DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020947/S-001
NDA 020947/S-002

SUPPLEMENT APPROVALS

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 applications, S-001 and S-002, dated and received, respectively, January 29 and March 17, 2010, submitted under 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 amendments to S-002 dated and received March 23 and 24, 2010, and your risk evaluation and mitigation strategy (REMS) assessment dated March 17, 2010.

We also acknowledge an additional January 29, 2010 submission which contained final printed carton and container labels as requested in the November 4, 2009 approval letter.

The "Changes Being Effected (CBE-0)" supplemental new drug application, S-001, makes editorial changes to the package insert and Medication Guide for PENNSAID, including changes to reflect the Transfer of Ownership of NDA 020947 that was effective November 10, 2010.

The "Prior Approval" supplemental new drug application, S-002, proposes modifications of the approved REMS to change the company name and logo on the REMS, REMS Supporting Document, and Medication Guide to reflect the Transfer of Ownership of NDA 020947, that was effective on November 10, 2009.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

RISK EVALUATION AND MITIGATION STRATEGIES (REMS) REQUIREMENTS

The REMS for PENNSAID (diclofenac sodium topical solution) was originally approved on November 4, 2009. The REMS consists of a Medication Guide and a timetable for the

submission of assessments of the REMS. The proposed modified REMS includes the change in the company name and logo on the REMS document and the Medication Guide.
Your proposed modified REMS, submitted on March 17, 2010 and appended to this letter, is approved. The REMS assessment plan will remain the same as that approved on November 4, 2009.

Prominently identify submissions containing REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020947
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 020947
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020947
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the package insert and Medication Guide. For administrative purposes, please designate this submission, "SPL for approved NDA 020947/S-001.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your January 29, 2010, submission containing final printed carton and container labels.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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, Regulatory Project Manager, at (301) 796-1183 or at dominic.chiapperino@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Deputy Director
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Package Insert
Medication Guide
Carton/Container Labels
REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20947	SUPPL-2	NUVO RESEARCH INC	DICLOFENAC SODIUM

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

/s/

SHARON H HERTZ
03/25/2010