

AGENCE  
DU  
MEDICAMENT  
[DRUG AGENCY]  
*Evaluation Department*

FRENCH REPUBLIC

Saint Denis, DECEMBER 17, 1998

Manager of the  
Market Authorization Office  
C.C.D. Laboratories  
60, rue Pierre Charron  
75008 PARIS

**Case followed up by:**

Mrs. A-M. CALLENS  
Mrs. B. VINAS

**Ref. to be quoted:**

NL 24 122  
DMF 93-037  
GTMG 21  
AMC/BV/VM

DECEMBER 22, 1998

Sir,

I am pleased to send you, enclosed, the expansion of the marketing authorization granted for the drug:

- VEINEVA 600 mg, tablet

This drug is a generic of **DIOVENOR 600 mg, tablet.**

**CLARIFICATIONS**

- validation of the manufacturing process must be supplied on two other pilot lots (IIB 3);
- taking into account the low solubility of the active principle, a granulometric control and standards are to be introduced in the specifications of the active principle (II C 1);
- validation of the dosage of methanol dosed by GC is to be completed (IIC 1);
- data concerning the identification of aluminum are to be supplied (IIC 3);
- specifications concerning disaggregation time are to be tightened up in light of the results obtained (IIE).

Sincerely,

General Director  
[signature]  
J.R. BRUNETIERE

AMC. NL 24 122.[illegible]

ARTICLE 3.- The information intended for the medical corps and health professions should conform to the provisions of addendum 1 (SUMMARY OF CHARACTERISTICS OF THE PRODUCT) of this decision.

The information intended for the public should conform to the provisions of addenda II (NOTICE) and addendum III (LABELING) of this decision.

ARTICLE 4.- The validity of this marketing authorization is limited to five years from the date of this decision. It may be renewed under the conditions set forth in article R. 5137 of the Public Health Code.

ARTICLE 5.- This decision is communicated to the interested party.

DECEMBER 17, 1998  
MADE IN ST-DENIS on

GENERAL DIRECTOR  
OF DRUG AGENCY

[stamp]  
Good for expansion  
Assistant to the Director of Evaluation  
In Charge of Medical Affairs  
[signature]  
Dr. F. MEYER

[stamp]  
General Director  
J.-R. BRUNETIÈRE

Encl.: 3 addenda

AMC.NL 24 122.a

2 PAGES TOTAL

REDACTED IN ITS  
ENTIRETY  
CONTAINS  
TRADE SECRET  
CONFIDENTIAL  
COMMERICAL  
INFORMATION