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RESEARCH**

APPLICATION NUMBER:

22-276

PHARMACOLOGY REVIEW(S)

NDA 22-276

PHARMACOLOGIST'S REVIEW OF ORIGINAL 505(b)(2) APPLICATION

SUBMISSION DATE: 28 September 2007

CENTER RECEIPT DATE: 01 October 2007

REVIEW COMPLETION DATE: 20 March 2008

REVIEWER: C.A. Resnick, Ph.D.

Supervisory Pharmacologist

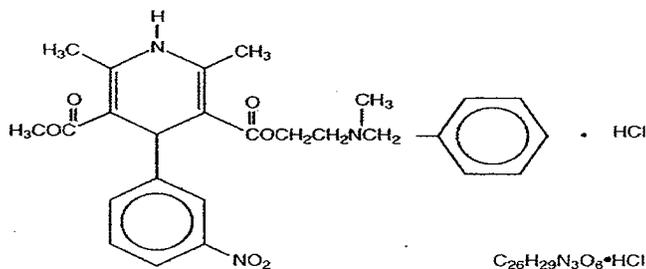
Division of Cardiovascular & Renal Products

SPONSOR: Teva Parenteral Medicines, Inc.

DRUG PRODUCT: Nicardipine Hydrochloride Injection

REFERENCED LISTED DRUG PRODUCT: Cardine® I.V. (PDL BioPharma, Inc.)
NDA 19-734

DRUG SUBSTANCE: nicardipine HCl



CAS No. 54527-84-3

Molecular Weight: 515.99

Pharmacologic Category: calcium channel blocker

PROPOSED INDICATION: Hypertension

FORMULATION AND PROPOSED ROUTE OF ADMINISTRATION: Each mL of Nicardipine Hydrochloride Injection contains 2.5 mg nicardipine HCl, 0.305 mg benzoic acid USP and 7.5 mg sodium chloride USP, in water for Injection USP. Nicardipine Hydrochloride Injection is intended for intravenous use. Required dilution of each 10 mL vial with 240 mL of compatible intravenous fluid results in 250 mL of solution at a concentration of 0.1 mg/mL.

PROPOSED DOSAGE REGIMEN: *The following is taken from proposed labeling:* For

b(4)

2 Page(s) Withheld

 Trade Secret / Confidential (b4)

 ✓ Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

Withheld Track Number: Pharm/Tox- 1

RECOMMENDATIONS: The application is approvable from the perspective of pharmacology. Note that changes in labeling are recommended for both this TEVA product as well as for the referenced listed product (see PROPOSED LABELING, above).

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/s/

Charles Resnick
3/31/2008 02:14:28 PM
PHARMACOLOGIST