DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-116/S-015
NDA 17-116/S-016

Mallinckrodt, Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis, MO 63134

Attention: Celeste M. Reisch
Sr. Regulatory Affairs Associate, Labeling

Dear Ms. Reisch:

Please refer to your supplemental new drug applications dated August 9 and August 23, 2002, received August 14 and August 28, 2002 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).

We acknowledge receipt of your submissions dated October 17, 2003, and May 3, 2005.

Your submission of May 3, 2005 constituted a complete response to our June 30, 2003 action letter.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the package insert to comply with 21 CFR 291 and 42 CFR Part 8 regulations regarding safe and effective use of this drug. The labels for both drug products have been combined into a single label.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 17-116/S-015 and S-016**." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Sara Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
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

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