

NDA 020947
PENNSAID® (diclofenac sodium topical solution)

Non-Steroidal Anti-Inflammatory Drug (NSAID)

Mallinckrodt Inc. (a Covidien company)
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RISK EVALUATION AND MITIGATION STRATEGY
(REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of PENNSAID® (diclofenac sodium topical solution).

II. REMS ELEMENTS:

A. Medication Guide

Mallinckrodt Inc. will ensure a Medication Guide will be dispensed with each PENNSAID® (diclofenac sodium topical solution) prescription in accordance with 21 CFR 208.24.

PENNSAID® is packaged as a single unit package and the Medication Guide is included as part of the secondary package. It is not intended to be divided prior to dispensing.

Pursuant to 21 CFR 208.24(d), Mallinckrodt Inc. will include the appropriate statement on the outer cartons of the medication to remind the dispenser to provide the patient with the Medication Guide.

B. Timetable for Submission of Assessments

Mallinckrodt Inc. will submit REMS Assessments to the FDA 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Mallinckrodt Inc. will submit each assessment so it will be received by the FDA on or before the due date.

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-20947

SUPPL-2

NUVO RESEARCH
INC

DICLOFENAC SODIUM

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/s/

SHARON H HERTZ

03/25/2010