CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-201 / S-018

ADMINISTRATIVE AND CORRESPONDENCE DOCUMENTS

Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products

REGULATORY PROJECT MANAGER REVIEW
Of Final Printed Labeling

Application Number: NDA 19-201/S-018

Name of Drug: Voltaren (diclofenac sodium) Enteric-coated Tablets 50 mg and 100 mg.

Applicant: Novartis Pharmaceuticals Corporation

Material Reviewed:

Submission Date: January 22, 2003

Receipt Date: January 28, 2003

Background and Summary

The original supplemental application was submitted April 27, 1994 in response to an FDA request to submit a labeling supplement for Voltarin, NDA 19-201 in order to add the newly approved Cataflam, NDA 20,142 to the labeling. An approval letter was issued on November 26, 2002. The final printed labeling (FPL) in response to that letter was submitted on January 22, 2003.

Review

The FPL submitted January 22, 2003 will be compared to the approved label for Cataflam, NDA 21-142 and the latest approved labeling submitted in the most recent annual report, Y-014, dated July 20, 2001.

Since the submission of the original supplemental application dated April 2, 1994, another diclofenac product, Voltarin XL, NDA 20-254, was approved March 1996. This product was added to the label in Supplemental Application NDA 19-201/S-023 and approved October 31, 2001. Information on this addition has also been included in this review.

The FPL labeling submitted on January 22, 2003 is identical to the labeling submitted for the annual report covering the period of July 31, 2000 through July 30, 2001.

Conclusions

The Final Printed Labeling is acceptable. An Acknowledge and Retain Letter should be issued.

Nancy Halonen , Regulatory Project Manager

Supervisory Comment/Concurrence:

Carmen DeBellas, Chief, Project Management Staff

Drafted:NH/4-18-03
Revised/Initialed: CD/4-21-03
Finalized:4-23-03
Filename: N19-201/S-018 CSO Review

CSO LABELING REVIEW

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

/s/

Nancy Halonen
4/24/03 09:11:30 AM
CSO

Carmen DeBellas
4/24/03 09:19:01 AM
CSO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 19-201/S-018

Ciba Pharmaceuticals Division
Geigy Corporation
Attention: Adrian L. Birch
Executive Director, Drug Regulatory Affairs
556 Morris Avenue
Summit, N.J. 07901

Dear Mr. Birch:

Please refer to your supplemental new drug application dated April 27, 1994, received May 2, 1994, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Voltaren (diclofenac sodium) Delayed-Release (enteric coated) Tablets.

We also refer to the Approval Letter dated November 26, 2002, in which the Final Printed Label was inadvertently excluded. Please find attached below the Final Printed label.

If you have any questions, call Nancy Halonen, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Carmen DeBellas, R. Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic,
And Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Attachment: Final Printed Label
cc: Original
HFD-550/Div. Files

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-201/S-018

Novartis Pharmaceuticals Corporation
Attention: Roxanne Tavakkol
Senior Regulatory Project Manager
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Tavakkol:

We acknowledge receipt of your January 22, 2003 submission containing final printed labeling in response to our November 26, 2002 letter approving your supplemental new drug application for Voltaren (diclofenac sodium) Tablets 25, 50, and 75 mg.

We have reviewed the labeling that you submitted in accordance with our November 26, 2002 letter and we find it acceptable.

If you have any questions, call Nancy Halonen, Project Manager, at 301-827-2040.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research