1.9201s018

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-201 / S-018

Trade Name: Voltaren

Generic Name: diclofenac sodium Tablets 25, 50, and 75 mg.

Sponsor: Ciba Pharmaceuticals

Approval Date: November 26, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-201 / S-018

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Final Printed Labeling	X
Medical Review(s)	X
Chemistry Review(s)	
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-201 / S-018

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-201/S-018

Ciba Pharmaceuticals
Division of Ciba-Geigy Corporation
Attention: Adrian L. Birch
Executive Director, Regulatory Affairs
556 Morris Avenue
Summit, NJ 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) Tablets 25, 50, and 75 mg.

We acknowledge receipt of your submission dated April 27, 1994.

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

Please submit a new supplement application that incorporates into the label information concerning special populations such as pediatrics and information on gender.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-201/S-018." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for the product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550, and two copies of both the promotional materials and the package insert directly to:

Division of Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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 Nancy Halonen, Regulatory Project Manager, at (301) 827-2090.

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

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

/s/

Lee Simon
11/26/02 04:03:31 PM

APPEARS THIS WAY
ON ORIGINAL