DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-204/S-011

Novartis Pharmaceuticals Corporation
Attention: Lori Ann Bolognese
Senior TA Manager, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Bolognese:

Please refer to your supplemental new drug application dated January 15, 2008, received January 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Starlix (nateglinide) Tablets.

We acknowledge receipt of your submissions dated July 14, 2008.

This supplemental new drug application provides for the following changes to the Package Insert, which were requested in a supplement request letter dated November 21, 2007.

1. The INDICATIONS AND USAGE section was changed to "Starlix (nateglinide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

2. The following statement was added to the PRECAUTIONS section: "Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Starlix or any other anti-diabetic drug."

We 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 (text for the package insert, submitted July 14, 2008**)**. 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 21-204/S-011."

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 Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Mary Parks

7/15/2008 03:10:48 PM