DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-276

NDA APPROVAL

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

Dear Ms. O'Brien:

Please refer to your new drug application (NDA) dated September 28, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Nicardipine Hydrochloride Injection, 2.5mg/mL solution.

We acknowledge receipt of your submissions dated October 30, November 15, December 11, 2007 and March 6, May 2, 28 and June 2, 2008.

This new drug application provides for the use of Nicardipine Hydrochloride Injection, 2.5 mg/mL solution, for the short-term treatment of hypertension when oral therapy is not feasible. For prolonged control of blood pressure, patients should be transferred to oral medication as soon as their condition permits.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

Expiration Date:
Based on the provided stability data, 9-month expiry is granted for the Nicardipine Hydrochloride Injection drug product.

CONTENT OF LABELING

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 enclosed labeling. 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."

CARTON AND IMMEDIATE CONTAINER LABELS

The total drug content on the vial and carton labeling is presented as "25 mg". We would recommend that the total drug contents be presented as the total contents of drug / total volume meaning that the total drug contents are presented as 25 mg/10 mL. Then the expression of strength, 2.5 mg/mL, should immediately follow the total drug contents.

25 mg / 10 mL
(2.5 mg / mL)

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels, except with the revision listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-276**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

Because this application does not represent a new active ingredient, new dosage forms, new indications, new routes of administration, and new dosing regimens, PREA does not apply.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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

If you have any questions, please call:

Alisea Crowley, Pharm.D.
Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Drug 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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