



Notification Number: 2015/318/F

Pro Pharmacopoeia technical notes Nos 1260 (Nadolol), 1261 (Natural Sodium PPH) and 1262 (Hops PPH)

Date received : 22/06/2015

End of Standstill : 23/09/2015

Issue of comments by : Germany

Message

Message 002

Communication from the Commission - TRIS/(2015) 01867

Directive 98/34/EC

Translation of the message 001

Notification: 2015/0318/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 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: 201501867.EN)

1. Structured Information Line

MSG 002 IND 2015 0318 F EN 22-06-2015 F NOTIF

2. Member State

F

3. Department Responsible

Direction générale des entreprises – SQUALPI – Bureau de la réglementation des produits - Bât. Sieyès
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3. Originating Department

Agence nationale de sécurité du médicament et des produits de santé
Direction des contrôles/pôle Standardisation, Pharmacopée, Normalisation



143-147, Bd Anatole France
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4. Notification Number

2015/0318/F - C30P

5. Title

Pro Pharmacopoeia technical notes Nos 1260 (Nadolol), 1261 (Natural Sodium PPH) and 1262 (Hops PPH)

6. Products Concerned

Pro Pharmacopoeia technical notes submitted for public inquiry Nos 1260, 1261 and 1262

7. Notification Under Another Act

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8. Main Content

Nadolol capsules (1 mg to 50 mg)
Natural sodium (chloride) PPH, Natrum muriaticum naturale PPH
Hops (fresh cones) PPH, Humulus lupulus recens 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 rules on information society services, and in particular notification No ..."

10. Reference Documents - Basic Texts

No basic text(s) 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 neither a technical provision nor a conformity assessment procedure.

SPS aspect

No - the draft is neither a sanitary nor a phytosanitary measure.

European Commission

Contact point Directive 98/34

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