



Notification Number: 2014/529/F

Pro Pharmacopoeia technical notes submitted for public inquiry (Nos 1254, 1255, 1256, 1257, 1258 and 1259)

Date received : 31/10/2014

End of Standstill : 02/02/2015

Issue of comments by : Germany

Message

Message 002

Communication from the Commission - TRIS/(2014) 03204

Directive 98/34/EC

Translation of the message 001

Notification: 2014/0529/F

No abre el plazo - Ne zahajuje 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 késések - Ma' jiftaħ 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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201403204.EN)

1. Structured Information Line

MSG 002 IND 2014 0529 F EN 31-10-2014 F NOTIF

2. Member State

F

3. Department Responsible

Délégué interministériel aux normes – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13

d9834.france@finances.gouv.fr

tél : 01 44 97 24 55

3. Originating Department

Agence nationale de sécurité du médicament et des produits de santé –

Direction des contrôles/Pôle Standardisation, Pharmacopée, Normalisation– 143-147, boulevard Anatole



France – F-93285 SAINT-DENIS CEDEX
pharmacopeefrançaise@ansm.sante.fr
tél. 01 55 87 36 85 – fax. 01 55 87 41 32

4. Notification Number

2014/0529/F - C30P

5. Title

Pro Pharmacopoeia technical notes submitted for public inquiry (Nos 1254, 1255, 1256, 1257, 1258 and 1259)

6. Products Concerned

Draft monograph

7. Notification Under Another Act

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8. Main Content

No 1254 Bergamot (essential oil)
No 1255 Glyceryl (trinitrate), PPH solution, Glonoinum PPH (rev.)
No 1256 Calcium (fluoride) PPH, Calcareo fluorica PPH (rev.)
No 1257 Common fumitory PPH, Fumaria officinalis PPH (rev.)
No 1258 Merc sol PPH, Mercurius solubilis hahnemanii PPH (rev.)
No 1259 Silver Dust PPH, Cineraria maritima PPH (rev.)

9. Brief Statement of Grounds

French pharmacopoeia, 11th edition. The text will be published by way of an order in the Official Journal of the French Republic with the following 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 Information Society services, and in particular notification No ...

10. Reference Documents - Basic Texts

No basic texts available

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

TBT aspect

No - the draft is not a technical provision or a conformity assessment procedure.

SPS aspect

No - the draft is not a sanitary or phytosanitary measure.

European Commission

Contact point Directive 98/34

Fax: +32 229 98043

email: dir83-189-central@ec.europa.eu