



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-116/S-018

NDA 17-116/S-019

Mallinckrodt Inc.
675 McDonnell Boulevard
P.O. Box 5842
St Louis, MO 63134

Attention: Ronald T. Groman
Manager, Regulatory Affairs

Dear Mr. Groman:

Please refer to your supplemental new drug applications dated February 2, and June 7, 2005, received February 3, and June 8, 2005, submitted pursuant to section 505(b)(2) 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 submissions dated June 9 and 17, 2005.

These "Changes Being Effected" supplemental new drug applications provide for the addition of a new 15 liter bottle container/closure system for Methadose Oral Concentrate (S-018) and for Methadose Sugar-Free Oral Concentrate (S-019) and shelf-life extension request from 18 to 24 months.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 17, 2005.

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

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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}

Ravi Harapanhalli, PhD
Chemistry Team Leader
Division of Anesthesia, Analgesia
and Rheumatology Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Ravi Harapanhalli
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