CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-122

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	October 17, 2007
To:	Bob A. Rappaport, M.D., Director Division of Anesthesia, Analgesia and Rheumatology Products
Thru:	Toni Piazza-Hepp, Pharm.D., Deputy Director Division of Surveillance, Research and Communication Support
From:	Sharon R. Mills, BSN, RN, CCRP Patient Product Information Specialist Division of Surveillance, Research and Communication Support
Subject:	Review of Medication Guide and Patient Instructions for Use
Drug Name(s):	Voltaren Gel (difenolac sodium topical gel), For topical use only
Application Type/Number:	N22-122
Applicant/sponsor:	Novartis Pharmaceuticals Corporation
OSE RCM #:	2007-2154

1 INTRODUCTION

Novartis Pharmaceuticals Corporation submitted NDA #22-122 on December 19, 2006. The proposed indication was: " [redacted] joints amenable to [redacted] treatment, such as the hands and knees."
DMETS was consulted to review the Patient Instructions for Use for Voltaren Gel by the Division of Anesthesia, Analgesia and Rheumatology Products. We were informally consulted by DMETS on October 16, 2007 to discuss concerns related to the Patient Instructions for Use. The Patient Instructions for Use are appended to a Medication Guide for this product. The Medication Guide has been developed using the NSAID Medication Guide template. Following discussion with DMETS, it was decided that DSRCS should also review the Medication Guide and Patient Instructions for Use. The Review Division is agreeable to our providing review comments on October 17, 2007 in order for them to take action on the pending application.

2 MATERIAL REVIEWED

The Review Division provided updated labeling on October 16, 2007. The file is titled: "DRAFT Labeling_NDA22122 10-16-07 MAK.doc." This includes the Medication Guide and Patient Instructions for Use.

3 DISCUSSION

See the attached document for the combined suggested changes to the Patient Instructions for Use (marked up and clean) from DSRCS and DMETS. Comments to the Review Division are ***bolded, highlighted and italicized.*** We have simplified language where possible, made the Patient Instructions for Use consistent with the PI, and removed unnecessary information. The concern about potential medication errors due to the complicated dosing instructions provided us with one of the main areas of concentration: phrasing the dosing information in patient-friendly language.

4 CONCLUSIONS AND RECOMMENDATIONS

- The proposed Voltaren Gel Medication Guide follows the NSAID Medication Guide template. The statement "This Medication Guide has been approved by the U.S. Food and Drug Administration" has been moved to the end of the Medication Guide. This is the proper location in accordance with the Medication Guide regulations as specified in 21 CFR 208.20 (a)(6).
- We have added language to the Patient Instructions for Use to more clearly define the joints to be treated, simplified but provided more detailed dosing instructions, and provided examples.
- We have provided a clean and marked up Word version of our revisions to the Review Division. We recommend using the clean version as the working document.
- All relevant future changes to the PI should be reflected in the Patient Instructions for Use.

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16 Page(s) Withheld

_____ Trade Secret / Confidential

✓ Draft Labeling

_____ Deliberative Process

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

/s/

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10/17/2007 01:20:36 PM
DRUG SAFETY OFFICE REVIEWER

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