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AGENCE
DU
MEDICAMENT
[DRUG AGENCY]
Evaluation Department

FRENCH REPUBLIC

Saint Denis, DECEMBER 17, 1998

Manager of the
Market Authorization Office
MERCK GENERIC Laboratories
34, rue Saint Romain
69359 LYON Cedex 08

Ref. to be quoted: NL 24 160
DMF 93-037
GTMG 21
COM 274
AMC/BV/VM

THE GENERAL DIRECTOR OF THE DRUG AGENCY,

PURSUANT TO Book V of the Public Health Code, especially articles L. 601 and R. 5128 to R. 5140 and R. 5143 to R. 5143-5-5

PURSUANT TO the request for marketing authorization filed by the pharmaceutical company

- MERCK GENERIC

laboratories for the pharmaceutical drug named:

- MERCK DIOSMIN 600 mg, tablet

PURSUANT TO the opinion of the commission referred to in article R.5140 of the Public Health Code:

DECIDES

ARTICLE 1.- The marketing authorization mentioned in article L. 601 of the Public Health Code is granted to the drug named:

- MERCK DIOSMIN 600 mg, tablet

ARTICLE 2.- The manufacturing methods and control techniques of this drug, indicated in the file, must be respected. They must be modified based on scientific and technical progress. Modification projects must be submitted for approval.

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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 Addendum 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 24 160.a

2 PAGES TOTAL

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INFORMATION