DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-513/S-004

Novartis Pharmaceuticals Corporation
ATTENTION: Jason Yap
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Yap:

Please refer to your supplemental new drug application dated December 12, 2007, and received December 12, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Enablex® (darifenacin hydrobromide) extended release tablets, 7.5 and 15 mg.

We also acknowledge receipt of your submission dated April 17, 2008.

This "Changes Being Effected in 30 days" supplemental new drug application provides for labeling changes that address a request from the Division that you revise the ADVERSE REACTIONS section of the package insert (PI) to include a subsection on Postmarketing Experience. We also acknowledge the additional changes you have made in the HOW SUPPLIED section and the editorial and formatting changes in both the PI and the patient package insert (PPI).

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.

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 21-513/S-004."

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Celia Hayes, M.P.H., R.D., Senior Regulatory Project Manager, at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of New Drugs III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Scott Monroe

4/18/2008 01:56:34 PM