Notification Number: 2005/416/F

Technical notes Pro Pharmacopoeia subject to public inquiry

Date received : 30/08/2005 End of Standstill : 30/11/2005

Message

Message 002

Communication from the Commission - SG(2005) D/51911

Directive 98/34/EC

Translation of the message 001 Notification: 2005/0416/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200501911.EN)

1. Structured Information Line

MSG 002 IND 2005 0416 F EN 30-11-2005 30-08-2005 F NOTIF 30-11-2005

2. Member State

France

3. Department Responsible

Délégué interministériel aux normes - SQUALPI -12 rue Villiot - 75572 PARIS CÉDEX 12 suzanne.piau@industrie.gouv.fr ou syrte@industrie.gouv.fr tél : 01 53 44 97 04 - fax : 01 53 44 98 88

lei . 01 33 44 97 04 - lax . 01 33 44 96 66

3. Originating Department

AGENCE FRANÇAISE DE SÉCURITÉ SANITAIRE DES PRODUITS DE SANTÉ - DLC/Unité pharmacopée 143-147, boulevard Anatole France - F-93285 SAINT-DENIS CEDEX

4. Notification Number

2005/0416/F - C30P

5. Title

Technical notes Pro Pharmacopoeia subject to public inquiry

6. Products Concerned

Technical notes Pro Pharmacopoeia (texts attached)

No 1048 : Calcium (oxide)

No 1049 : Calcium (hydroxide) (solution)

No 1050 : Cold cream No 1051 : Galen cream No 1052 : Starch glycerol No 1053 : Zinc oxide glycerol No 1054 : Carron cream

No 1055 : Carron oil

No 1056 : Zinc paste

No 1057: Salicylic acid pomade

No 1058 : Placebo tablets No 1059 : Placebo capsules

7. Notification Under Another Act

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8. Main Content

Quality requirements for the products referred to in paragraph 6 and the related legislation.

9. Brief Statement of Grounds

Protection of Public Health

10. Reference Documents - Basic Texts

French Pharmacopoeia - 10th edition. The texts shall be published in the Official Gazette of the French Republic with the wording: "Having regard to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, and in particular Notification No..." ".

11. Invocation of the Emergency Procedure

NO

12. Grounds for the Emergency

13. Confidentiality

NO

14. Fiscal measures



NO
15. Impact assessment
16. TBT and SPS aspects -
David O'Sullivan Secretary-General European Commission
Point de contact Directive 98/34 Fax: (32-2) 296 76 60 email: Dir83-189-central@cec.eu.int
sent to :
BELNotif Qualité et Sécurité Mme Descamps
BundesMinisterium für Wirtschaft Referat XA2 Frau Christina Jäckel
Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1 Frau MARKL Iris
Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1 Frau Brigitte WIKGOLM
Cyprus org. for the promotion of quality Ministry of Commerce, Industry & Tourism M. Antonis Ioannou
Czech Office for Standards, Metrology and testing Mrs. Fofonkova Helena
Department of Trade and Industry STRD2 Mr Philip Plumb
Délégation Interministérielle aux Normes Mme Piau

EFTA Surveillance Authority Mr. Gunnar Thor PETURSSON



ELOT

M.Mourtzanos K

EU internal market coordination (Ministry of Economics) Mrs Zanda Liekna

Erhvervs- og Boligstyrelsen Lene Hald Nielsen

European Free Trade Association

Hungarian Notification Centre Ministry of economy & transport Mr Zsolt Fazekas

Institut Belge de Normalisation Mme F. Hombert

Instituto Portugês da Qualidade Sra Cândida Pires

Kauppa-ja teollisuusministeri M. Tuomas Mikkola

Kommerskollegium Mme Kerstin Carlsson

Lithuanian Standards Board Daiva Lesickiene

Malta standards Authority Dr Lorna Cachia

Min. de Asuntos Exteriores Esther Perez Pelaez

Min. of Economic Affairs & Communication Mr. Karl Stern

Min. of Industry, Energy & Technology Mr K. Polychronidis

Ministerie van Financien Belastingsdienst - Douane / CDIU De Heer IJ.G. van der Heide

Ministero delle attivit produttive F1 - Ispettorato tecnico industria Signor Vincenzo Correggia

Ministry of Economy, Labour and Social Dept for Europe & multilateral relations Mrs Barbara Nieciak

NSAI Mr Tony Losty



National Agency for Enterprise & Housing Mrs Birgitte Spühler Hansen Office of standards, metrology & Testing Director of the department of European I Mrs Kvetoslava STEINLOVA Représentation Permanente de la Belgique auprès de l'Union européenne Représentation Permanente de la France Représentation Permanente du Luxembourg SL Service de l'Energie de l'Etat Mr J.-P. Hoffmann Slovenian Institute for Standardization SIST Mrs Vesna Stazisar sent to: Department of Trade and Industry STRD2 Mr Philip Plumb **EFTA Surveillance Authority** Mr. Gunnar Thor PETURSSON European Free Trade Association Hungarian Notification Centre Ministry of economy & transport Mr Zsolt Fazekas Kauppa-ja teollisuusministeri M. Tuomas Mikkola **NSAI** Mr Tony Losty Représentation Permanente de l'Irlande Denis Colfer Représentation Permanente du Royaume-Uni SL



EUROPEAN COMMISSION GROWTH DIRECTORATE-GENERAL

Single Market for goods Prevention of Technical Barriers

Undersecretariat of Foreign Trade General Directorate of Standardisation Mr Mehmet COMERT