Notification Number: 2018/163/F

Pro Pharmacopoeia Technical Note No 1272, submitted for public inquiry

Date received	:	12/04/2018
End of Standstill	:	13/07/2018

Message

Message 002

Communication from the Commission - TRIS/(2018) 00925
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2018/0163/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 - Não 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: 201800925.EN)

1. Structured Information Line
MSG 002 IND 2018 0163 F EN 12-04-2018 F NOTIF

2. Member State
F

3. Department Responsible
Direction générale des entreprises – 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 Politiques d'Autorisation et d'Innovation
Pôle pilotage et sécurisation des métiers, des processus et pharmacopée
143-147, boulevard Anatole France – F-93285 SAINT-DENIS CEDEX
contactspharmacopeefrançaise@ansm.sante.fr

tél. 01 55 87 41 57 – fax. 01 55 87 35 82

4. Notification Number
2018/0163/F - C30P

5. Title
Pro Pharmacopoeia Technical Note No 1272, submitted for public inquiry

6. Products Concerned
Monograph for pharmaceutical products

7. Notification Under Another Act
-

8. Main Content
The aim of the draft amendment to monograph No 1272 regarding sodium chloride capsules (50 mg – 1 g) is to:
- widen the therapeutic range,
- include the capsule size range, and
- amend the procedure for measuring the active ingredient (potentiometric method).

9. Brief Statement of Grounds
The texts, implemented in the 11th edition of the French Pharmacopoeia, will be published by way of a decision of the Director-General of the French National Agency for the Safety of Medicines and Health Products with the following wording: ‘Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical 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 regulation nor a conformity assessment procedure.

SPS aspect

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

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European Commission

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Fax: +32 229 98043
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