DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-116/S-014

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

Attention: Ronald T. Groman
Manager, Regulatory Affairs

Dear Mr. Groman:

Please refer to your supplemental new drug application dated June 8, 2001, received June 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methadose (methadone hydrochloride oral concentrate, USP), 10 mg/mL.

We acknowledge receipt of your submissions dated November 13, 2001, November 30, 2001, March 25, 2002, and March 26, 2002. Your submission of November 30, 2001, constituted a complete response to our October 11, 2001, action letter.

This supplemental new drug application provides for a new formulation of Methadose as dye-free, sugar-free, and unflavored. As stated in our February 8, 2002, letter, we have no objection to the use of the proposed proprietary name "Methadose Sugar-Free Oral Concentrate."

We have completed the review of this supplemental application, as amended, and it is 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, immediate container labels) submitted March 25, 2002, and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application. Furthermore, in an October 31, 2001, supplement request letter we requested that you update the label to reflect the changes to the regulations for 21CFR Part 291 and 42 CFR Part 8 (which became effective May 18, 2001).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to NDA 17-116. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-116/S-014." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2 FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara E. Shepherd, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Cynthia McCormick

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