanide to the list of acceptable colouring agents in the *Food and Drug Regulations*.

Compliance and Enforcement

This amendment would be subject to existing compliance mechanisms under the provisions of the *Food and Drugs Act* and regulations enforced by the Health Products and Food Branch Inspectorate. Direct enforcement is provided through complaints from the medical profession and competitors.

Contact

Presho Jesu
Policy Bureau

Therapeutic Products Directorate
1600 Scott Street
Holland Cross, Tower "B", 2nd Floor
Address Locator 3102C5
Ottawa, Ontario
K1A 1B6
Telephone: (613) 957-6447
FAX: (613) 941-6458
E-mail: presho_jesu@hc-sc.gc.ca

[Footnote a](#)

S.C. 1999, c. 33, s. 347

[Footnote 1](#)

C.R.C., c. 870

NOTICE:

The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



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