DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021217/S-001 **SUPPLEMENT APPROVAL**

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 dated and received March 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EXALGO (hydromorphone HCl) 8-, 12-, and 16-mg Extended-Release Tablets.

We acknowledge receipt of your submissions dated March 15 and 23, 2010.

This "Prior Approval" supplemental new drug application provides for changes to the company name, address, and logo in the approved Risk Evaluation and Mitigation Strategy (REMS) to reflect the Transfer of Ownership of NDA 021217, which was effective on March 4, 2010.

We have completed our review of this application, as amended. It is 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 Exalgo (hydromorphone HCl) was originally approved on March 1, 2010 and consisted of a Medication Guide, elements to assure safe use, and a timetable for the submission of assessments of the REMS. The proposed modifications to the REMS are the change in the company name, address, and logo on the REMS, REMS Supporting Document, Medication Guide, and REMS educational materials.

Your modified REMS, submitted on March 12, 2010, and amended March 23, 2010, and appended to this letter, is approved. The REMS consists of a Medication Guide, elements to assure safe use, and a timetable for the submission of assessments of the REMS. The REMS assessment plan will remain the same as that approved on March 1, 2010.

Prominently identify submissions containing REMS-related submissions with the following wording in bold capital letters at the top of the first page of the submission:

NDA 021217
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 021217 -PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 021217
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 21217/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 March 11, 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 Diana L. Walker, Regulatory Project Manager, at (301) 796-4029 or at diana.walker@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, M.D., M.H.S.
Deputy Director for Safety
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
- Package Insert
- Medication Guide
- REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21217	SUPPL-1	ALZA CORP	Exalgo (hydromorphone HCl) 8/12/16

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
03/24/2010
Signing for Larissa Lapteva, M.D.