



Notification Number: 1990/218/F

## Notice to applicants for marketing authorizations for proprietary medicinal products for human use.

Date received : 03/08/1990

End of Standstill : 09/11/1990

### Message

25681 UKECBR B  
26730 IVERN B  
206 2260426 01 RPGR  
226236 GSI GR  
ATT. MR. MITROPOULOS  
219621 ELOT GR  
ATT. MR. MELAGRAKIS  
8813148 DIHQ  
ATT. MR. J. WALKER  
32501 OLAS EI  
ATT. MR. J. NULTY  
COPY : III/B/2 - PRE 68

TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (90) D/50962/2  
DIRECTIVES 83/189/EEC AND 88/182/EEC  
TRANSLATION OF TELEX 001  
NOTIFICATION 90/0218/F

- 3B2 : 9000978.EN

#### 1. Structured Information Line

TLX 002 IND- 90 0218 F-- EN ----- 900803 --- ---

#### 2. Member State

France

#### 3. Department Responsible

Commissioner for standardization, 32 rue Guersant, 75017  
Paris, General Secretariat of the Interministerial Committee  
on European Economic Cooperation, 216 rue de l'Université,  
75700 Paris

#### 3. Originating Department

Ministry for Solidarity and for Health and Social Security,



Pharmaceutical and Medicinal Products Division, 1 Place de Fontenoy, 75350 Paris 07 SP

**4. Notification Number**

90/0218/F  
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**5. Title**

Notice to applicants for marketing authorizations for proprietary medicinal products for human use.

**6. Products Concerned**

Supporting documents and compilation of dossiers relating to applications for marketing authorizations.

**7. Notification Under Another Act**

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**8. Main Content**

Copy B of the marketing authorization dossier (dossier used for examination of the application): retention of paper copy.  
Copy A (file copy): choice available between microfilm with computer-assisted retrieval (in this case one copy on diazo microfilm and one on silver microfilm) and paper copy.  
Copy D (intended for the office of the national public health laboratory in Montpellier): temporarily on paper copy, ultimately to be replaced by diazo microfilm.  
Copies C and E: Retention of paper copy.  
Comments sheets: some must be submitted with copy B; all must be kept at the authorities' disposal.

**9. Brief Statement of Grounds**

Owing to serious difficulties resulting from the increase in quantity and volume of the dossiers in question, the technical solution of a microfilm filing system with computer-assisted retrieval has proved to be the best way of reducing the space occupied by these dossiers and of facilitating handling.

**10. Reference Documents - Basic Texts**

Notice to applicants issued by the Commission of the European Communities (Volume II of the "Rules governing Medicaments in the European Community").

**11. Invocation of the Emergency Procedure**

No

**12. Grounds for the Emergency**

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D. WILLIAMSON



EUROPEAN COMMISSION  
GROWTH DIRECTORATE-GENERAL

**Single Market for goods**  
Prevention of Technical Barriers

COMEUR  
NNNN