DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-037/S-014

Novartis Pharmaceuticals Corporation
Attn: Bridget Walton, M.S., RAC
Associate Director, Drug Regulatory Affairs
One Health Plaza, Building 701
East Hanover, NJ 07936-1080

Dear Ms. Walton:

Please refer to your supplemental new drug application dated December 13, 2000, received December 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Voltaren Ophthalmic (diclofenac sodium ophthalmic solution) 0.1%.

We acknowledge receipt of your submissions dated September 4, 2003 and November 23, 2004. Your submission of November 23, 2004 constituted a complete response to our August 22, 2003, action letter.

This 'Changes Being Effected in 30 days' supplemental new drug application provides for revised labeling of the package insert.

We completed our review of this application, as amended. It 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 November 23, 2004. 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 20-037/S-014."

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
WO22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please submit one market package of the drug product when it is available.

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 Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
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/

Wiley Chambers

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