DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-513/SCM 002 **PRIOR APPROVAL SUPPLEMENT**

Novartis Pharmaceutical Corporation
Nancy Del Viscio
Associate Director
Global Regulatory CMC
Novartis Pharmaceuticals Corporation

Dear Dr. McGrath:

Please refer to your supplemental new drug application dated June 20, 2005, received June 21, 2005 submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Enablex (darifenacin), 7.5 and 15 mg tablets.

We acknowledge receipt of your submissions dated October 18, 2005.

This "Prior Approval" supplemental new drug application provides for an alternate site for drug product manufacture, control, and stability testing.

We completed our review of this supplemental new drug application, as amended. This supplement is approved.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert), and the text for the cartons and containers must be identical to those provided in the June 20, 2005 submission.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-513/S-002**." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
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 Jean Makie, M.S., R.D, Regulatory Project Manager, at (301) 796-0952.

Sincerely,

{See appended electronic signature page}

Moo Jhong Rhee, Ph.D.
Chemistry Team Leader for the
Division of Reproductive and Urologic Products
(HFD-580)
DNDC II, Office of New Drug Chemistry
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/

Moo-Jhong Rhee

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