DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-122 **NDA APPROVAL**

Novartis Consumer Health, Inc.
200 Kimball Drive
Parsippany, New Jersey 07054-0622

Attention: Francis P. Barbone, Ph.D.
Regulatory Affairs

Dear Dr. Barbone:

Please refer to your new drug application (NDA) dated December 19, 2006, received December 20, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Voltaren® Gel (diclofenac sodium topical gel) 1%.

We acknowledge receipt of your submissions dated January 12, February 26 and 27, March 15 and 22, April 4 and 18, May 2 and 18, June 11 and 13, July 1, 12 and 13, and September 27, 2007.

This new drug application provides for the use of Voltaren® Gel (diclofenac sodium topical gel) 1% for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text for the Full Prescribing Information (FPI), Medication Guide, and dosing cards, indicated in the enclosed labeling.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

The revised comparability protocol as amended on July 12, 2007 may be used in the proposed post-approval changes described in the NDA and the changes may be reported in an annual report.

An expiration dating period of 36 months is granted for the drug product when stored at controlled room temperature.

CONTENT OF LABELING

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, text for the Medication Guide).These revisions are terms of the NDA approval. 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 22-122."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels, and dosing card labels identical to the enclosed carton and immediate container labels and dosing cards as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-122**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

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 this application.

POSTMARKETING COMMITMENTS

We remind you of your postmarketing study commitments in your submission dated October 17, 2007. These commitments are listed below.

1. Provide a study to evaluate the photo-contact allergic potential of Voltaren® Gel.

Protocol Submission:	by March 31, 2008
Study Start:	by June 30, 2008
Final Report Submission:	by December 31, 2009

2. Provide a rationale to support the safe use of the novel excipient cocoyl caprylocaprate that would preclude the submission of preclinical studies.

   Rationale submission: by January 31, 2008

   If the proposed rationale is determined to be inadequate, the following studies will be required:

   a. A dermal carcinogenicity evaluation of cocoyl caprylocaprate in two species. One of these studies may be conducted in a transgenic mouse model upon concurrence from the Agency.

      Protocol Submission: by July 31, 2008
      Study Start: by April 30, 2009
      Final Report Submission: by April 30, 2012

   b. A full reproductive toxicology evaluation of cocoyl caprylocaprate consistent with ICH-S5A unless the topical route can be demonstrated to produce non-detectable systemic exposure to the excipient.

      Protocol Submission: by April 30, 2008
      Study Start: by June 30, 2008
      Final Report Submission: by June 30, 2009

3. Provide a toxicological risk assessment of photo-degradants which are considered unique or are found at substantially greater levels when compared against a characterization of photo-degradants in the referenced drug Solaraze™.

   Protocol Submission: by June 30, 2008
   Study Start: by August 31, 2008
   Final Report Submission: by December 31, 2008

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the

proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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 www.fda.gov/cder/ddmac.

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

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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Lauren Tornetta, Regulatory Project Manager, at (301) 796-2246.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling

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

/s/

Bob Rappaport

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