

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
sBLA 125057/110

Other Review(s)



Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research

Office of Biotechnology Products
Rockville, MD 20852
Tel. 301-827-1274

Memorandum

PROJECT MANAGER'S REVIEW

Application Number: STN 125057/110

Name of Drug: Humira® (adalimumab)

Sponsor: Abbott Laboratories

Material Reviewed: Humira® (adalimumab) Carton and Container Labels

Submission Date: March 23, 2007

OBP Receipt Date: January 11, 2008

Background:

Abbott Laboratories has submitted a biologic efficacy supplement for a new indication for the treatment of moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Labels Reviewed:

Humira® (adalimumab) Carton Label

Humira® (adalimumab) Container Label

Review

The carton and container labels for Humira® (adalimumab) were reviewed at the time of original BLA 125057 approval and found to be adequate.

It is our understanding the lead review division (The Division of Dermatology and Dental Products) requested a medication guide be included in the packaging. Thus the carton label had to reflect this information as stated under 21 CFR 208.24.

A Medication Guide is required under part 208 of the chapter, the statement required under §208.24(d) of this chapter instructing the authorized dispenser to provide a Medication Guide to each patient to whom the drug is dispensed and stating how the

Medication Guide is provided, except where the container label is too small, the required

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statement may be placed on the package label.

Conclusions:

The proposed carton and container labeling changes are acceptable.

It is the Agency's understanding that these are the only changes to the labels and labeling and all other printing, fonts and coloring on the labels and labeling will remain unchanged.

Sheila M. Rawls 1/16/08

Sheila M. Rawls
Regulatory Project Manager
CDER/OPS/OBP/IOD

Comment/Concurrence:

Gurpreet Gill-Sangha 1/16/08

Gurpreet Gill-Sangha, Ph.D.
Product Reviewer
CDER/OPS/OBP/DMA

4 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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