DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-513

Novartis Pharmaceutical Corporation
Attention: Lynne McGrath, MPH, Ph.D.
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. McGrath:

Please refer to your December 3, 2002, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Enablex® (darifenacin) 7.5 mg and 15 mg extended release tablets.

We also acknowledge receipt of your submissions dated May 14, 19, 24, and 28, June 16 and 21, August 27, September 15, 17, 28 and 30, October 1, 11, and 22, November 24, and December 1, 2, 8, 10, 14, 16, 17, 20 and 21, 2004.

The June 21, 2004, submission constituted a complete response to our October 2, 2003, action letter.

This amended new drug application provides for the use of Enablex® (darifenacin) 7.5 mg and 15 mg extended release tablets for the treatment of overactive bladder.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the attached labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed package insert and patient package insert. Additionally, the immediate container and carton labels must be identical to those submitted on December 20, 2004 and the container label for the 7.5 and 15 mg blister tablet must be modified as agreed upon in your submission dated December 21, 2004. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-513**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit the content of the labeling in electronic format as required by 21 CFR 314.50(1)(5) and in the format described at the following web site, http://www.fda.gov/oc/datacouncil/spl.html.

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 ages birth up to six months and are deferring pediatric studies for ages six months to 17 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Pediatric studies under PREA for the treatment of pediatric patients aged six months and older with detrusor overactivity associated with a known neurological condition (e.g., spina bifida).

2. Pediatric studies under PREA for the treatment of overactive bladder in pediatric patients six to 11 years old and adolescents ages 12 to 17 years old.

Final Report Submission due: June 21, 2009

Submit clinical protocols to your IND for this product. Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

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 Reproductive and Urologic Drug Products (HFD-580) and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, call Jean Makie, M.S., R.D., Sr. Regulatory Health Project Manager, at (301) 827-4260.
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Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Deputy Director
Office of Drug Evaluation 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/

Julie Beitz

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