

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125289

PROPRIETARY NAME 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: February 5, 2009

To: Bob Rappaport, MD, Director
Division of Analgesics, Anesthetics, and Rheumatology Products

Thru: Kristina Arnwine, PharmD, Team Leader *K Arnwine 2/5/2009*
Division of Medication Error Prevention and Analysis

From: Carlos M. Mena-Grillasca, RPh, Safety Evaluator *CMena*
Division of Medication Error Prevention and Analysis *2/5/2009*

Subject: Proprietary Name Review

Drug Name(s): Simponi ~~_____~~ *b(4)*

Application Type/Number: BLA 125289

Applicant/sponsor: Centocor

OSE RCM #: 2008-1073

1 INTRODUCTION

This memorandum is in response to a request from the Division of Analgesics, Anesthetics, and Rheumatology Products for a proprietary name review for Simponi [redacted] autoinjector. Container labels and carton labeling will be reviewed under separate cover (RCM# 2008-1069).

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1.1 PRODUCT DESCRIPTION

[redacted]

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2 DISCUSSION

During the initial steps of the trade name review process, the Division of Drug Marketing, Advertising, and Communications (DDMAC) did not recommend the use of the proposed trade name, Simponi [redacted] DDMAC provided the following statement:

[redacted]

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The Division of Medication Error Prevention and Analysis also notes that the Applicant intends to employ a proprietary name for the device [redacted]

[redacted] The prominence and location of the device name with future products will be evaluated by means of Failure Mode Effects Analysis and may require Differentiation Studies (i.e. device color, labels and labeling) to ensure that the products will be adequately differentiated in the marketplace and minimize medication errors. DMEPA recommends that the proprietary name for the device [redacted] following the format "XX mg single-use, prefilled, <device name> autoinjector". We refer to the carton labeling presentation provided by email (see Appendix A).

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¹ The use of the proposed proprietary name [redacted] is being used solely to facilitate understanding of the example.

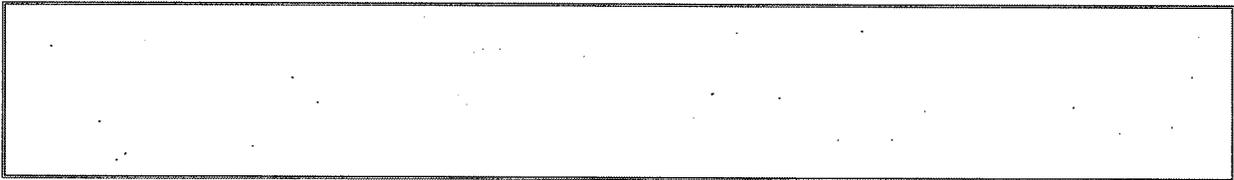
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3 CONCLUSIONS AND RECOMMENDATIONS

As per e-mail correspondence received on September 25, 2008 we were notified that the Division of Analgesics, Anesthetics, and Rheumatology Products concurs with DDMAC's assessment. Therefore, the Division of Medication Error Prevention and Analysis will not proceed with the safety review of the proposed proprietary name, Simponi [REDACTED], since the review Division supports DDMAC's objection to the name [REDACTED]. We recommend the Applicant be notified of the decision to object to the name based on [REDACTED] request that an alternate proprietary name be submitted for review. In addition, DMEPA recommends that the proprietary name for the device [REDACTED] following the format "XX mg single-use, prefilled, <device name> autoinjector". Container labels and carton labeling including the drug name and device name must be provided for review.

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If you have any questions for DDMAC, please contact the regulatory review officer, Sangeeta Vaswani, at 301-796-1252. Please copy us on any correspondence to the Applicant pertaining to this issue. If you have any further questions or need clarification, please contact Chris Wheeler, OSE Project Manager, at 301-796-0151.



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