



Notification Number: 1997/149/F

Pro Pharmacopea technical specifications submitted to public investigation.

Date received : 21/03/1997

End of Standstill : 23/06/1997

Message

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DEPT. OF TRADE AND INDUSTRY, QUALITY AND EDUCATION DIVISION,
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EUROPEAN FREE TRADE ASSOCIATION SURVEILLANCE AUTHORITY

EUROPEAN FREE TRADE ASSOCIATION
ATT. MS. BAKKE-D'ALOYA

TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (97) D/50706/2
DIRECTIVES 83/189/EEC, 88/182/EEC AND 94/10/EC
TRANSLATION OF TELEX 001



NOTIFICATION 97/0149/F

- 3B1 : 9700706.EN

1. Structured Information Line

TLX 002 IND- 97 0149 F-- EN ----- 970321 --- ---

2. Member State

France

3. Department Responsible

Ministère de l'Industrie
Délégation interministérielle aux Normes
Bureau de Normalisation et des Affaires Internationales

3. Originating Department

Agence du médicament

4. Notification Number

97/0149/F

5. Title

Pro Pharmacopoea technical specifications submitted to public investigation.

6. Products Concerned

Pro Pharmacopoea technical specifications (texts enclosed)
No. 846: Gliclazide (10th revision)
No. 847: Trimetazidine (dichlorhydrate of)
No. 848: Paliurus aculeatus for homeopathic preparations
No. 849: Ribes nigrum for homeopathic preparations (10th revision)
No. 850: Vaccinium myrtillus for homeopathic preparations (10th revision)
No. 851: Magnesium (glycerophosphate of)

7. Notification Under Another Act

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8. Main Content

Requirements with regard to quality for the products mentioned in paragraph 6 and related regulations.

9. Brief Statement of Grounds

Protection of public health.

10. Reference Documents - Basic Texts

French pharmacopeas, 10th edition. The texts will be published by means of an order in the Official Gazette of the French Republic with the wording: "Having regard to Directive 83/189/EEC laying down a procedure for the provision of



information in the field of technical standards and regulations, amended by Directives 83/182/EEC and 94/10/EC."

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

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14. Fiscal measures

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D. WILLIAMSON
COMEUR
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