DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-513/S-005

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 and received June 26, 2008, 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.

This "Changes Being Effected" supplemental new drug application provides for labeling changes requested in the April 21, 2008, supplement request letter that requested that you revise the Post-Marketing Surveillance subsection of the ADVERSE REACTION section to add the adverse event term palpitations.

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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on June 26, 2008. We will transmit this version to the National Library of Medicine for public dissemination.

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, call Meredith Alpert, Regulatory Project Manager, at (301) 796-1218.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: PI

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

/s/

George Benson
12/12/2008 03:29:00 PM