Notification Number: 2013/58/F

Pro Pharmacopoeia technical note submitted for public inquiry (texts appended hereto) No 1243: Senna alata (leaflet) (rev.) No 1244: Graphite for homeopathic preparations (rev.) No 1243: Recommendations for the clonogenic test for **CFU-GM** progenitors

Date received : 31/01/2013 End of Standstill: 02/05/2013

Message

Message 002

Communication from the Commission - SG(2013) D/5342

Directive 98/34/EC

Translation of the message 001

Notification: 2013/0058/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 - He се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201300342.EN)

1. Structured Information Line

MSG 002 IND 2013 0058 F EN 31-01-2013 F NOTIF

2. Member State

3. Department Responsible

Déléqué interministériel aux normes - SQUALPI - Bât. Sievès -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 41 41 – fax. 01 55 87 41 32

Mél. claire.zemp-ricchiuto@sante.gouv.fr

4. Notification Number

2013/0058/F - C30P

5. Title

Pro Pharmacopoeia technical note submitted for public inquiry (texts appended hereto)

No 1243: Senna alata (leaflet) (rev.)

No 1244: Graphite for homeopathic preparations (rev.)

No 1243: Recommendations for the clonogenic test for CFU-GM progenitors

6. Products Concerned

Draft monograph

7. Notification Under Another Act

8. Main Content

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 rules on information society services, and in particular notification No ..."

9. Brief Statement of Grounds

Pro Pharmacopoeia technical notes submitted for public inquiry prior to publication in the Official Journal of the French Republic.

10. Reference Documents - Basic Texts

No basic text(s) available.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency



EUROPEAN COMMISSION GROWTH DIRECTORATE-GENERAL

Single Market for goods Prevention of Technical Barriers

-

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.

Catherine Day Secrétaire général Commission européenne

Point de contact Directive 98/34

Fax: (32-2) 296 76 60

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