DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 022122/S-006

SUPPLEMENT APPROVAL

Novartis Consumer Health, Inc.
200 Kimball Dr.
Parsippany, NJ 07054-0622

Attention: George Marchesini
Associate Director

Dear Mr. Marchesini:

Please refer to your supplemental new drug application (NDA) application dated August 7, 2009 and received August 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Voltaren® Gel (diclofenac sodium topical gel) 1%.

We also refer to your submission dated September 10, 2009, received September 14, 2009.

Reference is also made to our letter dated July 8, 2009 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for diclofenac-containing products. This information pertains to the risk of elevations in liver enzymes.

This supplemental new drug application provides for revisions to the labeling for Voltaren® Gel consistent with our July 8, 2009 letter.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We remind you of your agreement to include “diarrhea” as a symptom of heptatotoxicity to Section 17.4 of your package insert.

CONTENT OF LABELING

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 022122/S-006**."

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Jessica Benjamin, Regulatory Project Manager, at (301) 796-3924.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures (3): Content of Labeling
Medication Guide
Instructions for Use

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22122	SUPPL-6	NOVARTIS CONSUMER HEALTH INC	VOLTAREN AT (DICLOFENAC SODIUM TOPICAL)

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

/s/

BOB A RAPPAPORT
09/22/2009