



Notification Number: 1998/172/F

Additional clause to the French Pharmacopoeia, 10th edition

Date received : 20/04/1998

End of Standstill : 22/07/1998

Message

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TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (98) D/50989/2
DIRECTIVES 83/189/EEC, 88/182/EEC AND 94/10/EC
TRANSLATION OF TELEX 001



NOTIFICATION 98/0172/F

- 3B1 : 9800989.EN

1. Structured Information Line

TLX 002 IND- 98 0172 F-- EN ----- 980420 --- ---

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

98/0172/F

5. Title

Additional clause to the French Pharmacopoeia, 10th edition

6. Products Concerned

Monographs in the French Pharmacopoeia (amendments and additions)

Revised monographs:

- Laotian benzoin
- Hydrastis
- Salicaria
- Benzoin dye
- Hymenoptera poisons for allergen products
- Agnus castus for homeopathic preparations
- Ribes nigrum for homeopathic preparations

New monographs

- Erysimum
- Robert weed geranium
- Alcohol solution of essential oil of peppermint
- Agaricus bulbosus for homeopathic preparations
- Juglans regia for homeopathic preparations.

7. Notification Under Another Act

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8. Main Content

Quality requirements for the products in paragraph 6 and in related regulations.

9. Brief Statement of Grounds

Protection of Public health.



10. Reference Documents - Basic Texts

French Pharmacopoeia, 10th edition. The texts will be published by way or order in the Official Gazette of the French Republic with the wording: "Having regard for Directive 83/189/EEC laying down provisions for the provision of information in the field of technical standards and regulations, amended by Directives 88/182/EEC and 94/10/EC.". These monographs were the subject of Notifications 95/0292/F, 96/0011/F, 96/0227/F, 96/0371/F and 97/0149/F at the time of their publication as part of a public enquiry.

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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13. Confidentiality

No

14. Fiscal measures

No

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NNNN