DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020947/S-007

SUPPLEMENT APPROVAL
REMS ASSESSMENT ACKNOWLEDGMENT
RELEASE REMS REQUIREMENT

Mallinckrodt, Inc.
675 McDonnell Boulevard
Hazelwood, MO 63042

Attention: Melissa D. Henry
Director, Regulatory Affairs

Dear Ms. Henry:

Please refer to your supplemental New Drug Application (sNDA) dated and received May 20, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PENNSAID (diclofenac sodium topical solution) 1.5% w/w.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated May 4, 2011. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be adequate.

This supplemental new drug application proposes to eliminate the requirement for the approved PENNSAID (diclofenac sodium topical solution) REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for PENNSAID (diclofenac sodium topical solution) was originally approved on November 4, 2009, and the most recent REMS modification was approved on March 24, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for PENNSAID (diclofenac sodium topical solution).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of PENNSAID (diclofenac sodium topical solution) outweigh its risks.

Therefore, we agree with your proposal, and a REMS for PENNSAID (diclofenac sodium topical solution) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Dominic Chiapperino, Senior Regulatory Health Project Manager, at (301) 796-1183 or Katherine Won, Safety Regulatory Project Manager, at (301) 796-7568.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

KATHERINE S WON
07/14/2011

BOB A RAPPAPORT
07/14/2011