

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**22-202**

**OTHER REVIEW(S)**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications

MEMORANDUM

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\*\*Pre-Decisional Agency Information\*\*

**Date:** December 4, 2007

**To:** Tanya Clayton – Regulatory Project Manager  
Division of Anesthesia, Analgesia, and Rheumatology Products

**From:** Michelle Safarik, PA-C – Regulatory Review Officer  
Division of Drug Marketing, Advertising, and Communications (DDMAC)

**Subject:** DDMAC labeling comments for Zipsor (diclofenac potassium) Soft Gelatin Capsules  
NDA 22-202

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DDMAC has reviewed the proposed product labeling (PI), proposed Medication Guide (Med Guide), and proposed container and sample labeling for Zipsor (diclofenac potassium) Soft Gelatin Capsules (Zipsor) submitted for consult on October 31, 2007. We acknowledge that this is a 505(b)(2) application referencing the non-clinical studies and human safety information for diclofenac in the Cataflam NDA (20-142). We offer the following comments.

**HIGHLIGHTS**



(b) (4)

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/s/

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Michelle Safarik  
12/4/2007 01:36:22 PM  
DDMAC REVIEWER