



NDA 21-990/S-003

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

Dear Ms. Vivelo:

Please refer to your supplemental new drug application (sNDA) dated September 24, 2007, submitted pursuant to section 505(b) 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 October 5, 2007 and January 24 and 29, March 31, May 30, June 27, July 3, 15 and 21, 2008.

This supplemental new drug application provides for the use of Exforge Tablets as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

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

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert and text for the patient package insert). These revisions are terms of the approval of this application.

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 (text for the package insert and text for the patient package insert). 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 21-990/S-003."

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 this Division 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

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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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:

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: Agreed-upon labeling text

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

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Norman Stockbridge  
7/23/2008 04:13:45 PM