



Notification Number: 2009/342/F

Pro Pharmacopeia technical notes submitted for public inquiry (texts enclosed) No. 1190: CEFUROXIME STERILE SOLUTION 10 mg/ml FOR INTRACAMERULAR INJECTION

Date received : 30/06/2009

End of Standstill : 01/10/2009

Message

Message 002

Communication from the Commission - SG(2009) D/51473

Directive 98/34/EC

Translation of the message 001

Notification: 2009/0342/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 - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 200901473.EN)

1. Structured Information Line

MSG 002 IND 2009 0342 F EN 01-10-2009 30-06-2009 F NOTIF 01-10-2009

2. Member State

F

3. Department Responsible

Délégué interministériel aux normes – SQUALPI – Bâtiment Le Bervil - 12, rue Villiot – 75572 Paris Cedex 12
d9834.france@finances.gouv.fr
tél : 01 53 44 98 24 – fax : 01 53 44 98 88

3. Originating Department

Agence française de Sécurité Sanitaire des Produits de Sante –
DLC/Unité Pharmacopée – 143-147, boulevard Anatole France –
F-93285 SAINT-DENIS CEDEX



pharmacopeefrançaise@afssaps.sante.fr
tél. 01 55 87 41 41 – fax. 01 55 87 41 32

4. Notification Number

2009/0342/F - C30P

5. Title

Pro Pharmacopeia technical notes submitted for public inquiry (texts enclosed) No. 1190: CEFUROXIME
STERILE SOLUTION 10 mg/ml FOR INTRACAMERULAR INJECTION

6. Products Concerned

Draft monographs

7. Notification Under Another Act

-

8. Main Content

French Pharmacopeia, 10th Edition (national proforma). The texts will be published by order in the Official Journal of the French Republic with the reference: "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, in particular notification No."

9. Brief Statement of Grounds

-

10. Reference Documents - Basic Texts

-

11. Invocation of the Emergency Procedure

NO

12. Grounds for the Emergency

-

13. Confidentiality

NO

14. Fiscal measures

b) NO



15. Impact assessment

-

16. TBT and SPS aspects

TBT relevance

a) NO

b) i) The draft is not a technical regulation or procedure for assessing conformity within the meaning of Annex of the TBT Agreement

SPS relevance

a) NO

b) i) The draft is not a sanitary or phytosanitary measure within the meaning of Annex A of the Agreement on Sanitary and Phytosanitary Measures.

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

sent to :

European Free Trade Association

.

Työ- ja elinkeinoministeriö
Ms. Leila Vilhunen

Malta standards Authority
Sarah Jane Meli

Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

CU N Lovseth Hanne Leen

.

NSAI
Mr Tony Losty

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT



EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

Représentation Permanente du Royaume-Uni
.

Department for Business, Innov. & Skills
Mr Philip Plumb

State Agency for Metrological and Technical Surveillance
Violetta Veleva

SL
.

Hungarian Notification Centre Ministry of National Development and Eco
Mr Zsolt Fazekas

Représentation Permanente de l'Irlande
Denis Colfer

sent to :

European Free Trade Association
.

Työ- ja elinkeinoministeriö
Ms. Leila Vilhunen

Malta standards Authority
Sarah Jane Meli

Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

CU N Lovseth Hanne Leen
.

NSAI
Mr Tony Losty

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON



Représentation Permanente du Royaume-Uni

.

Department for Business, Innov. & Skills
Mr Philip Plumb

State Agency for Metrological and Technical Surveillance
Violetta Veleva

SL

.

Hungarian Notification Centre Ministry of National Development and Eco
Mr Zsolt Fazekas

Représentation Permanente de l'Irlande
Denis Colfer