CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-276

OTHER REVIEW(S)

RHPM Overview of NDA 22-276
Nicardipine Hydrochloride
2.5mg/mL Injectable
June 13, 2008

Sponsor:	Teva Parenteral Medicines, Inc.
Receipt Date:	October 1, 2007
User Fee Goal Date:	August 1, 2008
Approval Letter Issued:	**July 24, 2008**

Primary Reviewers
Medical: Tom Marciniak, MD
Secondary Medical: N/A
Statistician: N/A
Clinical Pharmacologist: N/A
Pharmacologist: Charles Resnick, PhD
Chemist: Lyudmila Soldatova, Ph.D.
Microbiologist: Bryan Riley, PhD

Background

Teva Parenteral Medicines submitted a 505(b)(2) application for Nicardipine Hydrochloride Injection, 2.5mg/mL. Cardene® I.V., NDA 19-734, is the referenced listed drug and Teva Parenteral Medicines is relying on the Agency's findings of safety and efficacy.

Teva's proposed drug product has the same active ingredient, dosage form,, strength, route of administration, and conditions of use as PDL Biopharma's Cardene I.V. However, Teva's proposed drug product contains a different quality and quantity of excipients than the previously approved drug. The formulation changes have been made to [redacted]. In Teva's formulation benzoic acid replaces citric acid [redacted], and sodium chloride replaces sorbitol [redacted] b(4)

Team Leader Medical Review

In his rmemo dated July 23, 2008, Dr, Marciniak recommended approval of Teva's nicardipine hydrochloride injection for the short-term treatment of hypertension when oral therapy is not feasible or desirable.

Secondary Medical Review

N/A

Pharmacology Review

In his review, dated March 31, 2008, Dr. Resnick recommended an approval of this application from a Pharmacology standpoint and included revised language [redacted] b(4)

Biopharmaceutical Review

N/A

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Statistical Review

N/A

Chemistry Review

In her review dated, June 4, 2008, Dr. Soldatova recommended an approval regulatory action from a CMC standpoint. The drug substance and drug product manufacturing facilities were found acceptable according to the overall OC recommendation dated March 30, 2008. Based on the provided stability data, 9-month expiry is granted for the Nicardipine Hydrochloride Injection drug product.

DSI

N/A

Pediatrics

The pediatric team has concluded that PREA does not apply, so no waiver or deferral is necessary.

Labeling

The sponsor submitted original electronic labeling dated October 1, 2007. We emailed final draft marked-up labeling to the sponsor on July 23, 2008. The sponsor agreed with all changes made by the Division.

Advisory Committee Meeting

No meeting held.

CSO Summary

Based on the recommendations of each reviewer, there are no issues that might prevent an approval on draft action for this NDA.

Alisea Crowley, Pharm.D.

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/s/

Alisea R. Crowley
7/25/2008 09:48:15 AM
CSO