

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**19-201 / S-018**

**MEDICAL REVIEW**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Center for Drug Evaluation and Research  
Division of Anti-inflammatory, Analgesic and Ophthalmic Drug Products (HFD-550)

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**NDA#:** 19-201  
**NAME:** Voltaren  
**SPONSOR:** Ciba-Geigy  
**DATE SUBMITTED:** April 27, 1994  
**DATE RECEIVED (reviewer):** October 21, 2002  
**DATE REVIEWED:** November 4, 2002  
**REVIEWER:** Joel Schiffenbauer  
**SUBMISSION TYPE:** supplement-CBE

On April 27, 1994 the sponsor submitted a labeling supplement "Changes being effected." The submission appears to be acceptable as it contains essentially all the appropriate sections that are in the NSAID labeling template with the exception of special populations including gender and pediatrics. It also appears that the label as presented in the PDR has already been updated since the submission in 1994 as it includes information about the extended release form in addition to a Table describing AUC, Cmax, Tmax, as well as an updated *Indications and Usage* section.

**RECOMMENDATIONS:**

- 1) The submission dated April 27, 1994 can be approved.
- 2) The label as submitted in 1994 has already been updated (see above for updated label). A letter should be sent to the sponsor requesting changes be made to the label to include information concerning special populations such as pediatrics and information on gender.

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**Joel Schiffenbauer, M.D.**

cc: Orig IND  
HFD-550  
HFD-550/CSO/  
HFD-550/Pharm  
HFD-550/Chem

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/s/  
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Joel Schiffenbauer  
11/22/02 10:11:19 AM  
MEDICAL OFFICER

Lawrence Goldkind  
12/4/02 09:57:15 AM  
MEDICAL OFFICER