DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-276/S-003

Teva Parenteral Medicines
Attention: Ms. Susan O'Brien
19 Hughes
Irving, CA 92618-1902

Dear Ms. O'Brien:

Please refer to your supplemental new drug application dated July 31, 2008, received August 1, 2008, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicardipine Hydrochloride Injection 25 mg/Vial, 2.5 mg/ml.

We acknowledge receipt of your submission dated December 16, 2008.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **WARNINGS AND PRECAUTIONS** section of the label as follows:

> **5.7 Intravenous Infusion Site**
>
> To reduce the possibility of venous thrombosis, phlebitis, local irritation, swelling, extravasation, and the rare occurrence of vascular impairment, administer drug through large peripheral veins or central veins rather than arteries or small peripheral veins, such as those on the dorsum of the hand or wrist. To minimize the risk of peripheral venous irritation, consider changing the site of the drug infusion every 12 hours.

In **HIGHLIGHTS OF PRESCRIBING INFORMATION/ WARNINGS AND PRECAUTIONS**, the following has been re ordered:

> "To reduce the possibility of venous thrombosis, phlebitis, and vascular impairment, do not use small veins, such as those on the dorsum of the hand or wrist. Exercise extreme care to avoid intra- arterial administration or extravasation (5.7)", has been moved to the first bullet and "To minimize the risk of peripheral venous irritation, change the site of infusion of nicardipine every 12 hours (5.7)", has been moved to the second bullet.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling (SPL) submitted on December 16, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the agreed-upon labeling text. Upon receipt, we will transmit that version to the national Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-276/S-003**."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call

Lori Anne Wachter, RN, BSN
Regulatory Project Manager
(301) 796 3975

Sincerely,

{See appended electronic signature page}
Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling text

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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