

# **CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**21-042 / S-017**

**21-052 / S-011**

**MEDICAL REVIEW**

**Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products**  
**Clinical Review of NDA 21-052(SLR-011)**  
**Labeling Supplement**

**Submission date:** April 23, 2002, October 15, 2002  
**Receipt date:** April 24, 2002, October 15, 2002  
**Review date:** October 28, 2002

**Drug:** Vioxx® (rofecoxib oral suspension)

**Sponsor:** Merck & Co., Inc.  
P.O. Box 2000, RY 33-720  
Rahway, NJ 07065-0900QLT Inc.

**Sponsor's Representative:** Ned S. Braunstein, M.D.  
Director of Regulatory Affairs  
(732) 594-2886

**Pharmacologic Category:** NSAID Analgesic

**Background and Summary:**

In pursuant to Section 505(b) of the Food, Drug, and Cosmetic Act and in accordance with 506A(d)B(ii) of the Food and Drug Administration Modernization Act, the applicant has submitted a Special Supplement-Changes Being Effected. The applicant seeks approval of the package circular and patient product information. Based on the WAES reports, the applicant has proposed the addition of the term, "hypertensive crisis" to the **ADVERSE EVENTS** section of the package insert. In addition, the applicant has revised the patient product information to include within the side effect section "blurred vision," "insomnia," and "severe increase in blood pressure."

**Submitted:**

- Electronic Submission including a package circular and patient product information
- October 15, 2002: Response to FDA Request for Information (WAES Reports)

Following is the labeling submitted by the company. Reviewer recommended deletions are noted by ~~strikeout~~ and additions by double underline within the review. The applicant proposed additions are designated by single underline.

**WITHHOLD 20 PAGE(S)**

Draft Labeling

Medical Review

**Recommendation:**

*The proposed revised labeling is recommended for approval. An approval letter should be drafted. The letter should advise the applicant that the term " \_\_\_\_\_ " should be removed from the text in the **ADVERSE REACTIONS** section of the package insert. Alternatively, the applicant may replace the term with a clinical adverse event that more clearly defines the medical condition occurring in patients leading to an "c \_\_\_\_\_ s described in this section. This recommendation is a deficiency and not a condition of the approval of this supplement.*

Hung Lam, Pharm.D. Candidate

Lisa M. Hubbard, R.Ph.

James Witter, M.D., Ph.D.

NDA 21-052  
HFD-550 Div files  
HFD-550/Dep Dir/Chambers  
HFD-550/Proj Mgr/Gould  
HFD-550/Clin Rev/Hubbard

Drafted: hcl/October 2, 2002, revised lmh 10/28/02  
Filename: NDA021052SL011.doc

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

/s/

-----  
Lisa Hubbard  
1/24/03 08:43:07 AM  
MEDICAL OFFICER

James Witter  
1/24/03 02:46:23 PM  
MEDICAL OFFICER  
Concur