FDA CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF ANTI-INFLAMMATORY, ANALGESIC, AND OPHTHALMOLOGIC DRUG PRODUCTS
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DEPUTY DIVISION DIRECTOR REVIEW AND BASIS FOR APPROVAL ACTION

DATE: August 5, 2004

DRUG: Vioxx (rofecoxib)

NDA: 21-042 (SE5-026)
21-052 (SE5-019)

SPONSOR: Merck & Co., Inc.

INDICATION: The treatment of the signs and symptoms of pauciarticular and polyarticular juvenile rheumatoid arthritis in patients 2 years and older and who weigh 10 kg or more

Merck & Co., Inc. submitted efficacy supplements for Vioxx™ (rofecoxib) for the indication of the treatment of the signs and symptoms of pauciarticular and polyarticular juvenile rheumatoid arthritis (JRA) to NDAs 21-042/S-026 (Tablets 12.5 mg and 25 mg) and 21-052/S-019 (Oral Suspension 12.5 mg/5 mL and 25 mg/5 mL) on December 5, 2003. An Approvable action was taken on June 4, 2004. Although agreement was reached that the study submitted in support of efficacy demonstrated noninferiority to the comparator, agreement was not reached on the language to be added to the package insert describing the pediatric clinical trial. Agreement was also not reached on the Division's proposal to update the language and the organization of the patient package insert. As this was a pediatric efficacy supplement, upon taking an approvable action, the package was to go before the Pediatric Advisory Committee. However, as there was no disagreement over the scientific basis for a finding of noninferiority, and in consultation with the pediatric team, it was decided that if agreement on the language for the package insert and patient package insert could be reached with only a small amount of additional negotiation, it would not be necessary to go before the advisory committee.

The sponsor submitted a package insert and patient package insert on July 19, 2004. Following a discussion by telephone with the sponsor on July 29, 2004, agreement was reached and the final, agreed upon package insert and patient package insert were submitted on July 30, 2004. In particular, the description of the clinical trial in the package insert refers

to an NSAID comparator [redacted] (b) (4) and includes the proviso that a single non-inferiority trial is not sufficient to support a conclusion of equivalence. The patient package insert, while not in Med Guide format, has been reorganized to emphasize important risk information.

Action recommended by the Division: Approval

Sharon Hertz, M.D.
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Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V, CDER, FDA

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/s/

Sharon Hertz
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MEDICAL OFFICER