DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-116/S-021 **SUPPLEMENT APPROVAL**

Mallinckrodt Inc.
675 McDonnell Boulevard
Hazelwood, MO 63042

Attention: Celeste M. Reisch
Manager, Corporate Labeling

Dear Ms. Reisch:

Please refer to your supplemental new drug application dated September 20, 2007, received September 24, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methadose Oral Concentrate (methadone hydrochloride oral concentrate, USP) and Methadose Sugar-Free Oral Concentrate (methadone hydrochloride oral concentrate, USP) dye free, sugar free, unflavored.

We acknowledge receipt of your submission dated November 8, 2007.

This supplemental new drug application provides for clarifying language regarding the use of methadone in breastfeeding mothers, as requested in our August 8, 2007, supplement request letter.

We have completed our review of this application, as amended, and it is approved effective on the date of this letter for use as recommended in the enclosed content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format submitted on November 8, 2007.

CONTENT OF LABELING

We will transmit the structured product labeling (SPL) format submitted on November 8, 2007, to the National Library of Medicine for public dissemination.

We note that your November 8, 2007, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Matt Sullivan, Regulatory Project Manager, at 301-796-1245.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Bob Rappaport

2/4/2008 10:41:41 PM