DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-142/S-019

Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Attention: Susan Kummerer, M.S.
Director, Regulatory Affairs

Dear Ms. Kummerer:

Please refer to your supplemental new drug applications dated, and received December 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cataflam® (diclofenac potassium immediate-release tablets).

Reference is also made to an FDA letter dated October 3, 2008, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Cataflam® to address the risk of elevations in liver enzymes associated with the use of diclofenac products.

Your supplemental new drug application provides for revisions to the labeling of Cataflam®, consistent with our October 3, 2008, letter and email correspondence between FDA and Novartis dated February 10, 11, 13, 17, and 25, 2009, in which agreement was reached on these safety labeling changes.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert appended at the end of this letter).

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). 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 supplement NDA 20-142/S-019**."

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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 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

Enclosure: Cataflam® package insert 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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