CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-990

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-990

Novartis Pharmaceuticals Corporation
Attention: Ms. Donna Vivelo
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Ms. Vivelo:

Please refer to your new drug application (NDA) dated February 22, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Exforge (amlodipine and valsartan) 5/160, 10/160, 5/320, and 10/320 mg Tablets.

We acknowledge receipt of your submissions dated February 12 and 19, March 2, 7 (two), 9, 19, 23, and 30, April 11, 20, 24, and 30, May 1, 11 and 15, and June 1 and 7, 2007.

The June 7, 2007 submission constituted a complete response to our December 21, 2006 tentative approval letter.

This NDA provides for the use of Exforge (amlodipine and valsartan) Tablets for the treatment of hypertension.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final electronic labeling (package insert and patient package insert submitted March 7, 2007; immediate container and carton labels submitted December 18, 2006).

Based on the updated stability data for the drug product, the following expiration dating periods are granted for the strengths that are to be marketed:

5/160 mg, 10/160 mg, and 5/320 mg strengths:
18 months for all packaging configurations.

10/320 mg strength:
12 months:---count ------- bottles,---------- blister packs.
18 months: - - --------- 30 count, 90 count and 100 count ------- bottles.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardiovascular and Renal Products and two copies of both the promotional materials and the package insert directly 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

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 796-0510

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: PI and PPI

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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